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1 INTRODUCTION

The *HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI); Release 1, STU Release 3 (US Realm); HL7 Standard for Trial Use; May 2018* is the result of collaborative efforts between HL7 and the Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Laboratory Results Interface (LRI) Initiative. By consensus the HL7 V2.5.1 ORU^R01 Message was selected as the basis to define the profile constraints expressed in this guide to meet the requirements of the transmission of laboratory results. The Standards and Interoperability (S&I) Framework's Laboratory Result Interface Use Case was leveraged and revised, where agreed upon by the working group, to provide the Use Case content, diagrams and foundation for this Implementation Guide. Capabilities made available through HL7 V2.8.2 were selectively applied to further support the use case requirements.

1.1 Purpose

The Laboratory Results Interface Initiative identifies the requirements, defines specifications and standards to provide implementation guidance for electronic reporting of laboratory test results to ambulatory care providers in the US Realm. The scope of the Laboratory Results Interface Use Case includes requirements to enable the incorporation of clinical laboratory test results into an Electronic Health Record System (EHR-S) as standardized structured data using the defined inter-organizational laboratory transaction. The Use Case requirements are directed at laboratory test results reporting between a Laboratory Information System (LIS) and a result receiving system in different organizational entities.

1.2 Audience

This guide is designed for use by analysts and developers who require guidance on data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* relative to the Use Cases described within this guide. Readers are expected to be familiar with the details of HL7 message construction and processing starting with HL7 Version 2.5.1 through HL7 Version 2.8.2. This guide is not intended to be a tutorial on that subject.

1.2.1 RELEVANT LABORATORY IMPLEMENTATION GUIDES

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

- This publication[1], the *HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI); Release 1, STU Release 3 (US Realm); HL7 Standard for Trial Use; May 2018* in support of the lab result reporting to ambulatory care providers and Public Health;
- *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS); Release 2, STU Release 3 (US Realm); HL7 Standard for Trial Use; May 2018* in support of the transmission of a laboratory's directory of services to an EHR using HL7 Master File messages;

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

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

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

1.2.2 REQUISITE KNOWLEDGE

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

1.2.3 REFERENCED PROFILES - ANTECEDENTS

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

HL7 Ambulatory Care Laboratory Result Implementation Guide: EHR-Laboratory Interoperability And Connectivity Specification (ELINCS) - Release 1, July 1, 2008

HL7 Version 2.5.1 Implementation Guide: Orders And Observations; Interoperable Laboratory Result Reporting To EHR (US Realm), Release 1, November, 2007

HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1.1 (US Realm), May 2014

HL7 Version 2 Implementation Guide: Clinical Genomics; fully LOINC-Qualified Cytogenetic Model, Release 1 - US Realm, 2014

HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model (US Realm), 2013, referenced throughout this document as the 2013 HL7 Clinical Genomics Implementation Guide.

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.

[2] The referenced documents are all available from HL7 (www.hl7.org) – Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store.

1.3 Organization of this Guide

1.3.1 CONVENTIONS

This guide adheres to the following conventions:

- To minimize duplication, each Use Case builds on the primary Use Case in Section 2 Use Case – Laboratory Results, i.e., each use case may provide additional information regarding scope, audience, etc., but they are in addition to the statements made in the general use case.
- The guide is constructed assuming the implementer has access to the 2.5.1 through 2.8.2 versions of the HL7 Standard. Where there are variations from 2.5.1 the version that is used is referenced. Although some information from the standard is included in this Implementation Guide, much information from the standard has not been repeated here.
- The rules outlined in HL7 2.7.1, Chapter 2B, Section 2B5, Conformance Using Message Profiles, were used to document the use case for, and constraints applied to, the messages described in this guide.
- Data types have been described separately from the fields that use the data types.
- No conformance information is provided for optional message elements (“O”) or unsupported (“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 uses “X” as a conformance usage indicator very sparingly. Where the underlying standard indicates the segments/field/component is present for backwards compatibility (“B”) or withdrawn ("W") an “X” will be used. A small number of other message elements that are clearly out of scope for the use case have been given the "X" usage. All other message elements have either been further constrained to R/RE/C(a/b) or have been left as "O" to enable trading partners to explore additional capabilities. Labs would have insufficient information to populate these fields and if they would it would cause potential confusion with information present on the provider's system. Note that without a clearly agreed to complementary profile between trading partners, a Lab does not have to send any elements marked as an "O", nor does a receiver of a lab result have to process any elements marked as an "O". Neither trading partners can mandate the other to accept any such complementary profiles to enable basic laboratory results interfacing "out-of-the-box". The recipient should not return an error unless there is a clinical or regulatory impact as a result of discarding optional information.

1.3.2 MESSAGE ELEMENT ATTRIBUTES

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

TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES

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

TABLE 1-1. MESSAGE ELEMENT ATTRIBUTES	
Attribute	Definition
Segment	Three-character code for the segment and the abstract syntax (e.g., the square and curly braces). [XXX] Optional and singular { XXX } Required and may repeat XXX Required and singular [{ XXX }] Optional and may repeat Note that for segment groups there is no segment code present, but the square and curly braces will still be present. The Segment attribute only applies to the Message attribute table.
DT	Data type used by this profile for HL7 element. The data type attribute applies to data type attribute tables and segment attribute tables.
Usage	Usage of the message element for this profile. Indicates whether the message element (segment, segment group, field, component, or subcomponent) is R, RE, O, X or C(a/b) in the corresponding message element. Usage applies to the message attribute table, data type attribute table and the segment attribute table; see Section 1.3.4 Usage Conformance Rules.
Cardinality	Minimum and maximum number of times the element may appear. [0..0] Element never present. [0..1] Element may be omitted and can have, at most, one occurrence. [1..1] Element must have exactly one occurrence. [0..n] Element may be omitted or may repeat up to *n* times. [1..n] Element must appear at least once, and may repeat up to *n* times. [0..*] Element may be omitted or repeat an unlimited number of times. [1..*] Element must appear at least once, and may repeat unlimited number of times. [m..n] Element must appear at least *m*, and at most, *n* times. Cardinality applies only to message attribute tables and segment attribute tables.
Value Set	The set of coded values to be used with the field. The value set attribute applies only to the data type attribute tables and the segment attribute tables. The value set may equate with an entire code system part of a code system, or codes drawn from multiple code systems. See Sections 1.4.8 Value Sets and 10 Code Systems.
Name	HL7 descriptor of the message element. Name applies to the message attribute table, data type attribute table and the segment attribute table.
Description/Comments	Context and usage for the element. Description/Comments applies to the message attribute table, data type attribute table and the segment attribute table.

1.3.3 KEYWORDS

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

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

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

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

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

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

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

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; upon successful ballot and publication this material will be replaced with a reference to the normative documentation.

---------- *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 empty	The application shall implement "RE" elements.	The application shall populate "RE" elements with a non-empty value if there is relevant data. The term "relevant" has a confounding interpretation in this definition[4].
C(a/b)	Conditional	An element with a conditional usage code has an associated condition predicate (See section 2.B.7.9, "Condition predicate" that determines the operational requirements (usage code) of the element. If the condition predicate associated with the element is true, follow the rules for ***a*** which shall be one of "R", "RE", "O" or X": If the condition predicate associated with the element is false, follow the rules for ***b*** which shall be one of "R", "RE", "O" or X". ***a*** and ***b*** can be valued the same.	
X	Not supported	The application (or as configured) shall not implement "X" elements.	The application shall not populate "X" elements.
O	Optional	None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X.	Not Applicable.

[4] There are multiple interpretations of "RE" when a value is known. One is "the capability must always be supported and a value is sent if known", the other is "the capability must always be supported and a value may or may not be sent even when known based on a condition external to the profile specification. The condition may be noted in the profile but cannot be processed automatically". This is what can be interpreted from the "relevant" part of the definition. Regardless of the interpretation the "RE" usage code, a set of test circumstances can be developed to sufficiently test the "RE" element. See the "Conformity Assessment of Conformance Constructs" section for more details.

Usage Rules for a Receiving Application

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

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

1.4 Key Technical Decisions

One of the primary features of this Implementation Guide is its focus on key points of broad interoperability. The HL7 Implementation Guides in Sections 1.2.1 Relevant Laboratory Implementation Guides and 1.2.3 Referenced Profiles - Antecedents have informed the content of this specification as analysis indicated that none of the candidate guides could satisfy the use case requirements without some adjustment. This guide is the result of combining the best practices from the current body of work while making further adjustment to meet the needs of inter-organizational data exchange and preparing for increased consistency of lab result reporting across care settings.

1.4.1 RELATIONSHIP TO ORDERS

This Implementation Guide imposes no constraints on data elements where the origination of the content for those data elements is a lab order. For all such data elements, the expectation is that the result message will support those elements as defined in the guide with the expectation that the lab will provide back in the result message either the original value from the order, or the most current available value the lab is aware of at the time the result message is generated. Note that this only involves data

that is sent in fields that are marked in the LOI as 'R', 'RE', or 'C(a/b)' where (a) or (b) is 'R' or 'RE'. Any other fields valued, i.e., those marked 'O' in the LOI guide, may be returned, but the Laboratory is under no obligation to do so unless specifically agreed to with the order sender. The definition of a common order is outside the scope of this Guide; see the companion specification "*HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STU Release 3 - US Realm, May 2018*" available at http://www.hl7.org.

1.4.2 PROFILE AND COMPONENT ARCHITECTURE

This guide extensively uses constrainable profiles to define a minimum set of requirements to enable the successful exchange of laboratory results. The main objective is to ensure that trading partners can exchange laboratory results with minimal, if any, modifications from one combination to another combination of software. This flexibility enables software developers to provide more capabilities using the same core message definitions. Section 6 Conformance to this Guide describes the mandatory and optional profiles to be used, as well as the rules on further constraining the guide.

Data type and segment definitions for elements that are used outside the LRI_Common_Component apply to the Component they are defined for, other profiles that would like to use these elements are encouraged to match the defined usage, but they are not required to do so.

1.4.3 USE OF ISO OBJECT IDENTIFIER (OID)

OIDs, or Object Identifiers, provide a strong identifier that uniquely identifies the object in question and is global in scope. 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 (LRI_GU_Component) (see Section 6.3.2) 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"[5], which provides guidance on how organizations can use and manage OIDs.

1.4.4 USE OF VOCABULARY STANDARDS

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

1.4.5 FIELD LENGTH AND TRUNCATION

This guide is silent as to 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.

The sole exception to truncation guidance in the base specification is that OBX-5 (Observation Value) **SHALL NOT** be truncated. The systems involved are expected to discuss the maximum size of data

[5] The current version of the HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 is available from HL7 (www.hl7.org). Members may obtain a copy without charge in the Members-only area of the site, others may purchase a copy for a nominal fee via the HL7 Store

sent in OBX-5 (Observation Value) and accommodate changes to insure that the totality of the data is not truncated. This may mean breaking up text into multiple OBX segments where that is necessary.

1.4.6 CONFORMANCE STATEMENTS

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

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

1.4.7 DATA TYPE FLAVORS

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

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

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

1.4.8 VALUE SETS

This Implementation Guide refers to a separate publication with detailed value set definitions for each component and field where they are used. See Section 6.1 Value Sets for the minimum version associated with the release of this document.

This separation is intended to set a minimum release version to be associated with the release of a Laboratory US Realm Implementation Guide such that the value sets can be versioned over time without always requiring a revision of the referring Implementation Guide. 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, and trading partners should agree on the version and an update mechanism over time.

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

1.4.8.1 VALUE USAGE REQUIREMENTS

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

In the case of a single fixed value, e.g., the value of MSH-12.1 (Version ID.Version ID), the table is listed but is also constrained by a Conformance Statement (e.g.LRI-9). 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.

1.4.8.2 BINDING STRENGTH

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

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

1.4.9 SCOPE OF IMPLEMENTATION

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

Due to receiving system variations and need, this guide does not specifically indicate for each field whether to store it or not. If desired, the HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1, US Realm can provide further guidance.

1.4.10 SNAPSHOT MODE

Result messages shall always be sent in snapshot mode, meaning that all information related to the smallest individually identifiable unit are complete. For this message type that would be the OBR and all related segments (OBX, NTE and SPM, OBX). I.e., if a correction and/or status update to at least one of the OBX segments under one OBR is necessary, all OBX segments, even if previously sent, shall be re-sent with the correction and/or current status and/or current values. For example, when a Complete Blood Count with manual differential is ordered, the blood count will be released and then at a later time the manual differential will be performed and released. When the blood count is released the report will provide only the count as final results. When the differential is completed, Snap Shot Reporting will send all previous results as well as the new results, in this case the blood count and the differential.

Also see sections 12.2 Culture and Susceptibilities Reporting, 12.3 Confirmatory and Reflex Testing, and 12.4 Add-On Testing regarding related tests/orders that may be under other one or more additional OBR/OBX(s) or under a new order, but must be included in the same message.

1.4.10.1 EXAMPLE HOW SNAPSHOT IS EVOKED

A CBC with Ordered Manual Differential panel –Blood is ordered. In this example, the initial result message includes a series of observations for the complete blood count. The subsequent message includes the most current status of all available observations for the complete blood count and for the manual differential.

Initial Message

```
MSH|...<cr>
PID|...<cr>
ORC|NW|...<cr>
// CBC with Manual Differential panel- Blood
OBR|1|...<cr>
// CBC Observations
OBX|1|...<cr>
OBX|2|...<cr>
...
SPM|1|...<cr>
...
```

OR

```
OBR|1|123456789^PlacerOrderNumber^2.16.840.1113883.19.0^ISO|9
   87654321^FillerOrderNumber^2.16.840.1113883.19.0^ISO
   |57782-5^ CBC with Ordered Manual Differential panel-
   Blood^LN||||||||||||||||||||P|...
OBX|1|SN|6690-2^Leukocytes [#/volume] in Blood by Automated
   Count^LN|||||||F|...
OBX|2|SN|789-8^Erythrocytes [#/volume] in Blood by Automated
   Count^LN|||||||F|...
...
SPM...
```

Subsequent Message

```
MSH|...<cr>
PID|...<cr>
ORC|NW|...<cr>
// CBC with Manual Differential panel- Blood
OBR|1|...<cr>
// CBC Observations
OBX|1|...<cr>
OBX|2|...<cr>
// Manual Differential Observations
```

```
OBX|3|...<cr>
OBX|4|...<cr>
SPM|1|...<cr>
```

OR

```
...
OBR|1|123456789^PlacerOrderNumber^2.16.840.1113883.19.0^ISO|9
   87654321^FillerOrderNumber^2.16.840.1113883.19.0^ISO
   |57782-5^ CBC with Ordered Manual Differential panel-
   Blood^LN||||||||||||||||||||P|...
OBX|1|SN|6690-2^Leukocytes [#/volume] in Blood by Automated
   Count^LN|||||||F|...
OBX|2|SN|789-8^Erythrocytes [#/volume] in Blood by Automated
   Count^LN|||||||F|...
OBX|3|SN|2626-8^Leukocytes [#/volume] in
   Blood^LN|||||||F|...
OBX|4|SN|30180-4^Basophils/100 Leukocytes in
   Blood^LN|||||||P|...
...
SPM...
```

In the previous example demonstrating when SNAPSHOT mode if invoked, you will notice that the 4th observation has a result status of P, or preliminary. In SNAPSHOT mode, you send the most up to date status of the observation. Please see discussion on relationship between ORB 25 and OBX 11 in Section 8.9.3. When this observation changes status to final, OBX 11 will change to F in the subsequent message (see example below). In effect, both the preliminary and the final version of the same observation will never be sent in the same message.

OR

```
...
OBR|1|123456789^PlacerOrderNumber^2.16.840.1113883.19.0^ISO|9
   87654321^FillerOrderNumber^2.16.840.1113883.19.0^ISO
   |57782-5^ CBC with Ordered Manual Differential panel-
   Blood^LN||||||||||||||||||||F|...
OBX|1|SN|6690-2^Leukocytes [#/volume] in Blood by Automated
   Count^LN|||||||F|...
OBX|2|SN|789-8^Erythrocytes [#/volume] in Blood by Automated
   Count^LN|||||||F|...
OBX|3|SN|2626-8^Leukocytes [#/volume] in
   Blood^LN|||||||F|...
OBX|4|SN|30180-4^Basophils/100 Leukocytes in
   Blood^LN|||||||F|...
...
```



```
SPM ...
```

1.4.11 TEXT ENTRIES AND ALLOWED ESCAPE CHARACTERS

For NTE segments, or when the FT, ST, or TX data type is used in OBX-2 (Value Type), the expectation is that content in either NTE-3 (Comment) or OBX-5 (Observation Value) is based on a mono-spaced font and may utilize specific formatting to communicate data relationships, e.g., tabular-aligned data. Both sending and receiving parties must agree on how to preserve and recreate the visual qualities of the mono-spaced formatting in the final display where required. The sender may not assume that such formatting is preserved without specific agreement with the receiver. The receiver is not obligated to conform to this guide to preserve that type of formatting.

The FT, ST, and TX data types allow use of the formatting escape sequences documented in *HL7 Version 2.5.1, Chapter 2, Section 2.7.1 - Use of Escape Sequences in Text Fields*. In this Implementation Guide, the only escape sequences supported are those allowed in *HL7 Version 2.5.1, Chapter 2, Section 2.7.4 - Special Characters*. These are the escape sequences for the message delimiters (i.e.,|^&~\ or|^&~\#).

Note that the ST data type is typically used for short text strings. No leading blanks (space characters) are permitted; trailing blanks are permitted.

The TX data type is used to carry string data intended for display purposes. It can contain leading blanks (space characters).

1.4.12 EXTENDED PROFILE USE

The sender may create other profile components or profiles that are defined outside of this Implementation Guide for use in conjunction with the profiles and profile components defined in this guide. However, those profiles and profile components are strictly voluntary and shall be properly constrained against the base standard and the profiles and profile components defined in Section 6.3 Result Profile Components. Neither the sender nor the receiver shall require the use of any additional profiles and profile components in combination with the profiles and profile components defined in this guide to achieve a successful send or receive of Lab Results.

1.4.13 ERROR HANDLING

EHR-System functional requirements to support the EHR-S handling of results in the inter-organizational exchange use case as described in this Implementation Guide have been published as the *HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1, US Realm, Draft Standard for Trial Use, April 2016*[6]. An excerpt from Section 6 EHR Error Responses is included below:

---------- *begin citation* ----------

The EHR is required to be able to respond to an LRI transaction with one or more success or failure responses. In most cases, the EHR will provide two responses; the first in a System acknowledgement (MSA-1 = CR or CA) to indicated that it has received the LRI transaction from the previous sender (this may be a gateway or HIE) and the second is an application level response to indicate the success (MSA-1 = AA or AE) or failure (MSA-1 = AR) of the transaction to meet the standards for the LRI guide and application requirement specified in this guide. In enhanced Acknowledgment mode, details about soft

[6] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=433

errors (MSA-1 = AE) or hard errors (MSA-1 = AR) are communicated through the use of the appropriate ERR segment elements (ERR-3 and/or ERR-5) as defined in the LRI IG.

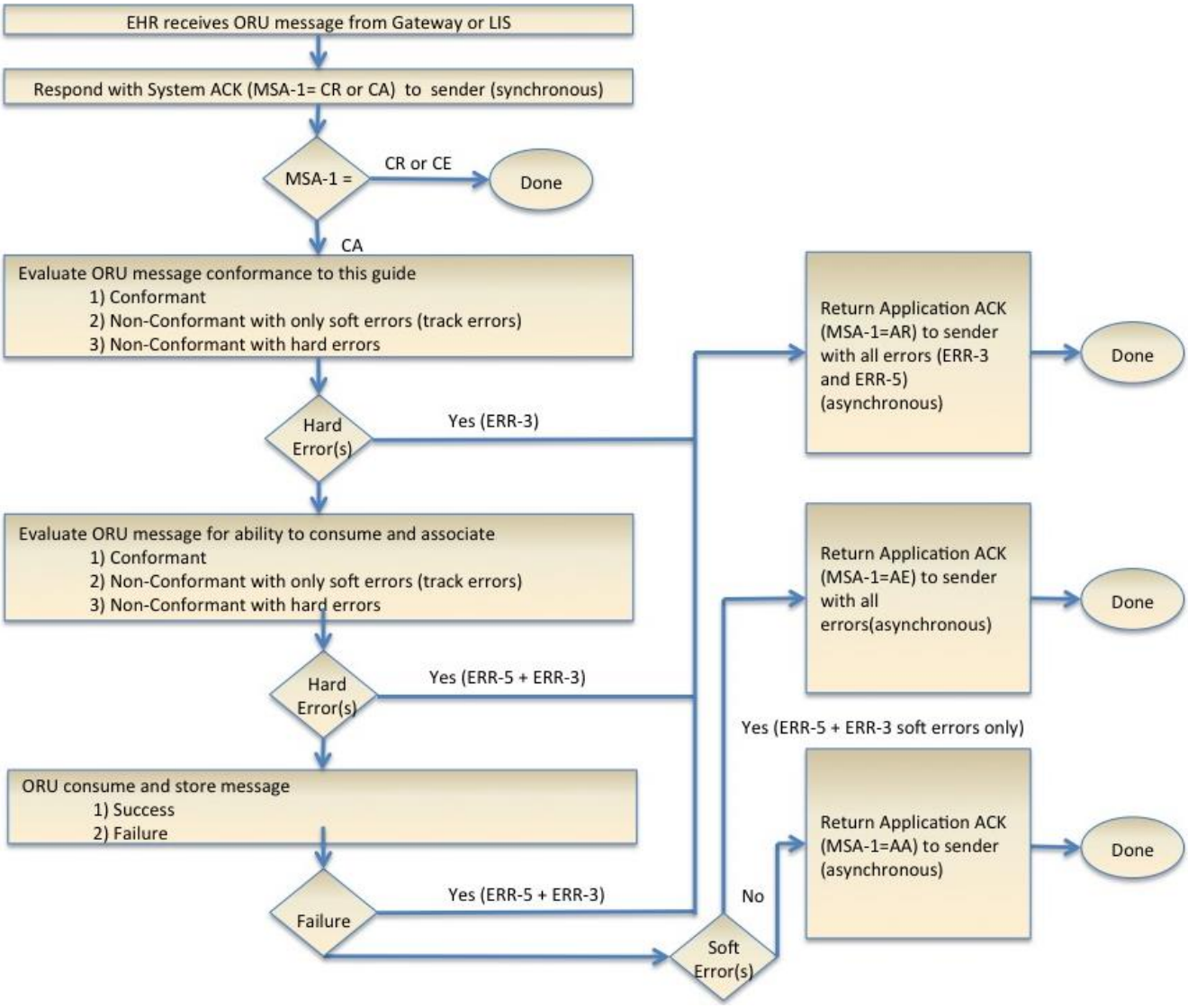

Figure 1-1. LRI Message Evaluation In EHR

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

2 USE CASE – LABORATORY RESULTS

In this Use Case, the laboratory provides results based on a request for laboratory services from an authorized Provider. It is assumed that the receiving system is an EHR-S that can receive lab results even if it is not aware of the request, as there is no assumption that the receiving EHR-S provided the request for lab services.

2.1 Scope

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

When developing this guide and scoping the use cases the project focused their attention primarily on inter-organizational use cases involving ambulatory providers and laboratories. This expanded to include public health reporting as well. With the addition of clinical genomics and newborn dried blood screening the clinical content has been further extended as well. That leaves a number of intra-organizational use cases that may be found within a hospital or larger health system in particular that may not have been fully accommodated.

Our goal is to fully validate these use cases in a subsequent version and may in fact already have been covered. For example, complete administrative/financial data are typically sent separately from orders and results in hospital settings where other systems already manage that. The guide already accommodates inclusion/exclusion of such data. Within the clinical content there is less likely variation in what data to send separately. Therefore, we encourage use of this guide for intra-organizational use cases as well to maintain consistency of use but recognize that at this stage those may not be fully supported. Any comments to fill any gaps that you may have identified are welcomed to inform the next version.

2.1.1 IN SCOPE

- Defining the core data elements required for inter-organizational clinical laboratory test results.
- Reporting of clinical laboratory test results for inter-organizational clinical care in the US Realm for an order that was placed either manually or electronically, including results from add-on and reflex testing.
- Sending clinical laboratory test results as standardized structured data so they can be incorporated that way into an EHR-S.
- Supporting ONC certification criteria and Meaningful Use (MU) requirements by developing requirements for an interface that enables the incorporation of clinical laboratory test results into an EHR-S when data is sent as standardized structured data.
- Some order specific data has been included to enable the receiving EHR-S to correlate the results back to the originating order.
- All applicable CLIA requirements, see Section 13.1 Clinical Laboratory Improvement Amendments Considerations.
- Receiving of laboratory results by a non-ordering provider, e.g., copy-to provider.
- Advanced error messages related to application transport.

2.1.2 OUT OF SCOPE

- Specifications and implementation guidance on laboratory ordering transactions. However, the establishment of requirements in the laboratory result message that will allow the matching of the reported result to an existing order initiated from the ordering clinician's EHR-S is within the scope of this guide.
- Querying for laboratory results.
- Querying for historical laboratory results.
- Receiving historical laboratory results.
- Secondary use of laboratory data (i.e., public health or bio surveillance uses of the reported laboratory results) except as specifically identified in this implementation guide.
- In hospital ordering and reporting of laboratory results.
- Results not transmitted using a standardized structured format, e.g., scanned documents, direct entry into EHR.
- Requirements on what data the Lab is to include from the original order in the result based on considerations such as public health, results copies to, interpretations, etc. will be addressed in a separate document functional requirements for a Lab system which is a separate project yet to be started. Until such time Labs are expected to work with their stakeholders to determine what data to include.

2.2 Actors

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

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

2.3 Results for Ambulatory Care Use Case and Context Diagrams

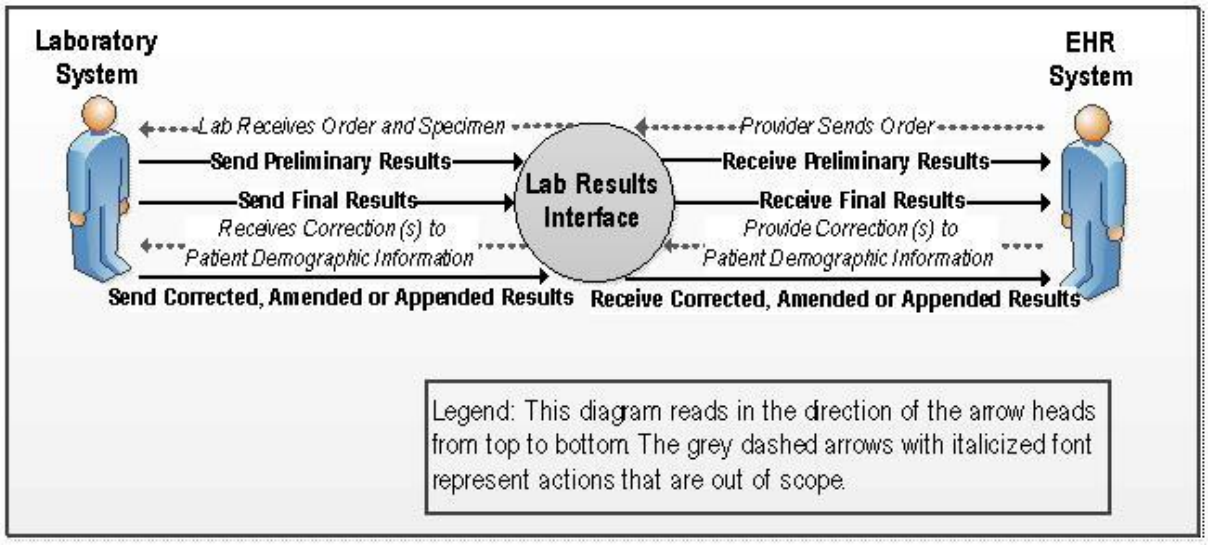

Figure 2-1. Context Diagram

2.4 User Story

A Provider (order placer) enters a laboratory order into an ambulatory EHR-S, generating either a paper or electronic laboratory requisition that is sent to the laboratory. The information is then entered manually or captured electronically into the LIS. The specimen is collected and delivered, if necessary, to the laboratory for processing.

If the specimen is satisfactory for testing the laboratory will attempt to perform the test. Prior to successful completion of a test, communication may be necessary to indicate test cancellation or failure to perform the test and the related reasons (for example, specimen is not appropriate for ordered test). The test cancellation and/or specimen rejection is communicated using the result message in this IG.

Upon successful completion of testing, results are entered and/or released into the LIS. Authorized laboratory personnel review and approve the test results or the results are released from LIS via an auto-verification process. The result is electronically transmitted to the EHR-S where the EHR-S incorporates the result into the patient's electronic record. The ordering and, if needed, other copy-to providers (result receiver) then review the laboratory result to inform patient care.

2.5 Use Case Assumptions

Providers securely access clinical information through an EHR-S.

Appropriate security and transport protocols; patient identification methodology; requisition (order) identification methodology; consent; privacy and security procedures; coding, vocabulary and normalization standards have been agreed to by all relevant participants.

All relevant parties have agreed on a structured laboratory test results message format.

This Use Case covers all CLIA reporting requirements.

For the specimen collection process the data included in the dataset considerations table[7] are assumed to be available and reported in the result.

[7] Section 13.0 - LRI Use Case: http://wiki.siframework.org/LRI - FINAL Use Case

Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect.

Established network and policy infrastructure to enable consistent, appropriate, and accurate information exchange across provider systems, data repositories and locator services. This includes, but is not limited to:

- Methods to identify and authenticate users;
- Methods to identify and determine Providers of care;
- Methods to enforce data access authorization policies;
- Methods to ensure the veracity of data;

Detailed audit trails are kept as necessary by all participating systems.

Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of patient privacy and security; i.e. HIPAA, HITECH and EHR certification criteria.

An LIS will be the sender of laboratory test results while an EHR will be the receiver.

The transport mechanism will provide guaranteed delivery and error handling.

This Use Case acknowledges the variations in requirements for reporting across local, state, tribal, and territorial boundaries as well as voluntary versus mandatory requirements.

Laboratories meet accreditation criteria according to jurisdiction requirements or agency criteria.

2.5.1 PRE-CONDITIONS

Rules, regulations, and protocols are in place to send specimens and test orders to the appropriate public health laboratory when specific results are produced. These tests are for various public health purposes including but not limited to confirmation of initial results, speeding up outbreak detection and identification, etc.

An order has been generated by an Ordering Provider for one or more laboratory test results to be produced.

When indicated, the Laboratory receives request to send laboratory results to a non-order placer.

The Laboratory receives an order (electronic, paper, etc.) or the Laboratory receives a request to re-run (repeat) a test, or determines a need to re-run a test for possible correction, or determines that reflex testing (which is based on criteria set by the medical review board) is required or determines the need to amend a test result based on erroneous information.

The Laboratory receives the appropriate clinical information to perform the ordered test.

Laboratory has entered, manually or through the interface, pertinent (or corrected) data from an order into the LIS

Laboratory has received and processed properly identified specimen(s) related to the ordered test(s).

Laboratory entered or received from the ordering EHR-S, pertinent data from/about the specimen into the LIS.

Laboratory performed the ordered tests on received specimens and/or incorporated calculated and reference data to produce the results to be exchanged.

The laboratory result message contains both the appropriate patient information and the originating order information to associate the laboratory results to the correct patient and original order.

The LIS is capable of and ready to send laboratory results electronically and in standardized structured format.

EHR-S is in place and capable of receiving laboratory results electronically and in standardized structured format.

The laboratory result is verified and ready for release.

2.5.2 POST CONDITION

Laboratory results are accurately reported and successfully transmitted electronically from the LIS to the Ordering Provider's (*order placer's*) EHR-S, module or other results receiver.

The LRI result receiver has electronically received the laboratory results, incorporated in a standardized structured format, and if available, associated with a patient and laboratory order.

2.5.3 FUNCTIONAL REQUIREMENTS

TABLE 2-1. INFORMATION INTERCHANGE REQUIREMENTS

Initiating System	Action	Requirement	Action	Receiving System(s)
Laboratory Information System	Sends	Laboratory Test Result	Receives	Electronic Health Record System Public Health Information System

Note: Receiving systems vary by use case.

TABLE 2-2. SYSTEM REQUIREMENTS

Systems	System Requirement
Laboratory Information System	Form a laboratory message with standardized structured data[8] meeting CLIA and other federal and state regulatory requirements.
Electronic Health Record System Public Health Information System	Incorporate test data from the laboratory message as standardized structured data.

2.6 Sequence Diagram

Figure 2-2. Sequence Diagram is the Interaction Diagram between the Lab Results Sender and the Lab Results receiver in the order that they occur. These interactions can be in response to a previous order which is not shown in the diagram. The top boxes identify the systems. The boxes along the vertical represent trigger events with associated messages. This shows the Node-to-Node (or End-to-End) acknowledgements using HL7 Enhanced Application Acknowledgements.

[8] See the S&I LRI Use Case, Section 2.3 Structured Data Definition

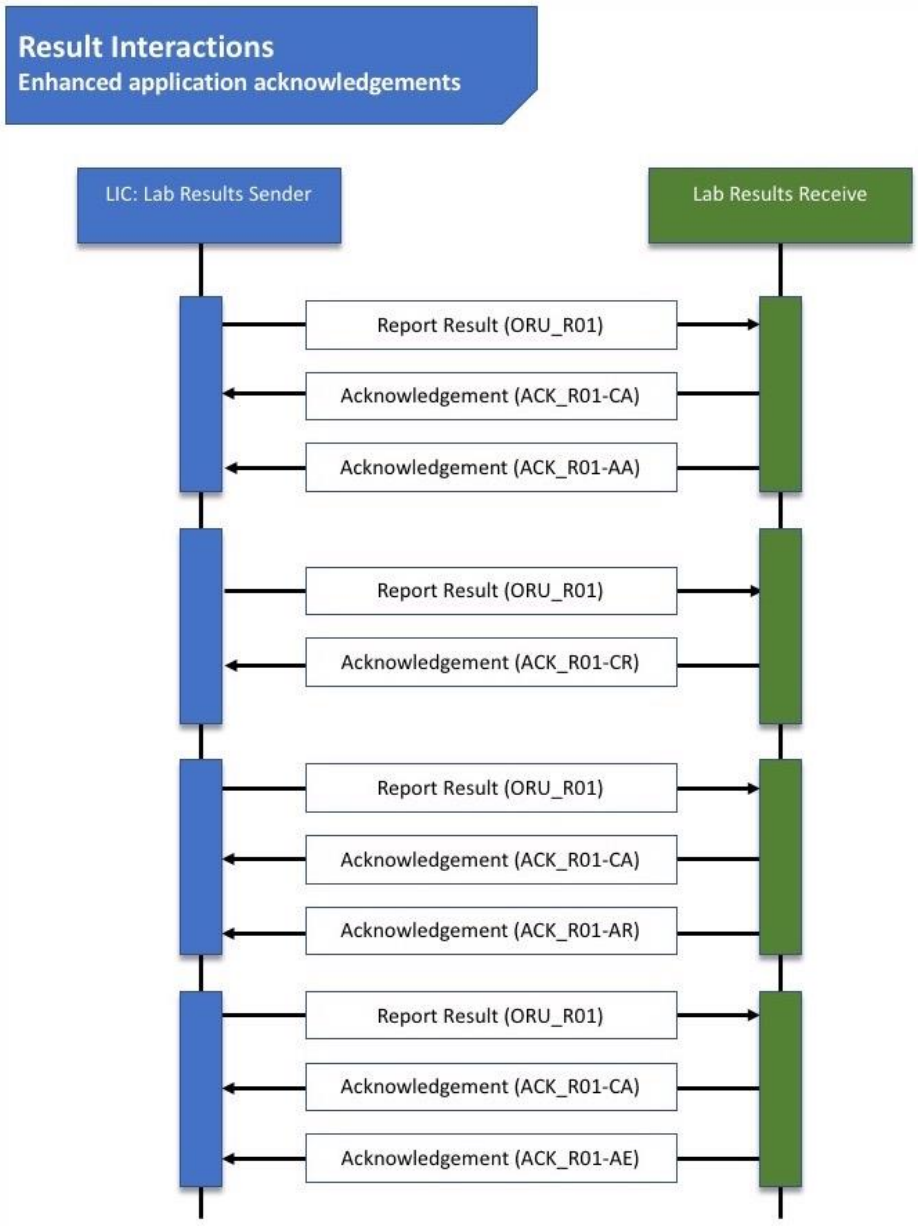

Figure 2-2. Sequence Diagram

The first message shows the Lab Results Sender transmitting a message to the Lab Results Receiver which is committed to safe storage by the receiver (ORU_R01-CA). The Lab Receiver then further processes the message. Upon completion of processing, the Lab Results Receiver sends an application acknowledgement indicating that the result was successfully incorporated in the application (ACK_R01-AA).

The next transaction begins the same way, but the Receiver rejects the message and does not commit it to safe storage (ACK_R01-CR).

The third transaction shows the Lab Results Sender transmitting a message to the Lab Results Receiver. The message is committed to safe storage by the Lab Results Receiver. In this case the Receiver processes the message and is unable to incorporate it into the application. The Lab Results receiver responds with an Application level error (ACK_R01-AR). This is an Application Rejection. The specific reason for the rejection will be in the ERR segment of the message. Note that this could be a retry of the

second transaction. It could be that corrections were made in the systems which enable the Receiver to accept the message but other errors exist that prevent the receiver from incorporating the result. The sender could correct and try to send the message again.

Each message could have one of the four outcomes shown. The last (fourth) transaction is just like the third transaction except that the Lab Results Receiver application sends back an Application Error (ACK_R01-AE) instead of a reject. The details of why the transaction failed will be in the ERR segment. The sender could correct and send the message again and have any one of the four outcomes shown.

3 USE CASE – PUBLIC HEALTH REPORTING

This use case is supported by the LRI_PH_Component; see Section 6.3.11 LRI_PH_Component – ID: 2.16.840.1.113883.9.195.3.5.

This profile component describes the additional constraints and guidance needed to transmit reportable laboratory observations to appropriate local, state, territorial and federal health agencies using the HL7 2.5.1 ORU^R01 message.

3.1 Message Requirements

This implementation guide defines components that are combined into profiles to define specific conformance requirements that must be combined to create a valid Profile for a particular transaction. As of this version a valid profile for this use case consists of a minimum of four components:

1) LRI_Common_Component
2) LRI_GU_Component
3) LAB_FRU_Component
4) LRI_PH_Component – Public Health Reporting

3.2 Audience

This component is designed for use by analysts and developers who require guidance on data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* relative to the *Public Health Lab Result/ELR Use Case*.

3.3 Scope

The following scope statements are in addition to those listed in Section 2.1 Scope. For LRI_PH_Component, the receiving system is the Public Health Disease Surveillance System, defined as LRI_PH_Component Receiver below, and not the Electronic Health Record System (EHR-S).

3.3.1 IN SCOPE

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

3.3.2 OUT OF SCOPE

- Querying patient demographics.
- The use case for public health laboratory test orders.

- Reporting of results to Cancer Registries.
- Results from nonliving subjects (water, food, air).
- Reporting of Healthcare Associated Infections (HAI) to the National Healthcare Safety Network (NHSN).

3.4 User Story

The laboratory result is determined to be a reportable laboratory result for the patient's and/or the provider's public health jurisdiction. The results sender, e.g., LIS or EHR, transmits the results to the appropriate public health jurisdiction. The public health jurisdiction's LRI_PH_Component Receiver incorporates the results in their disease surveillance system allowing for the appropriate follow up by the public health jurisdiction.

3.5 Use Case Assumptions

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

3.6 Sequence Diagrams

3.6.1 SINGLE ORU MESSAGE

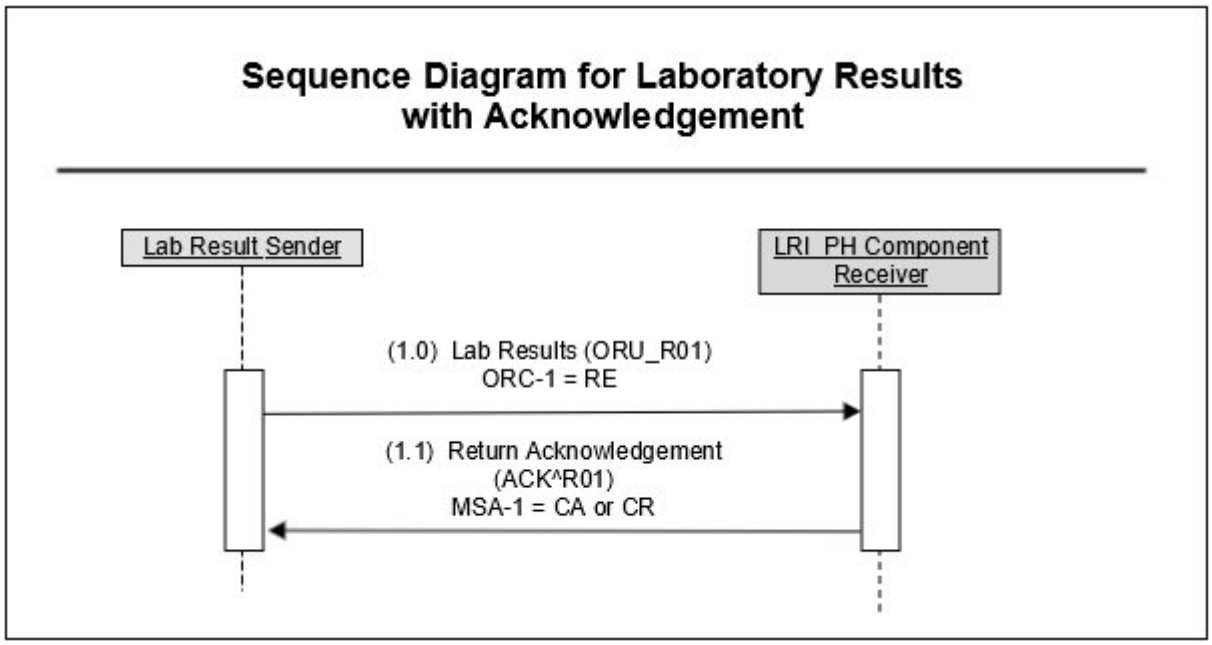

Figure 3-1. Sequence Diagram for Laboratory Result with Acknowledgement

The sequence begins with the Lab Results Sender transmitting an ORU^R01^ORU_R01 message (ORC-1=RE) to the LRI_PH_Component Receiver (1.0).

Upon receipt of the message, an acknowledgement is sent by the LRI_PH_Component Receiver to the Lab Result Sender using the ACK^R01^ACK message type (1.1). Conformant systems are only required

to support the LRI_ACKNOWLEDGEMENT_COMPONENT (2.16.840.1.113883.9.26) to fulfill this use case.

The LRI_PH_Component Receiver either accepts (MSA-1=CA) or rejects (MSA-1 = CR) the message.

3.6.2 BATCH MESSAGE

Transmission of LRI_PH_Component messages using batch protocol is optional and not a requirement of this guide.

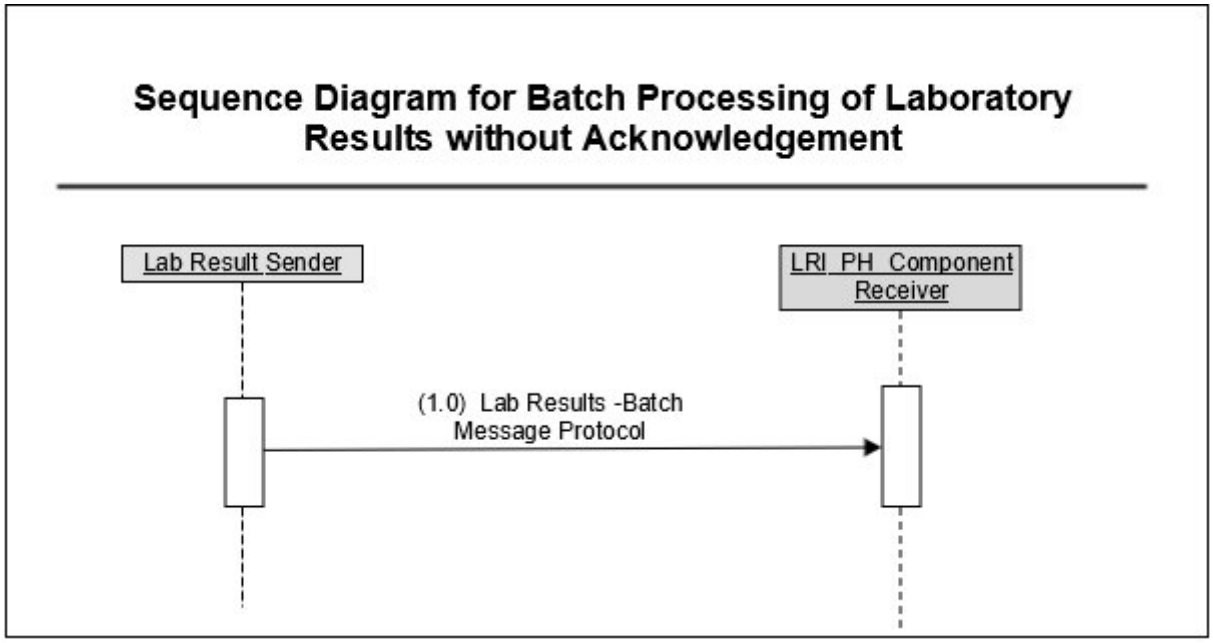

Figure 3-2. Sequence Diagram for Batch Processing of Laboratory Result without Acknowledgement

The sequence consists of Lab Results Sender transmitting zero or more ORU^R01^ORU_R01 messages to the LRI_PH_Component Receiver (1.0) using the batch protocol.

The LRI_PH_Component Receiver sends no acknowledgement.

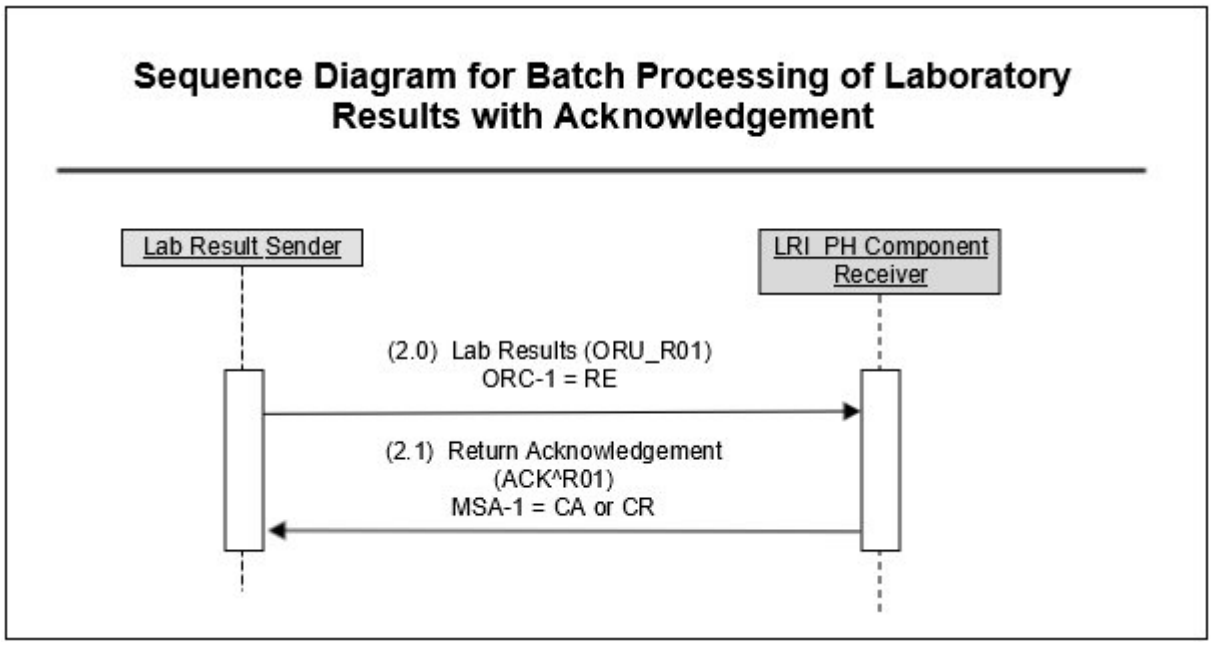

Figure 3-3. Sequence Diagram for Batch Processing of Laboratory Result with Acknowledgement

The sequence consists of Lab Results Sender transmitting zero or more ORU^R01^ORU_R01 messages to the LRI_PH_Component Receiver using the batch protocol (2.0). A batch containing zero HL7 messages may be sent to meet a requirement for periodic submission of batches when there are no messages to send.

Upon receipt of the message, a single acknowledgement is sent by the LRI_PH_Component Receiver to the Lab Result Sender for the batch message using the ACK^R01^ACK message type (2.1) .

The LRI_PH_Component receiver either accepts (MSA-1=CA), rejects (MSA-1 = CR), or errors the message (MSA-1= CE).

4 USE CASE – RESULTS FOR NEWBORN DRIED BLOOD SPOT (NDBS) SCREENING

This use case is supported by the NDBS_Component; see Section 6.3.12 LRI_NDBS_Component – ID: 2.16.840.1.113883.9.195.3.6.

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

In this Use Case, the Newborn Screening Laboratory provides NDBS results to an authorized results receiver. It is assumed that the receiving system can receive lab results even if it is not aware of the request, as there is no assumption that the receiver provided the request for lab services. However, it is important to note that the primary focus of this guide is to provide a framework for reporting results back to the facility that collected the specimen and gathered the associated data elements.

4.1 Scope

The following scope statements are in addition to those listed in Section 2.1 Scope. The scope is the sending of NDBS results from a newborn screening laboratory to receivers of the results, which may include primary care physicians, birth hospitals, public health agencies, health information exchanges (HIEs), and vital records departments. Any variations that are specific to Newborn Dried Blood Spot (NDBS) are identified in separate subsections where appropriate and prefacing them with "LRI_NDBS_Component".

4.1.1 IN SCOPE

Describing the specifications that may be used for the reporting of electronic lab results in the current state of business process flow in Newborn Dried Blood Spot Screening.

Specifying the interaction between laboratories that conduct NDBS results testing and the receivers of the results, including primary care physicians, birth hospitals, and health information exchanges (HIEs), as well as public health agencies and vital records departments (more data elements may be required than what is defined here). The main focus is the originators of the order, e.g., primary care physicians and birth hospitals.

4.1.2 OUT OF SCOPE

Reporting of point of care results for newborn screening for Early Hearing Detection and Intervention (EHDI) and Critical Congenital Heart Disease (CCHD)

Newborn hearing screening (refer to *HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Results Release 1*)

Sending results of diagnostic follow-up testing triggered by abnormal results within newborn dried blood spot screening (because this component has not been specifically reviewed for those requirements).

NDBS screening practices and specifications of electronic messages exchanged for newborn screening conducted internationally outside of the United States. However, NDBS programs outside the U.S. could adopt this Implementation Guide.

This Implementation Guide provides a general set of specifications for an electronic NDBS laboratory

results message. It does not identify, eliminate or override variations in state or local jurisdiction requirements for data collection, reporting, or protection of privacy and security of patient data. Variations in local laws and practices may result in additional data requirements for NDBS screening.

4.2 User Story

Some states by policy test and report unsatisfactory specimens, otherwise the user story is identical to Section 2 Use Case – Laboratory Results.

4.3 Use Case Assumptions

Each ORU^R01 message contains laboratory test result information for a single Newborn Dried Blood Spot card (the specimen).

5 USE CASE – CLINICAL GENOMICS RESULTS REPORTING

This use case is supported by the LRI_CG_Component; see Section 6.3.13 LRI_CG_Component – ID: 2.16.840.1.113883.9.195.3.8.

Simple genomic studies are often reported in structured format as a simple categorical test with encoding. The studies typically include the variant name in the test name and report whether that mutation is present or absent. An example is "`LOINC code 24475-6 "F2 gene c.20210G>A [Presence]...`".

However, the majority of complicated genetic test results are reported as purely narrative reports with no computer accessible coding. The goal of this component is to encourage and make it easier to add coded results to the purely narrative genomic reports. Structuring genetic reports defined by this IG would enable the delivery of data that could be used in decision support and medical record queries, and adoption could be relatively simple for the clinical laboratories that already use HL7 v2.x. It is not intended to satisfy all of the needs of all genomic studies.

5.1 Key Technical Decisions

The following items are specific to this use case.

5.1.1 SUPPORT FOR NUMERIC RANGE (NR) DATA TYPE

The Numeric Range (NR) HL7 data type is used to specify the lowest and highest values in a series of data. This component uses the NR data type for a number of variables in the specification (e.g. LOINC 51959-5 Ranges of DNA sequence examined; see Table 5-1, Row A.6), to specify the start and end location of the DNA sequence. Each repeat of an NR requires a separate OBX, and the OBX-4 values will have to differ among such repeats. See Section 5.4 OBX-4 (Observation Sub-ID) Dot Notation To Represent The Message Hierarchy for how to specify the OBX-4 values.

5.1.2 OBX-4 DOT NOTATION TO REPRESENT THE MESSAGE HIERARCHY

Please note that the OBX-4 notation used in the LRI_CG_Component uses the OG_02 data type flavor, which has changed since the 2013 Clinical Genomics Implementation Guide. See Section 9.3.5 for the CWE data type definition and Section 5.1.2 for more details on how to use the OBX-4 numbering in the CG component.

5.1.3 GUIDELINE FOR REPRESENTING CODED ELEMENTS

Value sets are comprised of a code and text (made of a print string) as defined in a code system. The following examples describe best practices for representing coded elements in Clinical Genomics reports.

5.1.3.1 HUGO GENE NOMENCLATURE COMMITTEE (HGNC)

This code system has a single code (e.g., "HGNC:1884") and two potential names: the symbol (e.g. "CFTR") and the full name (e.g., "cystic fibrosis transmembrane conductance regulator"). The gene coding system in this guide uses the symbol as the "name" in CWE.2 (Text), not the full name.

5.1.3.2 NON-STRUCTURED CODE SYSTEMS

While the HGNC has two possible names, some coding systems have no obvious name defined. The dbSNP database, which carries more than 150 million "rs" codes, is a case in point. This guide recommends the code be reported in CWE_05.1 (Identifier) and CWE_05.2 (Text) as demonstrated in the examples.

Some code systems do not have specific codes, but define a syntax for expressing a value, e.g., HGVS and ISCN. For the LRI_CG_Component, the guidance is to convey the syntax in CWE_05.2, consistent with guidance for reporting using code-only code systems.

5.1.4 CONVENTIONS FOR DIRECTION AND NUMBERING OF GENETIC SEQUENCES

All of the genomic data reported in this type of panel uses a coordinate system beginning with 1 and assumes the variants are reported from the positive strand and have an inclusive start-end. This is the assumption embedded in HGVS, the NCBI's public distributions, Ensembl, COSMIC, and most other genomic databases. This choice does not constrain receivers from converting to a different (e.g. 0 to start) coordinate system, it only specifies what goes in the message.

5.2 Scope

The following scope statements are in addition to those listed in Section 2.1 Scope.

5.2.1 IN SCOPE

- Reporting one or more simple genetic variants – those with a contiguous set of changes in the tested sample compared to a reference sequence.
- Reporting structural and copy number variants – those with large changes in contiguous nucleotides, often including very large variants, tens of thousands to millions of nucleotides in length.
- Reporting pharmacogenomics studies, which look for simple or complex variants that affect the rate of metabolism, efficacy, or the risk of one or more drugs, and often include suggestions about possible change in dosing or the use of a different drug. These may or may not be linked to the very specific details reported about other types of variants covered in this guide.
- Reporting complex variants – those made up of multiple simple or structural variants, which together define or influence a phenotype. Haplotypes and Compound Heterozygotes (Hets) are examples. This guide provides variables for reporting information about the complex variant as a unit and for reporting full details about related simple and structural variants using the same variables as used for reporting unrelated simple and structural variants.
- Reporting germline and somatic variants.

The following are explicitly included in the guide to be unambiguous, even though they are already in scope by implication in this guide:

- Reporting partial or complete DNA sequencing, including whole genome and exome studies. Use the LOINC term, 81293-3 "Description of ranges of DNA sequences examined" to assert whether the study is a whole genome or whole exome study, and whether it is targeting only specific exons.
- Reporting mosaicism – Mosaics can be reported in ISCN syntax as the value of LOINC 81291-7 Variant ISCN (Table 5-1 Row A.11). The abbreviation for the mosaicism is in ISCN "mos" and a slash (/) is used to separate between karyotypes for each cell line in the mosaic, e.g.: mos 47,XXX[25]/46,XX[5] using ISCN syntax.
- Reporting mitochondrial DNA variation – Use NC_012920 as the genomic reference sequence for all mitochondrial variations. All of the mitochondrial genes are located in the RefSeq as though they had their own chromosome. Transcript reference sequences will each have their own NM_ RefSeq.

5.2.2 OUT OF SCOPE

- Non-human genetic studies (Genetic studies with non-human subjects)

- Single variants that are reported as simple tests, e.g. LOINC 24475-6 F2 gene c.20210G>A [Presence].
- Gene/chromosome fusions (and trinucleotide repeats), and similar studies that are also reported as simple lab tests whose quantitative results may be the number of blood cells containing a specified anomaly, the ratio of a marker gene, or the number of trinucleotide repeats, and are accommodated by existing LOINC codes.
- Commercial Cell Free Prenatal studies and DNA based colon cancer screening tests, which at present, report conclusions and risk for various anomalies, but not raw genetic data.
- Reporting cytogenetic variants that use legacy techniques, such as conventional banding (e.g. G-banding), which are covered in the HL7 Version 2 Implementation Guide: Clinical Genomics; fully LOINC-Qualified Cytogenetics Model, Release 1 - US Realm, published in July 2014.

5.3 Model For V2 Genetics Reporting Message

Figure 5-1. Object Model Of The Coded Clinical Genomics Results Message represents the clinical genetics report message showing all of the major LOINC panels that can make up a report and how they are related; this model does not show single observations that may repeat within a panel.

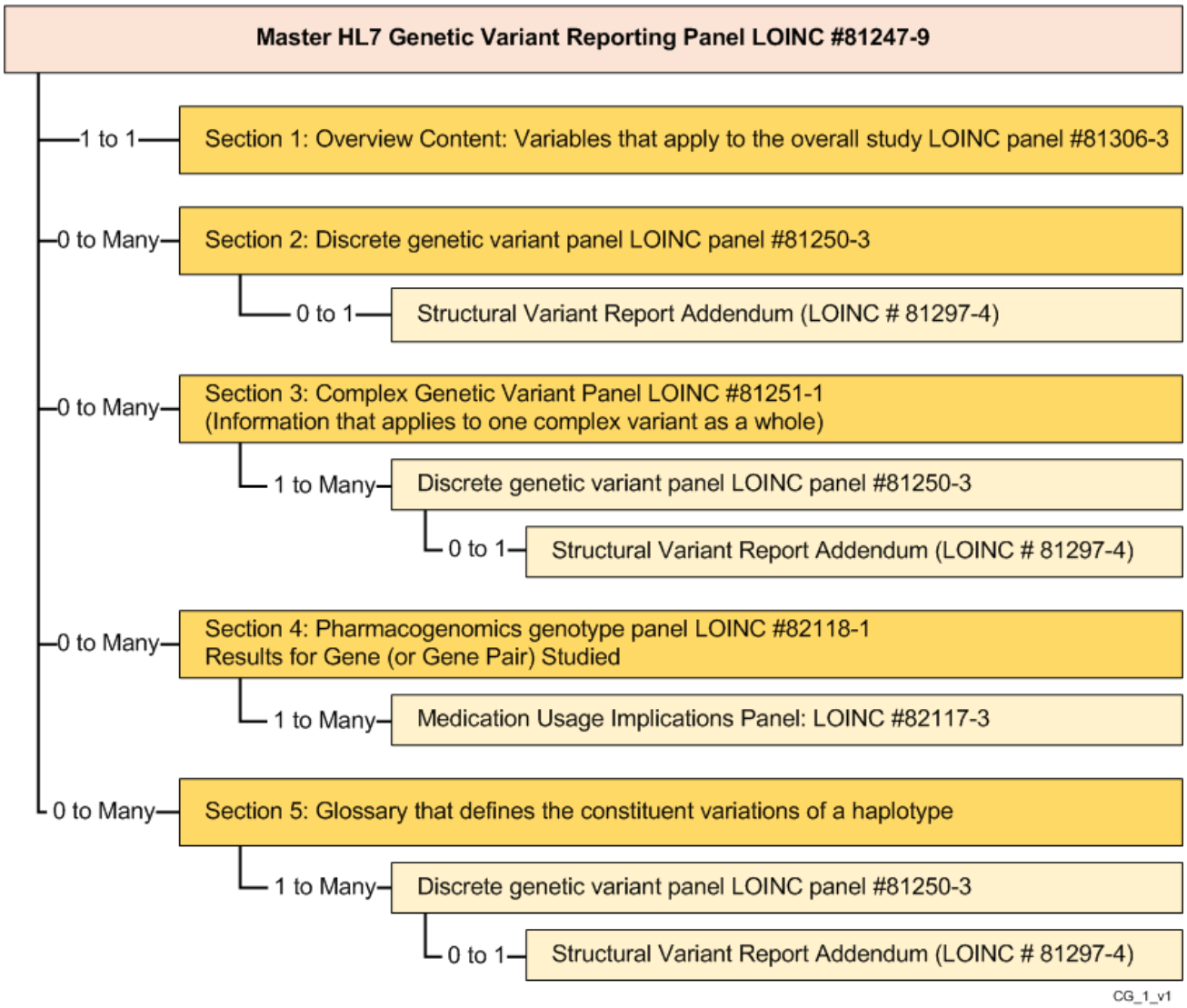

Figure 5-1. Object Model Of The Coded Clinical Genomics Results Message

5.4 OBX-4 (Observation Sub-ID) Dot Notation To Represent The Message Hierarchy

This LRI_CG_Component uses nested OBR-OBX relationships to represent the hierarchy of the message. The hierarchical panel structure in LOINC defines the message structure and the hierarchy is defined by a dot notation recorded in the OBX-4 (Observation Sub-ID) values of the message.

While the 2013 HL7 Clinical Genomics Implementation Guide for Clinical Genetics used nested OBR-OBX relationships to represent the structure of the message, the HL7 Clinical Genomics Work Group believes using dot notation (like a Dewey decimal) to represent nesting structure in OBX-4 is better. The message is still defined conceptually by a hierarchy of LOINC panels (as shown in the example/definition), but the LOINC panel codes are not included in the message at all, and the hierarchy is indicated by the dot notation in OBX-4 rather than as parent-child relationships between OBRs and OBXs. The message contains just one OBR, which carries the code for the order.

However, in the future, the CG component will choose a single method for specifying the OBX-4 before it becomes a normative standard.

Please see Section 8.11.2 Grouping of Related OBX Segments for how other components in the LRI groups OBX segments and represents OBX-4 numbering.

5.4.1 ALGORITHM FOR DEFINING OBX-4 VALUES

The dot notation for all variables in a given section always begins with the parent section number. For the clinical genomics message, the section numbers are stable, and assigned by the report section topic, as seen in Table 5-1 through Table 5-6. Working top-down, the OBX-4 value for each question under that panel would begin with the section number. For example, if the message reports on a complex variant, the OBX-4 values for each question would begin with the number 3 to correspond to Section 5.6.3.3 Report Section 3 – Complex Variants. For all panels that can repeat, each question has a letter (without a dot) attached to the number, starting from "a". So because Report Section 3 can repeat, the questions in that panel would have OBX-4 values of 3a, (without a dot). If the panel that repeats is repeated a second time, then questions would be labeled 3b, and so on. If any individual question in this panel can repeat, then increment the OBX-4 values by the "dot-letter" starting with ".a", e.g. 3a.a, 3a.b, 3a.c, etc.

For a child panel nested inside of the parent panel, add a numbered level to the dot notation for each new child panel by incrementing by 1. Thus, all of the OBX-4s in the first panel at the first level in Section 3 would be valued with "3a", and its child panels would be "3a.1", "3a.2", etc. If the child panel itself can repeat, a letter (without a dot) is added to its section number, e.g. 3a.1a, 3a.1b, etc. If there is an individual question that repeats within the child panel, use the "dot-letter" notation, e.g. 3a.1a.a, 3a.1a.b, etc.

See HL7 V2 example messages in Section 5.9 Example Messages. The OBX-4 numbering following this algorithm is labeled in red colored font. For an example message that shows the full scope of the OBX-4 numbering, see the example report in Section 5.9.3.1 Example Of Pharmacogenomics Study Of 4 Genes With Guidance About Selected Drugs Nested In Results For Each Gene which illustrates repeated questions within repeated panels.

This description is written as pseudo-code below, in Section 5.4.2.

5.4.2 PSEUDO CODE FOR OBX-4 ALGORITHM

5.4.2.1 TERM DEFINITIONS

Containing Section: A section/panel that includes other sections/panels or questions.

Section Sequence Number (N): A sequence number starting from 1 used to differentiate unique sections on the same level of the structure.

Repeating Instance Letter (L): A letter starting from "a" to differentiate instances of a repeating section or question. If letter "z" is ever used, the next one would be "aa", and so on.

Note: The form itself is NOT treated as a Containing Section.

5.4.2.2 RULES FOR CREATING THE DOT NOTATION

On a form, with or without multiple instances of repeating questions or sections, go through each questions/sections starting from top of the form to the bottom as follows:

1) Set a new **Section Sequence Number (N)** to 1. Within each **Containing Section**, a separate "N" starting with 1 is used.

2) If it is a non-repeating section:

a) Its OBX-4 value is its **Containing Section's** OBX-4 value plus "." plus "N"; or just "N" if there is no **Containing Section**.

b) For all questions and sections within this non-repeating section, repeat step (1) through (5)

c) Increase "N" by 1.

3) If it is a repeating section:

a) Its OBX-4 value is its Containing Section's OBX-4 value plus "." plus "N" plus "L"; or just "N" plus "L" if there is no Containing Section.

b) For all questions and sections within this instance of the repeating section, repeat steps (1) through (5).

c) Repeat steps (3.a.) and (3.b) until all the instances of the same repeating section are processed.

d) Increase "N" by 1.

4) If it is a non-repeating question:

a) Its OBX-4 value is its Containing Section's OBX-4 value or just an empty value if there is no Containing Section "N".

5) If it is a repeating question:

a) Its OBX-4 value is its Containing Section's OBX-4 value plus "." plus "L"; or just "L" if there is no Containing Section.

6) Repeat step (5.a). until all repeating instances of the same question are processed.

5.5 Clinical Genomics Code Systems

Table 14-1. Clinical Genomics Coding Systems lists the 31 coding systems used by the LRI_CG_Component and defined in the HL7 Vocabulary Table 0396 – Coding Systems (http://www.hl7.org/special/committees/vocab/table_0396/index.cfm.) The table carries one system per row, where each row includes information from the HL7 Vocabulary Table 0396, including their HL7 V2.x linkage names, coding long names, and OIDs. For each coding system, Table 14-1 also includes a description, and when available, a URL that provides an overview of the source table for that coding system, a URL that permits viewing/exploring the content of that table, and/or a URL for downloading that table.

The LOINC coding system is used to identify the observations in the message in OBX-3. UCUM is the units of measures for OBX-6. The remaining code systems provide codes for variables that use coding systems to report their values in OBX-5.

Table 14-1. Clinical Genomics Coding Systems includes only *external* coding systems, such as ICD-9-CM and SNOMED CT and NCBI/EBI genetic content. It does *not* include the short answer lists that are linked to specific LOINC terms in the LOINC database. The next set of tables (Table 5-1 through Table 5-6) provides the short answer lists associated with LOINC codes, which identify the LOINC observations used in this guide along with LOINC definitional content, such as the description, cardinality, and answer lists, etc.

For the LRI_CG_Component, the CWE_05.2 component is declared to have lengths of at least 500 characters to accommodate potentially long syntax codes (i.e. HGVS or ISCN). For details of the CWE_05 data type see Section 9.3.5.

5.5.1 USE OF OIDS FOR CODING SYSTEMS OUTSIDE OF THIS GUIDE

A method to report genomic identifiers for reference sequences and variants from *public* databases that are not listed in Table 14-1. Clinical Genomics Coding Systems, or "HL7 Vocabulary Table 0396 – Coding Systems" or in the HL7 OID registry, is described below.

The LRI_CG_Component uses the CWE_05 data type flavor as shown in Table 9-7 (and similarly CNE_02 data type flavor as shown in Table 9-2). The code system ID would be communicated in CWE_05.1 (Identifier), and either CWE_05.3 (Name of Coding System) and/or CWE_05.14 (Coding System OID) must also be valued. Consider the recording of a transcript reference ID as the value of LOINC 51958-7, *Transcript reference sequence* (see Table 5-2, Row B.4 for an example). The ID for the reference sequence from that public source would be communicated in CWE_05.1 (Identifier) and the source OID in CWE_05.14 (Coding System OID). This same approach could be used for other genomic identifiers including genetic variation IDs, genomic reference sequence IDs, etc., that come from public sources not registered in HL7 Table 0396. Implementers are encouraged to request an HL7 OID and a coding system name for that source's genomic table from HL7 so that the identifiers for that source could be treated like all of the other coding systems used in this guide.

While this same OID mechanism could be used for identifying source tables for genomic identifiers from private databases, the submission of new variations and other genomic content to public registries such as NCBI or Ensembl is strongly encouraged, instead of, or in addition to, only keeping that data in a private database.

5.6 Structure of Clinical Genomics Messages

The set of closely related tables in Section 5.7 carry all of the LOINC codes (variables) that can be used in this component. They define the message structure and are organized in the form of an example "message". Each table describes one section of a clinical genomics report. This specification does not exemplify the content for each repeat of the potentially repeating panels, but instead, indicates that a given panel can repeat. The full V2 example messages in Section 5.9 do include many repeated panels based on real genomic reports.

Depending on the kind of analysis, clinical genomic reports will usually include observations from only a few of these sections. Almost all reports will carry some variables from Report Section 1, attributes that apply to the whole report. Typical variant analysis will carry content from Report Section 2. Pharmacogenomics reports typically carry only variables from Report Sections 1 and 4, but some pharmacogenomics labs want to be able to send the detailed genetic data that underlies their star allele results in the glossary specified in Report Section 5.

Note that the first column of each table has short alphanumeric row labels (e.g. A, A.1, A.2, etc.) to provide an easy way to reference specific content in this table. These labels have no meaning outside of this document, and have no role in HL7 messaging.

5.6.1 EXAMPLE MESSAGE CONTENT AND LOINC USAGE RULES

To make it easier for readers to interpret the LOINC codes and how they are organized, each row in Table 5-1 through Table 5-5 corresponds to an OBX segment with example content for OBX-2, OBX-3.1, OBX-3.2, OBX-4 and OBX-5 appropriate to that row's LOINC code. For easy readability, these pseudo OBX's carry their values in table columns rather than as delimited text as one would see in a real message; see Section 5.9 for a series of example Coded Clinical Genomics Lite messages in standard delimited HL7 text.)

These tables also contain fields that carry information about the LOINC term itself: its optionality, its cardinality, narrative text that explains the term and how to use it, and for terms with coded answers,

either its answer list or coding systems. Please note: the R/O/C and cardinality listed here are LOINC attributes that describe the "required-ness" of a LOINC term within a panel. They have no relationship to the field requirements in HL7, which are recorded separately in the tables, and indicate whether the term is required and how many repeats are permitted. For example, "optional with no upper bound" is displayed as "[0..*]". "Required but not permitted to repeat" is displayed as "[1..1]". So most of the information about a LOINC term is integrated into the same row that carries example data. More information about each coding system can be found in Section 14 Clinical Genomics Code Systems.

5.6.1.1 COMMENTS ON THE NUMBER OF LOINC CODES AND PANELS IN THIS GENETICS MESSAGE STRUCTURE

The Clinical Genomics component carries many variables (wherein the LOINC fields are equivalent to fields) to satisfy the interest of many kinds of reporting services and receivers. But most of these are optional and some represent alternative ways of saying the same thing. For example, the discrete variant ID is informationally equivalent to more than 10 of the variables that follow, because they are carried in the ClinVar, or some analogous public database, record that is identified in Row B.1. Indeed, the LHC-Forms demo auto-populates these variables when specific ClinVar records are identified. These 10 components are included as separate observations so that reporters can fill this information in themselves when they are reporting a variation that is not registered in ClinVar, and to make it easier for receivers to access these individual components. Thus, the very large number of variables in the simple variant panel should not be off-putting. Much of what is currently reported could be reported by filling in one variable: LOINC 81252-9 (row B.1) using the coding system from ClinVar or COSMIC simple or structural variation codes. Further, the name of that variable includes the reference sequence, the gene symbol, the c.HGVS and the p.HGVS in one variable.

Ultimately, a laboratory professional should not have to use many of the LOINC codes to enrich their narrative report with a few important structured elements. So those interested in minimalist reports could report simple variants with one or two LOINC codes.

Also note that this guide uses ISCN to provides a compact way to report large deletion duplications in structural variant as a single variable. Using this syntax to report cytogenetic variants it outside the scope of this guide.

5.6.2 CONVENTIONS FOR NESTED AND REPEATING PANELS

Table 5-1 through Table 5-6 show the gist of a V2 clinical genomics message. The tables include groups of related rows that are defined by LOINC panels. The tables include these panels and their children to provide the hierarchy structure. However, these LOINC panel IDs are not included in the message as OBRs as they were in the 2013 HL7 Clinical Genomics Guide. Many of these panels are designed to repeat as many times as needed. Note that Table 5-1 through Table 5-6, with a few exceptions, do not include more than one instance of a repeating panel to save space. Instead, this version uses OBX-4 dot notation to define the hierarchy. In a real message, the LOINC terms from the panel that describe a discrete variation will repeat as many times as there are simple variations to report; the same applies to pharmacogenomics and complex variations. The pharmacogenomics part of the example table (Table 5-5) shows how a real message defined by this guide might look.

The examples in Section 5.9 show repeats that might appear in real genomics reports.

5.6.3 OVERVIEW OF A CLINICAL GENETICS REPORT

Table 5-1 through Table 5-6 correspond to the five different sections of a V2 clinical genetics report, and together, they conceptually can represent one whole table and message. Within a given report section, the example content will represent a single consistent real world result. Across sections, they may not.

Report sections 1 and 2 (Table 5-1, Table 5-2) represent the Master HL7 Reporting Panel and the Discrete Variant Panel, which are comprised of a single panel each, and all of the rows within any such panel begin with the same letter (A or B, respectively, in this case). Although the HL7 message will not contain nested OBR sections, the illustrative tables include the LOINC panels to show the source panels and hierarchical relationship among groups of variables represented by the OBX-4 dot notation. Report sections 3 and 4 (Table 5-4, Table 5-5) represent the Complex and Pharmacogenomics variants, respectively, contain nested LOINC panels and the rows within these different panels begin with different letters i.e. “C” and “D” or “E” and “F”, for complex and pharmacogenomics variants respectively. Report section 5 (Table 5-6). Remember these lettered row labels are not codes and do not represent OBX-4 values – they are merely a convenient way to reference the tables for the discussions in this guide, not a formal part of the standard or the message.

5.6.3.1 REPORT SECTION 1 – VARIABLES THAT APPLY TO THE OVERALL STUDY

Table 5-1 carries the observations that would apply to the whole report. Some of these observations carry detailed technical content, such as the version number for the SNP codes in the report, the set of variants sought in targeted mutation study, overall impression, and a copy of the whole report as delivered traditionally. The variable for reporting large deletion-duplications in ISCN syntax can include everything that has been observed, so it is also part of the overall report section. Some content from this first section should be part of almost every clinical genetics report message. The other four sections are more specialized and only one or two of them are usually included in addition to the overall results in Report Section 1.

5.6.3.2 REPORT SECTION 2 – DISCRETE VARIANTS

Table 5-2 reports discrete variations. All of the variables in this section are part of one large panel, (LOINC 81250-3) – the discrete variant panel. This panel includes 31 variables, but most laboratories will use only four to six of them to designate a single variant. The rows for the discrete variant have labels beginning with “B”.

The “Discrete variant panel” now includes simple and structural variants because ClinVar includes both simple and structural variants, and because the both kinds of variants reflect a change in a single contiguous sequence, and share many attributes. The attributes that apply only to structural variants are part of a panel called the structural variant addenda (Table 5-3) for visual separation but in the HL7 V2 message, they are just part of the discrete variant panel.

Of note, in this section is LOINC 69548-6 Genetic variant assessment in row B.23. Most genetic reporting of negatives is by default. The front of the report describes what was tested for – either a list of discrete variants or regions of the genome that were sequenced and the results call out only the “abnormal” variations found. LOINC 69548-6 is the term that enables statements about all loci of interest whether normal or not, and carries “no call” as one of its answers. With this variable reporters can specify whether each locus examined was “normal” or “abnormal”.

This report section also includes a variable for reporting the phase of each variant (Row B.28) and the kind of evidence used to decide the phase (Row B.29).

5.6.3.3 REPORT SECTION 3 – COMPLEX VARIANTS

Table 5-4 reports complex variants, which are those for which many discrete (simple or structural) mutations taken together have one effect or phenotype. The reason for this section is to provide a way to report something about a set of variants that together have a special meaning and to list the individual constituent variations nested below them. This section which reports the overall effect of the complex variant (whose row labels are C), thus also holds children panels (with row labels D) that make up the

discrete variant panel constituents. The child panel can be used to specify details about the two or more constituent variants within the complex variant.

When the report recipients need only HGVS representation of the complex variant and no separate genetic details about each component simple variant, such child panels are not needed.

5.6.3.4 REPORT SECTION 4 – PHARMACOGENOMICS

Table 5-5 is dedicated to pharmacogenomics test reporting. It includes two nested panels. The first panel, whose row labels all begin with E, can repeat for each gene or gene pair with variants that would influence drug metabolism or efficacy. The second panel, nested inside of the first, whose row labels begin with F, provides guidance about adjustment for drugs whose actions (e.g. metabolism, efficacy, or risk) might be influenced by the mutations reported in the parent panel. These latter nested panels repeat per drug, and provide guidance about the use of that drug given the pharmacogenomics variations reported above. In some cases the laboratory will only provide guidance about the drugs about which the ordering provider inquired, and in other cases, the laboratory reports this information about all common drugs.

Examples 5.9.3.1 and 5.9.3.3 show multiple genotypes and multiple drug guidance statements for each of them.

5.6.3.5 REPORT SECTION 5 – GLOSSARY THAT DEFINES THE CONSTITUENT VARIATIONS OF A HAPLOTYPE

Table 5-6 reports the constituent variants that define a haplotype, , most commonly star alleles, which are commonly used in pharmacogenomic reports as shorthand to specify one or more specific variants in a gene that is known to impact drug metabolism or response. A star allele can identify either a single variant or a group of variants found in cis, and therefore it usually represents a haplotype. See Table 14-1 for more details.

However, the star nomenclature system is inadequately defined and inconsistently adopted. Therefore, although the system we are proposing supports the inclusion of pharmacogenomics star alleles as a legacy syntax, we strongly encourage messages that include star alleles to rigorously define those alleles in this section, which allows the reporting lab to specify the exact variants they mean by the star allele. The structures specified in this section provide a mechanism to mimic the way many laboratories present such information in their hard copy reports. Receivers can link the definitions up with the report via the gene allele names if desired.

The HGVS nomenclature is more robust than star nomenclature, but its implementation can be inconsistent so we also offer a coordinate-based method, e.g., VCF-like fields as another way to describe the variant (rows B.9-B.13 in **Error! Reference source not found.**).

The structure of the glossary consists of an upper level panel (with row labels H) that identifies the gene-star allele pair contains two variables and is followed by discrete variant panels (with row labels I, J, K), one for each variant in the star allele. The whole structure would repeat for each star allele in the report.

Examples 5.9.3.2 and 5.9.3.4 show two examples of the glossary:

1. CYP2C9 *18/*3 alleles where *18 is defined by 3 variants, and *3 by 1 variant
2. A glossary for two alleles on two different genes CYP2C9 *2/*5 alleles and VKORC1 *A/*A.

The first uses six LOINC codes per variant to describe the variations. The second example uses SNPs and Alt Alleles to specify the same variations. Reporters can choose any of the variables in the discrete variant panel to detail the constituent variables for a star allele.

5.7 Clinical Genomics Report Structure Tables

Usage Notes

When OBX-2 indicates the use of CWE, OBX-5 must be formatted according to CWE_05. Other coding systems may be used beyond those listed in the Term Description.

When OBX-2 indicates the use of CNE, OBX-5 must be formatted according to CNE_02. Other coding systems may not be used beyond those listed in the Term Description.

5.7.1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL

	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
	N/A	81247-9	Master HL7 genetic variant reporting panel		This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[1..1]	This panel term provides a handle within the LOINC database that holds together all of the terms and panels that are available for use in a V2 Clinical Genomics message. In the variables below, we list the answers for short answer lists or the choice of external coding systems when available. The kind of variations that is described uses skip logic, which is useful to the receiver to cue them to the right variables. Because this guide uses the OBX-4 to organize the hierarchy of "records" in the message (see details in Section 5.1.2), the LOINC codes for panels after the master panel will not appear as OBRs in the message as was the case in the 2013 HL7 clinical genomics message. All of the genomic data reported in this panel uses a coordinate system beginning with 1, assumes the variants are reported from the positive strand, and have an inclusive start-end.
Report Section 1 - Variables That Apply To The Overall Study								
A	Panel	81306-3	Variables that apply to the overall study	1	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[1..1]	

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
A.1	TX	53577-3	Reason for study	1	**"Worried about family planning"**	O	[0..1]	HL7 provides OBR-31 for recording the reason for the study. The LOINC code is included in this panel for convenience of form definition, because it is often captured in a form with this variable. But ideally, in a lab message it should be delivered in HL7 OBR-31.
A.2	CWE	51967-8	Genetic disease assessed	1.a	2971795010^**Deficiency of isobutyryl-coenzyme A dehydrogenase (disorder)**^SCT	C	[0..*]	**Coding systems:** 1. SCT (SNOMED-CT) 2. I9CDX 3. I10C 4. MedGen-Dis 5. HPO (Human Phenotype Ontology) Applies only to studies that target a disease. While this can be supplied by either the placer or the test performer, this question is typically answered by the placer. Any or all of the above coding systems could be used in the message. It will be up to the message generator to specify the coding system within the message. We encourage the use of SNOMED CT in this field because it is the preferred direction in the US, which is in the example values OBX-5 column. However, the LHC-forms demo of this draft specification shows the content from NCBI MedGen, because it is the most complete with respect to genetic diseases, and public. Further, MedGen includes mappings to SNOMED CT when available.

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
A.3a	CWE	51963-7	Medication assessed [ID]	1.a	50005^**Fluoxetine**^RxT-Ingrd	C	[0..*]	**Coding system: RxT-Ingrd** Applies only to pharmacogenomics studies (See Table 5.6.3.4). Carries the medications for which there is concern that genetic variation might influence the efficacy and/or the rate of metabolism. This content will usually be an Ask-at-Order-Entry (AOE) question. Repeats must be entered in separate OBX fields, as shown in the example where the OBX-4 must be different for each OBX segment (e.g. 1.a, 1.b, 1.c) – see Section 5.1 for an overview of OBX-4 content.
A.3b	CWE	51963-7	Medication assessed [ID]	1.b	84701^**Atorvastatin**^ RxT-Ingrd	C	[0..*]	See row A.3a for the description of LOINC# 51963-7 Medication assessed [ID].
A.3c	CWE	51963-7	Medication assessed [ID]	1.c	45000^**Naproxen**^RxT-Ingrd	C	[0..*]	See row A.3a for the description of LOINC# 51963-7 Medication assessed [ID].
A.3d	CWE	51963-7	Medication assessed [ID]	1.d	11289^**Coumadin**^RxT-Ingrd	C	[0..*]	See row A.3a for the description of LOINC# 51963-7 Medication assessed [ID].
A.4	CNE	48018-6	Gene studied [ID]	1.a	21497^**ACAD9**^HGNC-Symb	C	[0..*]	**Coding system choices:** 1. HGNC-Symb 2. NCBI-gene code This variable identifies the gene on which the variant is located. However, the gene identifier is also carried in the transcript reference sequence database, and is part of a full HGVS expression. The preferred coding system is HGNC-Symb but NCBI has created gene IDs that cover the genes that are not registered by HGNC, and the NCBI gene codes should be used in this case.If the study includes more than one gene, each gene will be entered into separate OBX's and the content of OBX-4 will be unique for each such repeat. See Section 5.4 for a specification of OBX-4 content. In this guide we focus only on human genetics. (Will address extension to other species in the future).

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
A.5	CWE	36908-2	Gene mutations tested for	1.a	7129^**NM_000492.3(CFTR):c.3846G>A (p.Trp1282Ter)**^ CLINVAR-V	C	[0..*]	The list of gene mutations tested for is required if the study is a targeted mutation analysis (i.e. either a study for known family mutations, or for a fixed set of mutations offered by the laboratory). Because laboratories will routinely report on only a subset of the mutations included in a gene chip, the identification of the gene chip alone is not enough. Instead, the gene chip information goes in 81293-3 "Description of ranges of DNA sequences examined" (row A.8). The whole list of the gene mutations testing for (usually a subset of the gene chip) should be listed here, each requiring its own separate OBX if more than one mutation is test for. Laboratories often report the mutations tests for as HGVS.p notation in narrative reports. However, the HGVS expression usually includes the gene symbol when applied as shown in the example. Multiple mutations need to be reported in a separate OBX. See Section 5.1 for a specification of OBX-4 content.
A.6	NR	51959-5	Ranges of DNA sequence examined	1.a	**2000753^2234579**	C	[0..*]	Preferred if the method is a sequencing study. The first value of the numeric range defines the start location and the second value defines the end location of the Sequence. We recognize that this information may be proprietary and is often not revealed. The locations are specified to the associated Genomic reference sequence if the range is discontinuous where each distinct range is reported in a separate OBX, and the OBX-4 values will have to differ among such repeats. See Section 5.1 for a specification of OBX-4 content.

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
A.7	TX	81293-3	Description of ranges of DNA sequences examined	1	**"All coding regions and appropriate flanking regions"**	C	[0..1]	Genetic test reports only rarely include explicit numeric ranges (as row A.6 could carry) because they are often proprietary. So reports tend to describe the regions in narrative (e.g. "all coding regions and appropriate flanking regions"). It is only relevant to sequencing studies. Either this code or LOINC 51959-5 Ranges of DNA sequence examined should be included when reporting structural variants. Whole genome studies should be identified first within either the string "Whole genome," whole exome studies with the string, "Whole exome," and individual exons, with the exon names in a list.
Summary Results								
A.8	CNE	51968-6	Genetic analysis overall interpretation	1	LA6576^**Positive**^LN^ 10828004^**Positive**^SCT	R	[0..1]	**Answer List: LL541-4** 1. Positive LA6576-8 2. Negative LA6577-6 3. Inconclusive LA9663-1 4. Failure LA9664-9 Reported when variant analysis (sequencing or targeted variants) is done. Equivalent SCT codes are or will be available for LA codes in this guide. Provides a coarse overall interpretation of the results reported. More detailed interpretations are also associated with each distinct reported variant below. Note the example controls both the LOINC LA code and controls both the SNOMED code and the LOINC LA code.

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
A.9	CWE	83006-7	Deletion-duplication overall interpretation	1	LA26803-9^**No deletion duplications detected in studied regions**^LN	C	[0..1]	**Answer List: LL4166-6** 1. No deletion or duplication detected in studied region LA26803-9 2. Deletion and/or duplication detected in studied region LA26804-7 3. Inconclusive LA9663-1 Only reported when deletion/duplication studies performed.
A.10	FT; ED	51969-4	Genetic analysis report	1	See Section 5.9 Example Messages	O	[0..1]	This attribute can carry the full narrative report in two different data types, e.g. FT=Formatted text or as ED=encapsulated data which can accommodate Word DOCs, PDFs and other special MIME media types. In most cases these will be full reports with page headers and footers, similar or identical to the existing "paper" report. But this could be just narrative text to complement the other structured data delivered. If this content is not reported as the simple formatted text, follow HL7 V2 specifications for recording the media type and other attributes of an HL7 encapsulated data type.
A.11	CWE	81291-7	Variant ISCN	1	**arr 16p13.11(14,686,844x2, 14776269-16486370x3, 16,494,405x2)(hg18)**^ISCN	C	[0..1]	**Coding System: ISCN** Like HGVS, ISCN is a syntax. It came out of cytopathology and its focus ranges from normal and abnormal chromosome numbers (e.g. XXX down to smallish copy number changes). It can fully describe mosaics: the abbreviation is "mos" and a slash (/) is used between karyotypes for each cell line, e.g.: mos 47,XXX[25]/46,XX[5]. Reference: An International System for Human Cytogenetic Nomenclature, J McGowan-Jordan, Simons A, M. Schmid (eds). S. Karger, Basel 2016

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
Versions of Coding Systems								
A.12	CWE	62374-4	Human reference sequence assembly version [ID]	1	LA14029-5^**GRCh37**^LN	C	[0..1]	**Answer List: LL1040-6** 1. NCBI35 LA14031-1 2. NCBI36 LA26805-4 3. GRCh37 LA14029-5 4. GRCh38 LA26806-2 May or may not be needed depending on the reference sequences to which the results are anchored. It is not needed for transcript reference sequences nor for NCBI genomic reference sequences when they include version numbers (the numbers after the dots). It is needed for genomic reference sequences if they lack the version number and for Ensembl genomic and chromosome reference sequences when the build is not part of the variant name. The overall report section includes only one slot for the assembly build, assuming that this term applies to all repeated variations.
A.13	ST	81303-0	HGVS version [ID]	1	"**15.11**"	O	[0..1]	HGVS (Human Genomic Variation Society) now includes new version numbers. As of November 2016, the most recent version number is 15.11. Reference: 2016 update. Hum. Mutat. 25: 37: 564-569. http://varnomen.hgvs.org/
A.14	NM	82115-7	dbSNP version [Num]	1	"**137**"	O	[0..1]	dbSNP version changes are only made to correct errors. The version # does not change the meaning of the dbSNP RS # per se, but may change the value of the location number in relation to the build. The current version number, as of April 2016 is 147. Details can be obtained from NCBI at http://www.ncbi.nlm.nih.gov/projects/SNP/buildhistory.cgi

TABLE 5-1 CLINICAL GENOMICS REPORT SECTION 1 – MASTER HL7 REPORTING PANEL								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
A.15	NM	83007-5	COSMIC version [Num]	1	"**v84**"	O	[0..1]	As of April 2018, the latest COSMIC version number is 84. More information can be found here: http://cancer.sanger.ac.uk/cosmic/download
A.16	NM	83008-3	ClinVar version [ID]	1	"**1.53**"	O	[0..1]	As of April 2018, the latest ClinVar release is version 1.53. More information can be found here: https://www.ncbi.nlm.nih.gov/clinvar/docs/maintenance_use/#releases

5.7.2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
B	N/A	81250-3	Discrete genetic variant panel	2a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[0..*]	Repeats for each discrete variant reported. A discrete variant is a contiguous set of changes in the tested sample compared to a reference sequence. It can be a simple or structural variant. This panel variable does not carry values in its OBX-5. It provides a handle for holding all of the LOINC terms needed to define a discrete variation. It is not included in the message because the guide uses the content of OBX-4 to define the hierarchy and grouping rather than nested OBRs and OBX's.
B.1	CWE	83005-9	Variant category	2a	LA26801^**Simple Variant^**LN		[0..1]	**Answer List: LL4165-8** 1. Simple Variant LA26801-3 2. Structural Variant LA26802-1 Not essential to the message, but can be used to distinguish the discrete variant as simple or structural.
B.2	CWE	81252-9	Discrete genetic variant	2a	Example of simple variant:	C	[0..1]	**Simple Variant coding systems:**

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
					30880^**NM_014049.4(ACAD9):c.1249C>T (p.Arg417Cys)**^CLINVAR-V Example of structural variant: nsv995237^**17p12(chr17:14616-15581544)x1**^dbVar-GL 155448^**GRCh38/hg38 1q21.2-25.2(chr1:149854269-180267197)x3**^CLINVAR-V			1. CLINVar-V 2. COSMIC-Smpl Structural Variant coding systems: 3. dbVar-GL 4. dbVar-Som 5. COSMIC-Strct If the discrete genetic variant is fully specified with an ID in a coding system, none of the following fields are required because they can be retrieved from the reference database. However, for convenience of access, laboratories may include them. Message implementers will insert the appropriate coding system from the list above to indicate the coding system source. The code for the genetic variant would usually be the ID from the given database. The name (print text) is that given by the public database—usually a combination of attributes (e.g. the RefSeq, gene symbol, c.HGVS, or the HGVS expression for the variant etc.). If the variant has been registered in COSMIC or ClinVar, many of the following attributes under the Transcript specification and Genomic Specification subsections can be automatically pulled from the public database and loaded into separate LOINC terms (see those that follow this panel). Before a variable has been registered in a public allele registry, laboratories can enter these attributes in the OBXs specified by the terms that follow. NCBI is our primary source for the non-somatic structural variants because their files carry all of the European (EBI) structural variant as well as the US variants. Reporters could also code a structural variant with any HL7 OID structural variant identifiers.
Transcript Specification (Separate observations for each of the components of the Discrete genetic variant name)								
B.3	CWE	48018-6	Gene studied [ID]	2a	21497^**ACAD9**^HGNC-Symb	C	[0..1]	**Coding systems:** 1. HGNC-Symb

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								2. NCBI-gene code This variable identifies the gene on which the variant is located. See row A.4 for the full description of LOINC 48018-6 Gene studied [ID].
B.4	CWE	51958-7	Transcript reference sequence [ID]	2a	NM_014049.4^ **NM_014049.4**^ RefSeq-T	C	[0..1]	**Coding systems:** 1. RefSeq-T 2. Ensembl-T 3. LRG N.B: Most structural variants are based on genomic reference sequences, and the transcript reference sequences would not apply. At least one of the transcript or genomic reference sequence (rows B.4, B.9) must be included. If the LOINC# 48004-6 DNA change c.HGVS (B.5) is included, the transcript reference sequence must be included.
B.5	CWE	48004-6	DNA change c.HGVS	2a	c.1249C>T^**c.1249C>T**^ HGVS.c	C	[0..1]	**Coding system: HGVS.c** HGVS specification of the change at the DNA level relative to the transcript RefSeq.
B.6	CWE	48005-3	Amino acid change p.HGVS	2a	p.Arg417Cys^ **p.Arg417Cys**^HGVS.p	C	[0..1]	**Coding system: HGVS.p** HGVS specification of the change at the amino acid (protein) level caused by the DNA change. If the change is in a non-coding region, this variable will not be reported. HGVS recommends that amino acid changes never be reported without also reporting the DNA change. There is no ambiguity about the amino acid change with transcript reference sequences, e.g. because they correspond to one and only one protein.
B.7	CWE	48019-4	DNA change [Type]	2a	LA6690-7^**Substitution**^LN	O	[0..1]	**Discrete Variant Answer List: LL4033-8** **Simple Variant and Structural Variant types:** 1. Wild Type LA9658-1 2. Deletion LA6692-3 3. Duplication LA6686-5 4. Insertion LA6687-3

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								5. Insertion/Deletion LA6688-1 6. Inversion LA6689-9 7. Substitution LA6690-7 **Structural Variant Types only:** 8. Copy number gain LA14033-7 9. Copy number loss LA14034-5 10. Mobile element insertion LA26324-6 11. Novel sequence insertion LA26325-3 12. Tandem duplication LA26326-1 13. Intrachromosomal breakpoint LA26327-9 14. Interchromosomal breakpoint LA26328-7 15. Translocation LA26331-1 16. Complex LA26330-3 17. Sequence alteration LA26329-5 Type of DNA variation reported. Taken from: 2013 HL7 V2 Clinical Genomics Implementation Guide. See also HGVS DNA variant descriptions. http://varnomen.hgvs.org/
B.8	CWE	48006-1	Amino acid change [Type]	2a	LA6698-0^**Missense**^LN	O	[0..1]	**Answer List: LL380-7** 1. Wild Type LA9658-1 2. Deletion LA6692-3 3. Duplication LA6686-5 4. Frameshift LA6694-9 5. Initiating Methionine LA6695-6 6. Insertion LA6687-3 7. Insertion and Deletion LA9659-9 8. Missense LA6698-0 9. Nonsense LA6699-8 10. Silent LA6700-4 11. Stop Codon Mutation LA6701-2 Type of amino acid change reported. Taken from http://www.hgvs.org/mutnomen/recs-prot.html.

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
Genomic specification (Separate observations for each of the components of the Discrete genetic variant name)								
B.9	CWE	48013-7	Genomic reference sequence [ID]	2a	NG_017064.1^ **NG_017064.1**^RefSeq-G	C	[0..1]	**Coding system choices:** 1) RefSeq-G 2) Ensembl-G If the genomic specification is given, then this and the following 3 terms must be presented: LOINC# 69547-8 (Row B.11), 81254-5 (Row B.12) and 69551 (Row B.13).
B.10	CWE	81290-9	Genomic DNA change g.HGVS	2a	Example for simple variant: NC_000003.11:g.128625063C>T^ **NC_000003.11:g.128625063C>T**^ HGVS.g Example for structural variant: NC_000017.10:g.(?_14087933)_(15484858_?)del^ **NC_000017.10:g.(?_14087933)_(15484858_?)del**^ HGVS.g	C	[0..1]	**Coding system: HGVS.g** If this is a structural variant, either the LOINC 81291-7 Variant ISCN (A.11) or this term should be included with every structural variant report.
B.11	ST	69547-8	Genomic ref allele [ID]	2a	**"C"**	C	[0..1]	The DNA string in the reference sequence (Ref Allele) with which the DNA string in the test sample differs, starting at the first position given in LOINC# 81254-5's Genome Allele start-end (B.12).
B.12	NR	81254-5	Genomic allele start-end	2a	**31731^31731**	C	[0..1]	The beginning and end of the Ref Allele that was replaced by the Alt Allele. The beginning is counted as the first position in the genomic reference showing a contiguous set of base changes in the sample DNA being tested. The end is the comparable last position.
B.13	ST	69551-0	Genomic alt allele [ID]	2a	**"T"**	C	[0..1]	The DNA sequence in the test sample (Ref Allele) that is different from the DNA sequence in the reference sequence (Ref Allele) – Note the examples of LOINC#s 69547-8 (Row B.11), 81254-5 (Row B.12) and 69551 (Row B.13) – could also be described in a HGVS.g expression as: g.31731C>T in 48013-7 Genomic Reference Sequence ID (row B.9).

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
Other optional codes related to a Discrete genetic variant								
B.14	CWE	84414-2	Haplotype name	2a	"***2**"	O	[0..1]	Coding Systems: 1. HLA Alleles 2. Star Alleles Reports the allele names to which the discrete variants belong. Most often used to report star alleles but might also be used to record HLA alleles. Not needed if the repeat includes an allele glossary – see Table 5-6 Clinical Genomics Report Section 5 – Glossary for Haplotype Definition
B.15	CWE	81255-2	dbSNP [ID]	2a	rs368949613^ **rs368949613**^dbSNP	O	[0..1]	**Coding system: dbSNP** More than 160 million dbSNP codes now exist (see https://lforms-service.nlm.nih.gov/apidoc/snps/v1/doc.html). Be aware that dbSNP codes cannot stand alone as a variant identifier -- it only identifies the position and the length of the variant, not the change. If you want to use dbSNP rs codes, you must also include the Genomic Alt allele (LOINC # 69551-0 in row B.13) in the message.
B.16	CWE	81257-8	CIGAR [ID]	2a	Example pending	O	[0..1]	Used primarily for alignment in earlier stages of genetic study analysis. We have not seen usage in routine clinical reports.
Other possible attributes								
B.17	CWE	48001-2	Cytogenetic (chromosome) location	2a	3q21^**3q21**^Chrom-Loc	O	[0..1]	**Coding system: Chrom-Loc** Chromosome location (aka chromosome locus or cytogenetic location), is the standardized syntax for recording the position of genes and large variants. See details in row 1 "Cytogenetic (chromosome) location" in the Appendix Section 14-1 in "Coding Systems".
B.18	CNE	48002-0	Genomic source class [Type]	2a	LA6683-2^**Germline**^LN	R	[0..*]	**Answer List: LL378-1** 1. Germline LA6683-2

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								2. Somatic LA6684-0 3. Fetal LA10429 4. Likely germline LA18194-3 5. Likely somatic LA18195-0 6. Likely fetal LA18196 7. Unknown genomic origin LA18197-6 8. De novo LA26807-0 The genomic class of the specimen being analyzed: Germline for inherited genome, somatic for cancer genome (e.g. DNA from tumor cells), and fetal for fetal genome. De novo is defined by NCBI to mean a novel variation present for the first time in one family member as a result of a variant in a germ cell of one of the parents, or a mutation that arises in the fertilized egg itself during early embryogenesis. Reported when mutation analysis (sequencing or targeted mutations) is done. Equivalent SCT codes are or will be available for LA codes in this guide. The reported genomic source class is not always precise, and more detailed interpretations also associated with each distinct reported variant can be found below. It is strongly recommended to use the full list of Genomic Source Class values at the mutation level; however, top level genomics source class (around the testing context) should only use the original three (somatic, germline or fetal) as it codifies the testing context (i.e. inherited genetic testing, tumor testing, or fetal testing) Note the example controls both the SNOMED code and the LOINC LA code. Taken from: NCBI Variation Glossary https://www.ncbi.nlm.nih.gov/variation/docs/glossary/ 2013 HL7 V2 Clinical Genomics Implementation Guide

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
B.19	CWE	81304-8	Variant analysis method [Type]	2a	LA26398-0^ **Sequencing**^LN	O	[0..*]	**Answer List: LL4048-6** 1. Sequencing LA26398-0 2. Oligo aCGH LA26399-8 3. SNP Array LA26400-4 4. BAC aCGH LA26401-2 5. Curated LA26402-0 6. Digital Array LA26403-8 7. FISH LA26404-6 8. Gene Expression Array LA26405-3 9. Karyotyping LA26406-1 10. MAPH LA26407-9 11. MassSpec LA26408-7 12. Merging LA26808-8 13. Multiple Complete Digestion LA26414-5 14. MLPA LA26415-2 15. Optical Mapping LA26417-8 16. PCR LA26418-6 17. qPCR (Real-time PCR) LA26419-4 18. ROMA LA26420-2 19. Denaturing high pressure liquid chromatography (DHPLC) LA26809-6 20. DNA hybridization LA26810-4 21. Computational analysis LA26811-2 22. Single-stranded conformational polymorphism (SSCP) LA26812-0 23. Restriction Fragment Length Polymorphism (RFLP) LA26813-8 The variable is especially important for structural variants because the precision of the start and end position of this kind of variation is determined so strongly by the type of method. Taken from NCBI's dbVAR data submission template. 2015 review of the newest methods at: PMCID: PMC4479793 and, Kitts A, Phan L, Ward M, et al. The Database of Short Genetic Variation (dbSNP) 2013 Jun

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								30 [Updated 2014 Apr 3]. In: The NCBI Handbook [Internet]. 2nd edition. Bethesda (MD): National Center for Biotechnology Information (US); 2013-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK174586/
Interpretations								
B.20	CNE	53037-8	Genetic sequence variation clinical significance [Imp]	2a	LA6668-3^**Pathogenic**^LN	O	[0..1]	**Answer List: LL4034-6** 1. Pathogenic LA6703-8 2. Likely pathogenic LA6704-6 3. Uncertain significance LA6705-3 4. Likely benign LA6706-1 5. Benign LA6707-9 Answer list taken from PMID 25741868 (PMCID: PMC4544753).
B.21	CWE	69548-6	Genetic variant Assessment	2a	LA9633-4^**Present**^LN	O	[0..1]	**Answer List: LL1971-2** 1. Present LA9633-4 2. Absent LA9634-2 3. No call LA18198-4 4. Indeterminate LA11884-6 Most genetic reporting of negatives is by default, the specific variants (or DNA ranges) tested are reported and only the positives are reported explicitly. For those who want to report interpretations on a set of specified locations whether normal or not, LOINC# 69548-6 is the term that enables this style of reporting, and it includes in its answer list the “no call” option. Thus it permits every examined loci to be described individually as present, absent, (no call), or indeterminate. Of note, ‘No Call’ is different from ‘Absent’, because ‘No Call’ did not result in the determination of the marker’s presence or absence. This may be due to test failure or specimen specific context, rendering the test ineffective. If "No Call" implies that 1) the assay failed or 2) the region of the chromosome/gene containing the sequence

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								variation being genotyped is deleted. For instance, if a portion of the PTEN gene is deleted, then all assays for mutations within the deleted region would be 'no call' rather than describing the finding then as deleted, because the assays covering this region of interest may have simply failed.
B.22	CWE	81259-4	Probable Associated Phenotype	2a	C1970173^**Acyl-CoA dehydrogenase family, member 9, deficiency of**^MedGen-Dis	O	[0..1]	**Coding systems:** 1. SCT (SNOMED-CT) 2. I9CDX 3. I10C 4. MedGen-Dis 5. HPO (Human Phenotype Ontology) The disorder with which this variant is associated. Allows same coding systems as for disease assessed. The message implementer inserts the approved coding system in CWE.3. See descriptions of the coding systems in Table A.1 of the Appendix.
Allelic State/Phase Information								
B.23	CNE	53034-5	Allelic state	2a	LA6706-1^ **Heterozygous**^LN	C	[0..1]	**Answer List: LL381-5** 1. Heteroplasmic LA6703-8 2. Homoplasmic LA6704-6 3. Homozygous LA6705-3 4. Heterozygous LA6706-1 5. Hemizygous LA6707-9 This variable describes the relationship between the alleles found at the same locus on different chromosomes. It is not always reported. Answer list taken from the 2013 HL7 V2 Clinical Genomics Implementation Guide.
B.24	NM	81258-6	Allelic Frequency [NFr]	2a	**"0.47"**	C	[0..1]	Reports the fraction of all of the reads at this genomic location that were represented by the given allele. For homozygotes it will be close to 1.0; for heterozygotes it will be close to 0.5. It can be a smaller number when

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								there are mosaics or multiple chromosome, or mixtures of tumor cells and normal cells.
B.25	NM	82121-5	Allelic read depth	2a	**"208"**	O	[0..1]	Specifies the number of reads that identified the allele in question whether it consists of one or a small sequence of contiguous nucleotides. Different methods and purposes require different numbers of reads to be acceptable. Often >400, sometimes as few as 2-4.
B.26	CWE	82120-7	Allelic phase	2a	LA6112-2^**1st set of variants in cis relation to each other**^LN	O	[0..1]	**Answer List: LL4025-4** 1. 1st set of variants in cis relation to each other LA26814-6 2. 2nd set of variants in cis relation to each other LA26815-3 3. 3rd set of variants in cis relation to each other LA26816-1 4. 4th set of variants in cis relation to each other LA26817-9 5. 5th set of variants in cis relation to each other LA26818-7 6. Maternal LA26320-4 7. Paternal LA26321-2 8. Unknown LA4489-6 9. Other LA46-8 Defines which variations are in cis relationship (on the same chromosome) to one another. The first and second set could be in cis relation to one another and yet not be on the same chromosome. Can accommodate trisomies, mosaics, and other special cases, and distinguish whether the chromosome is maternal or paternal when such details can be inferred (e.g. when the parent's genotype is also available).
B.27	CWE	82309-6	Basis for allelic phase [Type]	2a	LA26429-3^**Inferred from population data**^LN	O	[0..1]	**Answer List: LL4050-2** 1. Directly measured LA26426-9 2. Family DNA LA26427-7 3. Family history LA26428-5

TABLE 5-2 CLINICAL GENOMICS REPORT SECTION 2 - VARIABLES THAT DEFINE A DISCRETE VARIANT								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								4. Inferred from population data LA26429-3 If the allelic phase LOINC 82120-7 (row B.26) is included, this observation should also be included. This identifies the evidential basis on which the allelic phase and/or the allelic state was concluded.

5.7.3 CLINICAL GENOMICS STRUCTURAL VARIANT ADDENDA

TABLE 5-3 CLINICAL GENOMICS STRUCTURAL VARIANT ADDENDA								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
	N/A	81297-4	Structural variant addendum panel		This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message. Moreover, the terms of this panel is specific to structural variants, and will not be included in the message per se.		[1..1]	Provides variables that are unique to structural variants, most of which are not routinely included in clinical reports.
B.28	NM	82155-3	Genomic structural variant copy number	2a.1	**"1"**	O	[0..1]	The copy number of the large variant when applicable. In HGVS, this is the numeric value following the "X". It is a unit-less value. Note that a copy number of 1 implies a deletion. The copy number can usually be inferred from the HGVS or ISCN fields.
B.29	NM	81299-0	Genomic structural variant reported arrCGH [Ratio]	2a.1	**"0.48"**	C	[0..1]	Usually only applicable to ArrCGH and related studies. Its value can be more or less than 1, depending on if the variant is a deletion or duplication.
B.30	NM	81300-6	Structural variant length [Length]	2a.1	**"1396929"**	O	[0..1]	This content is uncommon in today's clinical reports. (The units of measure are base pairs.) A field in dbVar.
B.31	NR	81301-4	Structural variant outer start and end	2a.1	**13200589^15592000**	O	[0..1]	This content taken with inner start-end provides a way to describe the uncertainty in the edge positions of

TABLE 5-3 CLINICAL GENOMICS STRUCTURAL VARIANT ADDENDA								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
								structured variation. These are available in NCBI's dbVar file, not commonly reported today.
B.32	NR	81302-2	Structural variant inner start and end	2a.1	**14184616^15581544**	O	[0..1]	This content is uncommon in today's clinical reports. A field in dbVar.

5.7.4 CLINICAL GENOMICS REPORT SECTION 3 – COMPLEX VARIANTS

TABLE 5-4 CLINICAL GENOMICS REPORT SECTION 3 – COMPLEX VARIANTS								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
C		81251-1	Complex genetic variant panel	3a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.	NA	[0..*]	Repeats for each complex variant. The LOINC panel code defines the set of variables that may be included to describe a single complex variant, but the code itself is not included in the message. Complex variants are made up of two or more simple variants which together have phenotypic implications. In the OBX's that follow OBX-4 increments by 1 for each repeated complex variant. The example only presents one complex variant.
C.1	CWE	81260-2	Complex genetic variant [ID]	3a	16895^**NM_000106.5(CYP2D): c.[886C>T;457G>C] – Haplotype**^ CLINVAR-V	C	[0..1]	**Coding System: CLINVAR-V** Following the pattern of simple variant, the code is the identifier from a public genetic database and the name is a concatenation of the RefSeq, the gene symbol, the HGVS describing the multiple variants, and the complex variant type.
C.2	CWE	81262-8	Complex variant HGVS name	3a	c.[886C>T;457G>C]^ **c.[886C>T;457G>C]**^HGVS.c	C	[0..1]	**Coding System: HGVS.c** Includes HGVS.c for the separate variants that make this complex variant. The square bracket surrounding multiple variants indicates they are together on one chromosome. When each simple variant is surrounded by square brackets that means they are on separate chromosomes. HGVS syntax can also assert that the phase is unknown.

TABLE 5-4 CLINICAL GENOMICS REPORT SECTION 3 – COMPLEX VARIANTS								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
C.3	CWE	81263-6	Complex variant type	3a	LA26218-0^**Haplotype**^LN	O	[0..1]	**Answer List: LL3991-1** 1. Compound heterozygous LA26217-2 2. Double heterozygous LA26220-6 3. Haplotype LA26218-0 4. Hemizygous LA6707-9
C.4	CWE	81259-4	Probable Associated Phenotype	3a	688395015^**Debrisoquine adverse reaction (disorder)**^SCT	O	[0..1]	**Coding systems:** 1. SCT (SNOMED-CT) 2. I9CDX 3. I10C 4. MedGen-Dis 5. HPO (Human Phenotype Ontology)
C.5	CNE	53037-8	Genetic sequence variation clinical significance [Imp]	3a	LA6668-3^**Pathogenic**^LN	O	[0..1]	See row B.20 for the description of LOINC #53037-8 Genetic sequence variation clinical significance. This is the significance of the many simple variants in the first complex variant taken together.
C.6	CNE	53034-5	Allelic state	3a	LA6706-1^**Heterozygous**^LN	O	[0..1]	See row B.23 for the description of LOINC # 53034-5 Allelic state. But this is the allelic state of the many simple variants taken together in the complex variant. (It will not apply to all complex variant types).
C.7	CWE	82309-6	Basis for allelic phase [Type]	3a	LA26429-3^**Inferred from population data**^LN	O	[0..1]	See row B.27 for the description of LOINC# 82309-6 Basis for allelic phase.
D		81250-3	Discrete genetic variant panel	3a.1a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.	NA	[0..*]	See Table 5-2 for the complete definitions of each variable. The full HGVS for the complex variant in row C may be sufficient for many purposes in which case none of these children panels will be included. This child panel repeats for as many discrete variables as contained in the complex variant. We show a few of the variable in this discrete variation panel in the follow rows, but not the whole panel or any of the panels describing other constituents of this complex variant to save space. Full V2 examples appear in Section 5.6.

TABLE 5-4 CLINICAL GENOMICS REPORT SECTION 3 – COMPLEX VARIANTS								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
D.1	CWE	81252-9	Discrete genetic variant	3a.1a	31934^**NM_000106.5(CYP2D6):c.886C>T (p.Arg296Cys)**^CLINVAR-A	C	[1..1]	See Table 5-2 for the complete definitions of each variable.
D.2	CWE	51958-7	Transcript RefSeq ID	3a.1a	NM_000106.5^**NM_000106.5**^RefSeq-T	C	[0..1]	See row B.4 for the description and answer list in LOINC# 51958-7 Transcript RefSeq ID.
D.3	CWE	48004-6	DNA change c.HGVS	3a.1a	c.886C>T^**c.886C>T**^ HGVS.c	C	[0..1]	See row B.5 for the description and answer list in LOINC# 41103-3 DNA change c.HGVS.
D.4	CWE	48005-3	Amino acid change p.HGVS	3a.1a	p.Arg296Cys ^ **p.Arg296Cys** ^HGVS.p	C	[0..1]	See row B.6 for the description and answer list in LOINC# 48005-3 Amino acid change p.HGVS.
D.5	CWE	48019-4	DNA change [Type]	3a.1a	LA6990-7^ **Substitution**^LN	O	[0..1]	See row B.7 for the description and answer list in LOINC# 48019-4 DNA change [Type].
D.6	CWE	48006-1	Amino acid change [type]	3a.1a	LA6698-0^**Missense**^LN	O	[0..1]	See row B.8 for the description and answer list in LOINC# 48006-1 Amino acid change [type].
E		81250-3	Discrete genetic variant panel	3a.2a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.	NA	[0..*]	See row B.2 for the description and answer list in LOINC# 81252-9 Discrete genetic variant.
E.1	CWE	81252-9	Discrete genetic variant	3a.2a	38486^**NM_000106.5(CYP2D6):c.1457G>C (p.Ser486Thr)**^CLINVAR-V	C	[1..1]	See LOINC# 81252-9 in row B.1 description and answer list.
E.2	CWE	51958-7	Transcript RefSeq ID	3a.2a	NM_000106.5^**NM_000106.5**^RefSeq-T	C	[0..1]	See row B.4 for the description and answer list in LOINC# 51958-7 Transcript RefSeq ID.
E.3	CWE	48004-6	DNA change c.HGVS	3a.2a	c.1457G>C^**c.1457G>C**^ HGVS.c	C	[0..1]	See row B.5 for the description and answer list in LOINC# 41103-3 DNA change c.HGVS.

Note that to save space, we did not put in the full details for the second discrete variant that comprises the complex variant. Please see Table 5-2 for the complete overview and definition of each variable under a discrete variant.

5.7.5 CLINICAL GENOMICS REPORT SECTION 4 – PHARMACOGENOMICS STUDIES

TABLE 5-5 CLINICAL GENOMICS REPORT SECTION 4 – PHARMACOGENOMICS STUDIES								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
F	N/A	82118-1	Pharmacogenomics results panel		This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[0.*]	Will repeat for each gene tested
Results for 1st gene of study								
F.1.a	CNE	48018-6	Gene studied [ID]	4a.a	2623^**CYP2C9**^ HGNC-Symb		[1..*]	**Coding system: HGNC-Symb** Identifies the gene or genes known to influence drug metabolism or efficacy being tested for relevant variants. In some cases, such as in the example of CYP2C9 and VKORC1, changes in more than one gene are required to cause the reported effect on a specific drug's metabolism or efficacy, but they will still be listed in separate OBX-5 fields.
F.2.a	ST	84413-4	Genotype display name	4a.a	**"*2/*5"**		[1..*]	In this context, the corresponding alleles for each of the genes listed under gene(s) studied are also shown separated by a slash e.g., *1/*2 as is the common format. The genotype is almost always reported as a pair of star alleles in pharmacogenomics studies. If the metabolism/efficacy effect is based on 2 genes, the results for each gene are shown in separate OBXs and related to the gene via the same OBX-4 content. The implication variables e.g., 53040-2 the effect on metabolism, 51961-1 the effect on efficacy, or 83009-1 risk for hypersensitivity, specify the combined effect of the multiple alleles recorded in this panel. This content will be displayed using separate OBX-5 fields.
F.1.b	CNE	48018-6	Gene studied [ID]	4a.b	23663^**VKORC1**^ HGNC-Symb		[1..*]	See row F.1.a for description for LOINC# 48018-6 Gene studied [ID].
F.2.b	ST	84413-4	Genotype display name	4a.b	**"*A/*A"**		[1..*]	See row F.2.a for description for LOINC# 84413-4 Genotype display name.

TABLE 5-5 CLINICAL GENOMICS REPORT SECTION 4 – PHARMACOGENOMICS STUDIES								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
F.3	CNE	53040-2	Genetic variation's effect on drug metabolism	4a	LA9657-3^**Rapid metabolizer**^LN	C	[0..1]	**Answer List: LL3856-3** 1. Ultrarapid metabolizer LA10315-2 2. Rapid metabolizer LA25390-8 3. Normal metabolizer LA25391-6 4. Intermediate metabolizer LA10317-8 5. Poor metabolizer LA9657-3 If this variable has repeats they should each be reported in a separate OBX-5 using the dot notation as 3.1a, 3.1.b, etc. For pharmacogenomics studies, one of, 53040-2 (effect on drug metabolism) and/or 51961-1 (effect on drug efficacy) must be included in the panel. Answer list comes from CPIC, a professional society (https://cpicpgx.org/wp-content/uploads/2016/01/CPIC_term_standardization_project_final_terms.pdf).
F.4	CWE	51961-1	Genetic variation's effect on drug efficacy	4a	LA6677-4^**Responsive**^LN	C	[0..1]	**Answer List: LL539-8** 1. Resistant LA6676-6 2. Responsive LA6677-4 3. Presumed resistant LA9660-7 4. Presumed responsive LA9661-5 5. Unknown significance LA6682-4 6. Benign LA6675-8 7. Presumed Benign LA6674-1 8. Presumed non-responsive LA9662-3 For pharmacogenomics studies, either 53040-2 (effect on drug metabolism) and/or 51961-1 (effect on drug efficacy) and or 83009-1 risk for hypersensitivity must be included in the panel. Answer list comes from the 2013 HL7 V2 Clinical Genomics Implementation Guide.

TABLE 5-5 CLINICAL GENOMICS REPORT SECTION 4 – PHARMACOGENOMICS STUDIES								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
F.5	CWE	83009-1	Genetic variation's effect on high-risk allele	4a	LA19541-4^**High risk**^LN	C	[0..1]	**Answer list: LL2353-2** 1. Low risk LA19542-2 2. High risk LA19541-4 Reports the risk that occurs with the drug specificity in row F.1 (LOINC 51963-7 Medication assessed [ID]), when some variants, e.g. HLA alleles, are present, or the mutation RYR1 which causes malignant hypothermia. PMID: 17620823
Medication Panel								
G	-	82117-3	Medication usage implications panel	4a.1	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.	O	[0..*]	This panel provides guidance about drugs assessed in relation to variations observed in the above gene. It groups the set of variables that maybe reported per medication assessed, but is not itself included in the message. The set of variables that follow, or more extensive information can also be included as part of the results within the overall report PDF as it is commonly done now (See LOINC 51969-4 Genetic analysis report in row A.10 is provided for that purpose).
G.1	CWE	51963-7	Medication assessed [ID]	4a.1	11289^**Warfarin**^RxT-Ingrd	R	[1..1]	**Coding system: RxT-Ingrd** This variable identifies the medication about which assessments will be made in the next two fields. Required if medication usage panel is employed.

TABLE 5-5 CLINICAL GENOMICS REPORT SECTION 4 – PHARMACOGENOMICS STUDIES								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
G.2	CWE	821165	Medication usage suggestion [Type]	4a.1	LA26421-0^**Consider Alternative Medications not contraindicated or impacted by gene**^LN	C	[0..1]	**Answer List: LL4049-4** 1. Consider Alternative Medications not contraindicated or impacted by gene LA26421-0 2. Decrease Dose and titrate to response LA26422-8 3. Increase Dose and titrate to response if appropriate LA26423-6 4. Use with caution LA26424-4 5. Use standard dose LA26425-1 This variable (48005-3) or the following 83010-9 "Medication usage suggestion [narrative] should be included when any drug is named in Row E1.1. Answer list derived from example report with advice from CPIC expert.
G.3	TX	83010-9	Medication usage suggestion [Narrative]	4a.1	**"May need higher dosage than usual."**	C	[0..1]	Used to deliver whatever specific content, in narrative, laboratories want to deliver. At least one of the medication usage type or narrative variables should be included when the panel is implemented.

5.7.6 CLINICAL GENOMICS REPORT SECTION 5 – GLOSSARY FOR HAPLOTYPE DEFINITION

TABLE 5-6 CLINICAL GENOMICS REPORT SECTION 5 – GLOSSARY FOR HAPLOTYPE DEFINITION								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
H		83011-7	Haplotype definition panel	5a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[0..*]	This panel defines the variables that are reported for each haplotype.

TABLE 5-6 CLINICAL GENOMICS REPORT SECTION 5 – GLOSSARY FOR HAPLOTYPE DEFINITION								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
Haplotype Gene and Name								
H.1	CNE	48018-6	Gene studied [ID]	5a.a	2623^**CYP2C9**^ HGNC-Symb		[1..*]	**Coding system: HGNC-Symb** Identifies the genes known to influence drug metabolism or efficacy being tested for relevant variants.
H.2	CWE	84414-2	Haplotype name	5a.a	**"*18"**	O	[0..*]	Usually used to report star alleles.
Defines the discrete variants that constitute the haplotype								
I		81250-3	Discrete genetic variant panel	5a.1a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[1..*]	This panel repeats for as many discrete variants as are constituents of the haplotype as defined by the reporting lab. The definition may vary across reporting laboratories. We show a very compact example using only SNP codes and alt allele to define the variations. But reporting laboratories can use any of the variables listed in Table 5.6.3.2 for this purpose, and can repeat the panel for as many variations that define the haplotype.
I.1	ID	81255-2	dbSNP ID	5a.1a	1057910^ **rs1057910** ^dbSNP	O	[0..1]	See row B.15 for the description of LOINC# 81255-2 dbSNP ID.
I.2	ST	69551-0	Genomic alt allele [ID]	5a.1a	**"C"**	C	[0..1]	See row B.13 for the description of LOINC# 69551-0 Genomic alt allele [ID].
J		81250-3	Discrete genetic variant panel	5a.2a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[1..*]	See row I for the description of LOINC# 81250-3 Discrete genetic variant panel.
J.1	ID	81255-2	dbSNP ID	5a.2a	72558193^ **rs72558193**^dbSNP	O	[0..1]	See row B.15 for the description of LOINC# 81255-2 dbSNP ID.
J.2	ST	69551-0	Genomic alt allele [ID]	5a.2a	**"C"**	C	[0..1]	See row B.13 for the description of LOINC# 69551-0 Genomic alt allele [ID].
K		81250-3	Discrete genetic variant panel	5a.3a	This term identifies the set of LOINC terms that are part of this panel but is not, itself, part of the HL7 message.		[1..*]	See row I for the description of LOINC# 81250-3 Discrete genetic variant panel.
K.1	ID	81255-2	dbSNP ID	5a.3a	1057911^ **rs1057911**^dbSNP	O	[0..1]	See row B.15 for the description of LOINC# 81255-2 dbSNP ID.

TABLE 5-6 CLINICAL GENOMICS REPORT SECTION 5 – GLOSSARY FOR HAPLOTYPE DEFINITION								
	OBX-2	OBX3.1	OBX3.2	OBX-4	OBX-5	LOINC Panel/Definitional Terms		
Label	Type	LOINC	LOINC Name	Sub ID	Example values†	R/O/C	Cardinality	Term Description
K.2	ST	69551-0	Genomic alt allele [ID]	5a.3a	**"T"**	C	[0..1]	See row B.13 for the description of LOINC# 69551-0 Genomic alt allele [ID].

5.8 Message Content Model As A Data Capture Form

To provide an easy overview of the content of the LRI_CG_Component, the Lister Hill National Center for Biomedical Communications LHNCBC) at the U.S. National Library of Medicine has developed a web-based JavaScript tool called LHC-Forms[9], which generates input forms, based on definition files, for Web-based applications. LHC-Forms carries all of the observations that may be included in the Clinical Genomics component of the HL7 message. Users can access this model and generate HL7 messages through https://lhcforms.nlm.nih.gov/81247-9 which contains LOINC codes and their answers, as well as links to the coded data sources in the Clinical Table Search Service, a web service software programs can use for querying clinical data tables like ICD-10-CM or ClinVar Alleles (found here: https://clinicaltables.nlm.nih.gov)) for the look-up fields. Entering text into a field for a categorical observation in this form options (derived from the LOINC short answer lists or the coding system) appear as choices for auto-completion.

Figure 5-2, below, shows a screenshot of LHC-Forms, with the input fields filled for Discrete Variants. When a variation registered in ClinVar is chosen under the "Discrete genetic variant panel", as shown in the third field (LOINC 81252-9), many of its related fields are auto-populated from the ClinVar Clinical Search table in LHC forms. Users may also choose between NCBI and COSMIC identifiers for a few types of variables. In most cases, LHC-Forms assumes a default coding system for each variable, but V2 message implementers are free to insert the other coding systems associated with a given LOINC code as shown in Table 5-1 through Table 5-6 when they construct their messages directly.

Some of the coding systems are full enumerations and can be found in tables at their sources' web site (which are linked in Table 14-1. Clinical Genomics Coding Systems). These tables of enumerated codes are in some cases quite large (e.g. dbSNP's table carries 150 million rows). Others (e.g. UCUM, HGVS and ISCN) are defined by a syntax, and can't be fully enumerated though tables with common subsets of such codes may be available. Syntax validity checkers are available for UCUM (https://ucum.nlm.nih.gov/ucum-lhc/) and for HGVS (https://mutalyzer.nl).

Note that the LHC Clinical Table Search Service does not provide, or have readily accessible, tables for all potential coding systems in this guide. For example, the star alleles do not have a complete and consistent publically available table.

[9] Ye Wang Y, Lynch P, Kanduru A, Hook J, Mericle L, Ludet C, Vreeman DJ, Clement J. McDonald CJ. LHC-Forms and Related Widgets for Capturing and Tuning Health Data. AMIA Annu Symp Proc. 2016 (Accepted).

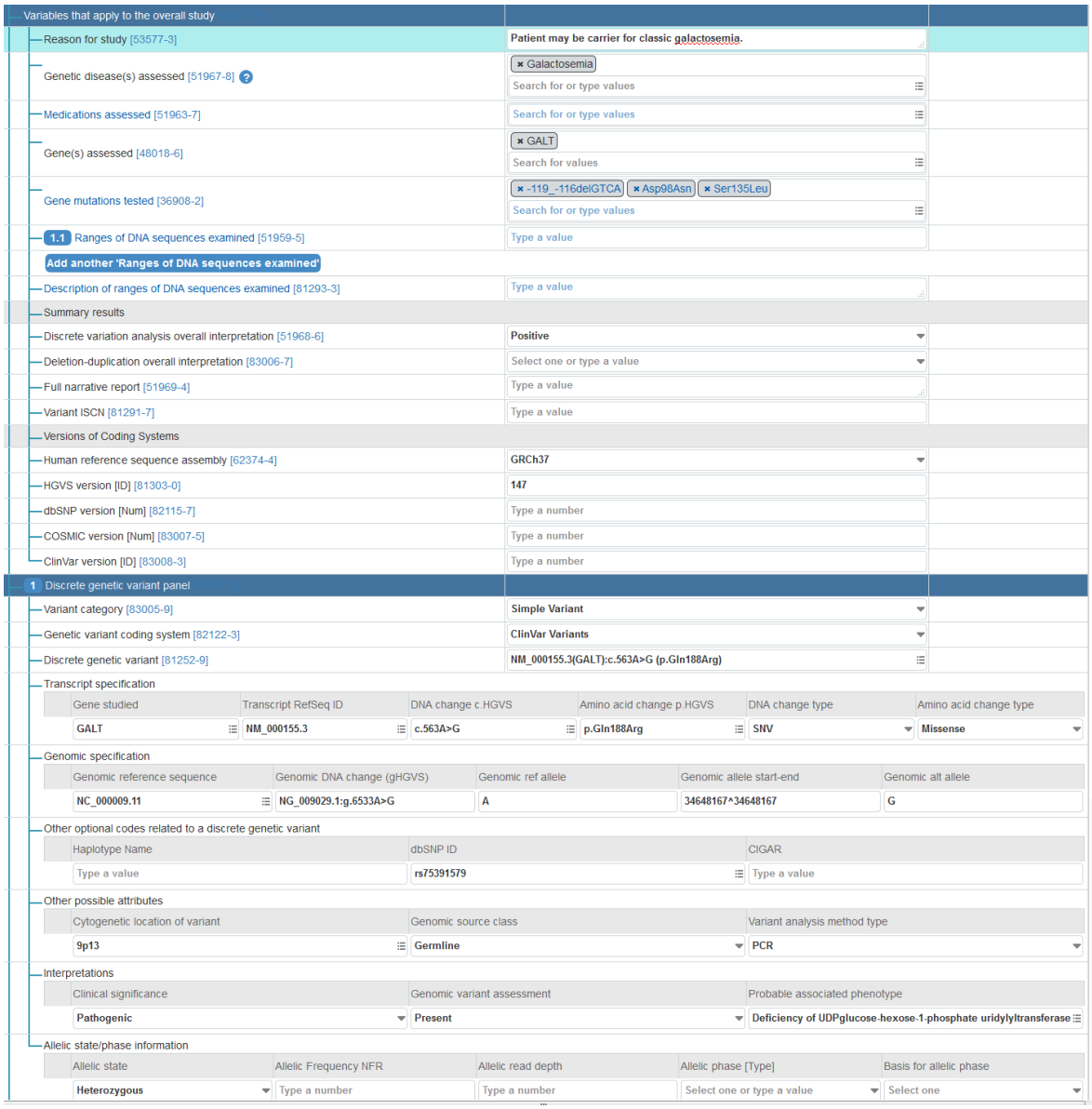

Figure 5-2. Screenshot Of LHC-Forms Widget for The LRI_CG_Component

The URL for the page that shows what you can do with these Clinical Table Search Services is available at: https://lhncbc.github.io/autocomplete-lhc/ and a developer's page is available at: https://lhncbc.github.io/autocomplete-lhc/docs.html**.**

The URLs for search service and for direct download of specific tables also appear in Table 14-1. Clinical Genomics Coding Systems). The URL for the UCUM validator developer's page is available at: https://github.com/lhncbc/ucum-lhc. The programs that deliver these autocomplete look-ups are available as open source as either JavaScript widgets or services from GitHub.

5.9 Example Messages

This section presents example V2 messages to illustrate the use of this specification for a variety of different genetic tests. These example messages are in a shortened form, leaving out the early segments like MSH and PID, which will not change across the examples, and have only populated the most important payload fields of the OBX segments, i.e., OBX-1 through OBX-6, to focus on the salient features of the examples.

The example messages of the variants are in the order of the five sections of the clinical genetics report. Please note that there are multiple examples for each variant, with each example addressing the different ways to report the kind of variant. The example messages were taken from published and harmonized sample reports. Much thanks to the vendors who posted example reports with positive findings on the web.

Some example messages use laboratory tests that do not have LOINC codes, so they are labeled as "Sample Orderable Test" without a LOINC code number attached.

Note that in LOINC 81254-5 "Genomic allele start-end", when the variation is at a single locus, the start and end locations of the allele have the same value, e.g. "37070354^37070354" to show the locations are the same. The data type also allows the location to be reported as a single number, e.g. "37070354."

Also, for LOINC 69551-0 "Genomic alt allele," when the alt allele is absent, the message shows "-", as recommended by the Variant Call Format from IGSR: The International Genome Sample Resource.

Note that in a complex variant example, some alleles are submitted with a complex variant as one package, and such variants have not yet been assigned IDs. So in these cases, the LOINC 81252-9 "Simple Variant" field uses the allele ID rather than the variant ID as a temporary expedient. These variants will be assigned variant IDs by NCBI.

For all examples of discrete variant examples in this guide, the variant ID is used in the LOINC 81252-9 "Discrete Variant" field.

An example of the Specimen Segment (SPM) is found in Example 1 in Section 5.9.1.1. For more information, please go to 8.12 SPM – Specimen Segment.

In the example messages, the text is selectively bolded to facilitate their reading. The bolded italic black text are to highlight the panel and subpanel subject headings, as well as explanatory comments within the message examples. The LOINC name and the example values are bolded in black text, and the OBX-4 numbering is bolded in red text. Note that real HL7 messages would not have bolded or italicized text.

5.9.1 DISCRETE GENETIC VARIANT EXAMPLE MESSAGES

5.9.1.1 SIMPLE VARIANT – VARIANT ANALYSIS OF ONE GENE BY SEQUENCING

The narrative text illustrates a sample report on Galactosemia Gene Analysis. The example shows that a heterozygous and known pathogenic variant was identified, indicating that the individual may be a carrier for galactosemia.

Note that the real tests will test for several gene variants. For brevity, this example lists only three of the gene mutations tested, but actual reports would list every mutation tested in a separate OBX field.

Example 1

```
OBR|1|Acme23469|Gen825750|42318-6^GALT gene targeted mutation
   analysis^LN|R|201608030830|201608091650|
Variables that Apply to Overall Study: Report Section 1
OBX|1|TX|53577-3^Reason for study^LN|1|Patient may be carrier for
   classic galactosemia.|
OBX|2|CWE|51967-8^Genetic disease(s) assessed^LN|1|
   C0016952^Galactosemia^MedGen-Dis|
```

```
OBX|3|CWE|51958-7^Transcript reference sequence
   [Identifier]^LN|1| NM_000249^NM_000249^RefSeq-T|

OBX|4|CNE|48018-6^Gene studied [ID]^LN|1.a|4135^GALT^HGNC-Symb|

OBX|5|CWE|36908-2^Gene mutations tested for^LN|1.a|-119_-
   116delGTCA^-119_-116delGTCA^HGVS.c|

OBX|6|CWE|36908-2^Gene mutations tested for^LN|1.b|
   Asp98Asn^Asp98Asn^HGVS.p|

OBX|7|CWE|36908-2^Gene mutations tested for^LN|1.c|
   Gln188Arg^Gln188Arg^HGVS.p |

OBX|8|CNE|51968-6^Discrete variation analysis overall
   interpretation^LN|1|LA6576-8^Positive^LN|

OBX|9|FT|51969-4^Full narrative report^LN|1|Result Summary-
   Positive \.br\\.br\ Result - The following heterozygous
   alteration was identified: Amino Acid change: p.Q188R
   (Gln188Arg). DNA change: c.563A>G (g.34648167), Classification:
   PATHOGENIC \.br\\.br\ Interpretation - Biochemical and
   molecular test results are in agreement. The observed GALT
   enzyme activity in red blood cells (12.2 nmol/h/mg Hb) and the
   presence of a single copy of p.Q188R suggest that this
   individual is a carrier of classic galactosemia. This
   individual should not be at risk for developing symptoms
   related to this disorder; however, he or she may be at risk for
   having offspring with galactosemia. If appropriate, enzymatic
   and molecular studies for this individual's reproductive
   partner are recommended to further clarify this risk.
   \.br\\.br\ Method - A multiplex PCR-based assay was used to
   test for the presence of the following mutations in the GALT
   gene.|

Technical details

OBX|10|CWE|62374-4^Human reference sequence
   assembly^LN|1|LA14029-5^GRCh37^LN|

OBX|11|NM|82115-7^dbSNP version^LN|1|147|

Attributes of Discrete Genetic Variants: Report Section 2

OBX|12|CNE|83005-9^Variant Category^LN|2a|LA26801-3^Simple
   Variant^LN|

OBX|13|CNE|81252-9^Discrete genetic variant^LN|2a|
   3614^NM_000155.3(GALT):c.563A>G(p.Gln188Arg)^ClinVar-V|

Transcript Specification Variables

OBX|14|CWE|48018-6^Gene studied^LN|2a|3614^GALT^HGNC-Symb|

OBX|15|CWE|51958-7^Transcript RefSeq ID^LN|2a|
   NM_000155.3^NM_000155.3^RefSeq-T|
```

```
OBX|16|CWE|41103-3^Transcript DNA Change (cHGVS)^LN|2a|
   c.563A>G^c.563A>G^HGVS.c|

OBX|17|CWE|48005-3^Amino acid change p.HGVS^LN|2a|
   p.Gln188Arg^p.Gln188Arg^HGVS.p|

OBX|18|CWE|48019-4^DNA change type^LN|2a|LA6690-
   7^Substitution^LN|

OBX|19|CWE|48006-1^Amino Acid change type|2a|LA6698-
   0^Missense^LN|

Genomic specification (HGVS code and VCF-like representation)

OBX|20|CWE|48013-7^Genomic reference sequence^LN|2a|
   NG_009029.1:g.6533A>G^NG_009029.1:g.6533A>G^RefSeq-G|

OBX|21|CWE|81290-9^Genomic DNA change(gHGVS)^LN|2a|
   NC_000009.11:g.34648167A>G^NC_000009.11:g.34648167A>G^HGVS.g|

OBX|22|ST|69547-8^Genomic ref allele^LN|2a|A|

OBX|23|NR|81254-5^Genomic allele start-
   end^LN|2a|34648167^34648167|

OBX|24|ST|69551-0^Genomic alt allele^LN|2a|G|

Other variables

OBX|25|CNE|81255-2^dbSNP ID^LN|2a|rs75391579^rs75391579^dbSNP|

OBX|26|CWE|48001-2^Cytogenetic (chromosome) location^LN|2a|
   9p13^9p13^Chrom-Loc|

OBX|27|CNE|48002-0^Genomic source class^LN|2a|LA6683-
   2^Germline^LN|

OBX|28|CNE|81304-8^Variant analysis method type^LN|2a|LA26418-
   6^PCR^LN|

Interpretations

OBX|29|CNE|53037-8^Genetic variation clinical significance^LN|2a|
   LA6668-3^Pathogenic^LN|

OBX|30|CNE|69548-6^Genetic variant assessment^LN|2a|LA9633-
   4^Present^LN|

OBX|31|CWE|81259-4^Probable associated phenotype^LN|2a|
   C0268151^Deficiency of UDPglucose-hexose-1-phosphate
   uridylyltransferase^MedGen-Dis|

Allelic state/phase information

OBX|32|CNE|53034-5^Allelic state^LN|2a|LA6706-1^Heterozygous^LN|

Specimen information

SPM|1|S-2015
   66&GoodHealthC_EHR&2.16.840.1.113883.3.72.5.24&ISO^S-9911-
   33&NIST Lab Filler&2.16.840.1.113883.3.72.5.25&ISO||
```

```
119342007^SAL^SCT^SalSpc^Saliva^^99USA^^^Saliva
Specimen|||||||| ||||20110103143428||||| ||||
```

5.9.1.2 SIMPLE VARIANT – TARGETED VARIANTS ANALYSIS THAT STUDIES MANY MUTATIONS (106)

The following example illustrates a sample report on Cystic Fibrosis Analysis. A heterozygous and known pathogenic variant was identified, which indicated the individual may be a carrier for cystic fibrosis.

Note that in LOINC 36908-2 "Gene mutations tested for," some reports will report variants as pure HGVS strings without the reference sequence and used the older amino acid representations as shown: deltaF508, delta I507, W1282X (TGG>TGA), 621+1G>T. This example replaces the pure HGVS strings with ClinVar variant IDs and also converts all of the amino acid one letter abbreviations to three letter abbreviations as required by today's HGVS. For the variation, "W1282X (TGG>TGA)," the text reported an amino acid change to "X", which represents a nonsense variant with the "X" signaling a terminate code. Currently, the three letter HGVS version uses a "*" or "Ter" in place of the "X" and this example uses a "Ter," e.g. "Gly542Ter."

The example includes the full HGVS expression and ClinVar ID just to show how a full expression in the list of variants targeted would look and to illustrate the fact that different coding systems can be used for different elements in the list. The other variants listed depend on the "Transcript reference sequence [Identifier]" for their reference sequence, and are a mix of HGVS.c, HGVS.p and raw text, which is the exception referenced in the "Coding with Exception" data type. In the current laboratory standard, such raw text goes into CWE.9 – the "original text" field and is preceded by eight carets, "^^^^^^^^". Be aware that some in the V2 community believe it should go into CWE.2 – with nulls in CWE.1 and CWE.3. But because this is a laboratory message, the example uses the CWE.9 convention. A case in point is the variation,"the deletion of exons 2-3" is recorded as "^^^^^^^^the deletion of exons 2-3".

As per the guide, this example populates both CWE.1 and CWE.2 with the same string when the coding system does not have a name (print string) that is distinct from the code.

Note that the real tests will test for several gene variants. For brevity, this example lists only ten of the gene mutations tested, but actual reports would list every mutation tested in a separate OBX field.

Example 2

```
OBR|1|Acme23469|Gen825750|38404-0^CFTR gene targeted mutation
   analysis in Blood or Tissue by Molecular genetics method
   Narrative^LN|R|201608030830|201608091650|

Variables that Apply to Overall Study: Report Section 1

OBX|1|TX|53577-3^Reason for study^LN|1|Patient may be carrier
   for cystic fibrosis|

OBX|2|CWE|51967-8^Genetic disease(s)
   assessed^LN|1|C0010674^Cystic fibrosis^MedGen-Dis|

OBX|3|CWE|51958-7^Transcript reference sequence
   [Identifier]^LN|1| NM_000492.3^NM_000492.3^RefSeq-T

OBX|4|CNE|48018-6^Gene studied^LN|1.a|1884^CFTR^HGNC-Symb|
```

```
OBX|5|CWE|36908-2^Gene mutations tested for^LN|1.a|
   7105^NM_000492.3(CFTR):c.1521_1523delCTT
   (p.Phe508delPhe)^ClinVar-V|
OBX|6|CWE|36908-2^Gene mutations tested for^LN|1.b|
   7106^NM_000492.3(CFTR):c.1519_1521delATC(p.Ile507del)^ClinVa
   r-V|
OBX|7|CWE|36908-2^Gene mutations tested for^LN|1.c|
   7129^NM_000492.3(CFTR):c.3846G>A (p.Trp1282Ter)^ClinVar-V|
OBX|8|CWE|36908-2^Gene mutations tested for^LN|1.d|
   38799^NM_000492.3(CFTR):c.489+1G>T^ClinVar-V|
OBX|9|CWE|36908-2^Gene mutations tested for^LN|1.e|
   Gly542Ter^Gly542Ter^HGVS.p|
OBX|10|CWE|36908-2^Gene mutations tested for^LN|1.f|
   Arg117His^Arg117His^HGVS.p|
OBX|11|CWE|36908-2^Gene mutations tested for^LN|1.g|
   711+1G>T^711+1G>T^HGVS.c|
OBX|12|CWE|36908-2^Gene mutations tested for^LN|1.h|
   Asn1303Lys(C>A)^Asn1303Lys(C>A)^HGVS.p|
OBX|13|CWE|36908-2^Gene mutations tested for^LN|1.i|
   Arg334Trp^Arg334Trp^HGVS.p|
OBX|14|CWE|36908-2^Gene mutations tested for^LN|1.j|
   Arg347Pro^Arg347Pro^HGVS.p|
OBX|15|CWE|36908-2^Gene mutations tested
   for^LN|1.k|^^^^^^^^the deletion of exons 2-3|
OBX|16|CNE|51968-6^Discrete variation analysis overall
   interpretation^LN|1|LA6576-8^Positive^LN|
OBX|17|FT|51969-4^Full narrative report^LN|1|Result Summary-
   Positive. \.br\\.br\ Result- The following heterozygous
   sequence change was identified. Amino Acid: p.F508del
   (Phe508del), DNA change: c.1521_1523delCTT
   (g.117199646_117199648), Classification: Pathogenic.
   \.br\\.br\ Interpretation- This result indicates that this
   individual is a carrier of cystic fibrosis (CF). This
   interpretation assumes that this individual is not
   clinically affected with CF. Since a mutation has been
   identified, genetic testing of at risk family members could
   be considered. If appropriate, genetic testing should be
   offered to this individual's reproductive partner to further
   clarify their risk of having a child with CF. \.br\\.br\
   Method- A multiplex PCR based was used to detect 106
   mutations, including the 23 mutations specified in the
   American College of Medical Genetics (ACMG) standards for
   population based carrier screening...Poly T determination
```

```
   and confirmatory testing of homozygous results are performed
   as reflex tests when appropriate.|

Technical details

OBX|18|CWE|62374-4^Human reference sequence assembly^LN|1|
   LA14029-5^GRCh37^LN|

OBX|19|NM|82115-7^dbSNP version^LN|1|147|

Attributes of Discrete Genetic Variants: Report Section 2

OBX|20|CNE|83005-9^Variant Category^LN|2a|LA26801-3^Simple
   Variant^LN|

OBX|21|CNE|81252-9^Discrete genetic variant^LN|2a|
   7105^NM_000492.3(CFTR):c.1521_1523delCTT
   (p.Phe508delPhe)^ClinVar-V|

Transcript Specification Variables

OBX|22|CWE|48018-6^Gene studied^LN|2a|1884^CFTR^HGNC-Symb|

OBX|23|CWE|51958-7^Transcript RefSeq ID^LN|2a|
   NM_000492.3^NM_000492.3^RefSeq-T|

OBX|24|CWE|41103-3^Transcript DNA Change (cHGVS)^LN|2a|
   c.1521_1523delCTT^c.1521_1523delCTT^HGVS.c|

OBX|25|CWE|48005-3^Amino acid change p.HGVS^LN|2a|
   p.Phe508delPhe^p.Phe508delPhe^HGVS.p|

OBX|26|CWE|48019-4^DNA change type^LN|2a|LA6692-
   3l^deletion^LN|

Genomic specification (HGVS code and VCF-like representation)

OBX|27|CWE|48013-7^Genomic reference sequence ID^LN|2a|
   NG_016465.4:g.98809_98811delCTT^NG_016465.4:g.98809_98811del
   CTT^RefSeq-G|

OBX|28|CWE|81290-9^Genomic DNA change(gHGVS)^LN|2a|
   NC_000007.13^NC_000007.13^HGVS.g|

OBX|29|ST|69547-8^Genomic ref allele^LN|2a|CTT|

OBX|30|NR|81254-5^Genomic allele start-end^LN|2a|
   117199646^117199648|

OBX|31|ST|69551-0^Genomic alt allele^LN|2a|-|

Other variables

OBX|32|CNE|81255-2^dbSNP
   ID^LN|2a|rs113993960^rs113993960^dbSNP|

OBX|33|CWE|48001-2^Cytogenetic (chromosome) location^LN|2a|
   7q31.2^7q31.2^Chrom-Loc|

OBX|34|CNE|48002-0^Genomic source class^LN|2a|LA6683-
   2^Germline^LN|
```

```
Interpretations
OBX|35|CNE|53037-8^Genetic variation Clinical
   significance^LN|2a| LA6668-3^Pathogenic^LN|
OBX|36|CNE|69548-6^Genomic variant assessment^LN|2a|LA9633-
   4^Present^LN|
OBX|37|CWE|81259-4^Probable associated phenotype^LN|2a|
   C0010674^Cystic fibrosis^MedGen-Dis|
Allelic state/phase information
OBX|38|CNE|53034-5^Allelic state^LN|2a|LA6706-
   1^Heterozygous^LN|
```

5.9.1.3 SIMPLE VARIANT – VARIANT ANALYSIS WITH SEQUENCE PLUS DELETION-DUPLICATION STUDY

The following example illustrates a full gene analysis for MLH1 where a heterozygous and known pathogenic variant was identified, which results in a diagnosis of Lynch Syndrome.

Note that in this example, in LOINC 81252-9 “Simple variant”, the HGVS expression includes “Profs” which references Proline and a frameshift variation (this notation is found in the HGVS manual).

Example 3

```
OBR|1|Acme23469|Gen825750|Sample Orderable Test]^MLH1 gene
   deletion+duplication and full mutation analysis in Blood
   or Tissue by Molecular genetics method Narrative
   ^LN|R|201608030830|201608091650|
Variables that Apply to Overall Study: Report Section 1
OBX|1|TX|53577-3^Reason for study^LN|1|Patient may have Lynch
   Syndrome|
OBX|2|CWE|51967-8^Genetic disease(s)
   assessed^LN|1|C0009405^Lynch syndrome^MedGen-Dis|
OBX|3|CWE|51958-7^Transcript reference sequence
   [Identifier]^LN|1| NM_000249^NM_000249^RefSeq-T|
OBX|4|CNE|48018-6^Gene studied^LN|1.a|7127^MLH1^HGNC-Symb|
OBX|5|TX|81293-3^Description of ranges of DNA sequences
   examined^LN|1|Bi-directional sequence analysis was
   performed to test for the presence of a mutation in all
   coding regions and intron/exon boundaries of the MLH1
   gene.|
OBX|6|CNE|51968-6^Discrete variation analysis overall
   interpretation^LN|1|LA6576-8^Positive^LN|
OBX|7|CWE|83006-7^Deletion-duplication overall
   interpretation^LN|1|LA26803-9^No deletion duplications
```

```
   detected in studied regions^LN|
OBX|8|FT|51969-4^Full narrative report^LN|1|Result Summary-
   Positive \.br\\.br\ Result- The following heterozygous
   alteration was identified: Amino Acid change: p.R497PfsX6
   (Arg497ProfsX6) DNA change: c.1489dupC (g.37070354)
   Classification: PATHOGENIC. \.br\\.br\ Interpretation -
   The c.1489dupC (p.R497PfsX6) alteration is a known
   pathogenic mutation. This result is consistent with a
   diagnosis of Lynch syndrome for this individual.
   \.br\\.br\ Method - Bi-directional sequence analysis was
   performed to test for the presence of a mutation in all
   coding regions and intron/exon boundaries of the MLH1
   gene. Array comparative genomic hybridization (aCGH) was
   used to test for the presence of large deletions and
   duplications in this gene.|
Technical details
OBX|9|CWE|62374-4^Human reference sequence
   assembly^LN|1|LA14029-5^GRCh37^LN|
OBX|10|NM|82115-7^dbSNP version^LN|1|147|
Attributes of Discrete Genetic Variants: Report Section 2
OBX|11|CNE|83005-9^Variant Category^LN|2a|LA26801-3^Simple
   Variant^LN|
OBX|12|CNE|81252-9^Discrete genetic variant^LN|2a|
   89753^NM_000249.3(MLH1):c.1489dupC
   (p.Arg497Profs)^ClinVar-V|
Transcript Specification Variables
OBX|13|CWE|48018-6^Gene studied^LN|2a|89753^MLH1^HGNC-Symb|
OBX|14|CWE|51958-7^Transcript RefSeq ID^LN|2a|
   NM_000249.3^NM_000249.3^RefSeq-T|
OBX|15|CWE|41103-3^Transcript DNA Change(cHGVS)^LN|2a|
   c.1489dupC^c.1489dupC^HGVS.c|
OBX|16|CWE|48005-3^Amino acid change p.HGVS^LN|2a|
   p.Arg497Profs^p.Arg497Profs^HGVS.p|
OBX|17|CWE|48019-4^DNA change type^LN|2a|LA6686-
   5^Duplication^LN|
OBX|18|CWE|48006-1^Amino acid change type^LN|2a|
   LA6694-9^Frameshift^LN|
Genomic specification (HGVS code and VCF-like representation)
OBX|19|CWE|48013-7^Genomic reference sequence^LN|2a|
   NG_007109.2:g.40514dupC^NG_007109.2:g.40514dupC^RefSeq-G|
OBX|20|CWE|81290-9^Genomic DNA change (gHGVS)^LN|2a|
   NC_000003.11^NC_000003.11^HGVS.g|
```

```
OBX|21|ST|69547-8^Genomic ref allele^LN|2a|C|
OBX|22|NR|81254-5^Genomic allele start-end^LN|2a|
   37070354^37070354|
OBX|23|ST|69551-0^Genomic alt allele^LN|2a|CC|
Other variables
OBX|24|CNE|81255-2^dbSNP
   ID^LN|2a|rs63751031^rs63751031^dbSNP|
OBX|25|CWE|48001-2^Cytogenetic (chromosome) location^LN|2a|
   3p22.2^3p22.2^Chrom-Loc|
OBX|26|CNE|48002-0^Genomic source class^LN|2a|LA6683-
   2^Germline^LN|
OBX|27|CWE|53037-8^Variant analysis method^LN|2a|LA26398-
   0^Sequencing^LN|
Interpretations
OBX|28|CNE|53037-8^Genetic variation clinical
   significance^LN|2a| LA6668-3^Pathogenic^LN|
OBX|29|CNE|69548-6^Genomic variant assessment^LN|2a|LA9633-
   4^Present^LN|
OBX|30|CWE|81259-4^Probable associated phenotype^LN|2a|
   C0009405^Lynch syndrome^MedGen-Dis|
Allelic state/phase information
OBX|31|CNE|53034-5^Allelic state^LN|2a|LA6706-
   1^Heterozygous^LN|
```

5.9.1.4 SIMPLE VARIANT – MULTI-GENE VARIANT ANALYSIS AND DUPLICATION-DELETION STUDY

The following example illustrates a sample report that tests for several genetic diseases associated with infantile epilepsy.

Note that this example message only reports three genetic diseases that are tested to save space but real messages would list all of them in separate OBX fields. Also, while real tests would test for several gene variants and list them in a separate OBX field, this example lists only five of the gene mutations tested to save space.

Example 4

```
OBR|1|Acme23469|Gen825750|Sample Orderable Test^Infantile
   Epilepsy Panel – Multi Gene targeted analysis^LN|R|
   201608030830|201608091650|
Variables that Apply to Overall Study: Report Section 1
```

```
OBX|1|TX|53577-3^Reason for study^LN|1|Patient may have
   infantile epilepsy.|

OBX|2|CWE|51967-8^Genetic disease(s) assessed^LN|1.a|
   C0268126^Adenylosuccinate lyase deficiency^MedGen-Dis|

OBX|3|CWE|51967-8^Genetic disease(s) assessed^LN|1.b|
   C0162635^Angelman syndrome^MedGen-Dis|

OBX|4|CWE|51967-8^Genetic disease(s) assessed^LN|1.c|
   C2748910^Atypical Rett syndrome^MedGen-Dis|

OBX|5|CNE|48018-6^Gene studied^LN|1.a|291^ADSL^HGNC-Symb|

OBX|6|CNE|48018-6^Gene studied^LN|1.b|877^ALDH7A1^HGNC-Symb|

OBX|7|CNE|48018-6^Gene studied^LN|1.c|30881^ALG13^HGNC-Symb|

OBX|8|CNE|48018-6^Gene studied^LN|1.d|14561^ARHGEF9^HGNC-
   Symb|

OBX|9|CNE|48018-6^Gene studied^LN|1.e|18060^ARX^HGNC-Symb|

OBX|10|CNE|51968-6^Discrete variation analysis overall
   interpretation^LN|1|LA6576-8^Positive^LN|

OBX|11|CWE|83006-7^Deletion-duplication overall
   interpretation^LN|1|LA26803-9^No deletion duplications
   detected in studied regions^LN|

OBX|12|FT|51969-4^Full narrative report^LN|1|Result-
   Heterozygous for a single PNKP mutation; Heterozygous for
   a single PRRT2 mutation. No other reportable variants
   detected by sequencing and deletion/duplication analysis
   of the 75 genes included on this panel. \.br\\.br\
   Interpretation: This individual is heterozygous for a
   novel disease-causing mutation in the PNKP gene. This gene
   is associated with an autosomal recessive disorder. A
   second mutation may exist that is undetectable by this
   test or this patient may incidentally be a heterozygous
   carrier of the PNKP mutation. The finding of a single
   mutation in PNKP is not sufficient to establish a
   diagnosis in this patient. This individual is heterozygous
   for a published missense variant in the PRRT2 gene. This
   gene is associated with autosomal dominant disorder. With
   the clinical and molecular information available at this
   time, the clinical significance of this variant is
   unknown. \.br\\.br\ Method - Using genomic DNA from the
   submitted specimen, the coding regions and splice
   junctions of 51 genes (all genes listed above except for
   CHRNA7 and MAGI2, since only large deletions have been
   reported in these genes) were sequenced with pair-end
   reads. Capillary sequencing was used to confirm all
   potentially pathogenic variants. Concurrent
   deletion/duplication testing was performed for the genes
```

```
   in the panel using exon-level oligo array CGH, except for
   FOXG1. Confirmation of copy number changes was performed
   by MLPA, qPCR, or repeat array CGH analysis. \.br\\.br\
   Additional Information - The test also found likely benign
   variants in genes KANSL1 and PNKP.|

OBX|13|TX|81293-3^Description of ranges of DNA sequences
   examined^LN|1|The sequencing component of the test
   includes all genes listed above except for CHRNA7 and
   MAGI2, since only large deletions have been reported in
   these genes.|

Technical details

OBX|14|CWE|62374-4^Human reference sequence assembly^LN|1|
   LA14029-5^GRCh37^LN|

OBX|15|NM|82115-7^dbSNP version^LN|1|147|

Attributes of First Discrete Genetic Variants: Report Section
   2

OBX|16|CNE|83005-9^Variant Category^LN|2a|LA26801-3^Simple
   Variant^LN|

OBX|17|CNE|81252-9^Discrete genetic variant^LN|2a|No Variant
   ID^NM_007254.3(PNKP):c.1315C>T(p.Arg439Ter)^ClinVar-V|

Transcript Specification Variables

OBX|18|CWE|48018-6^Gene studied^LN|2a|9154^PNKP^HGNC-Symb|

OBX|19|CWE|51958-7^Transcript RefSeq ID^LN|2a|
   NM_007254.3^NM_007254.3^RefSeq-T|

OBX|20|CWE|41103-3^Transcript DNA Change (cHGVS)^LN|2a|
   c.610C>T^c.1315C>T^HGVS.c|

OBX|21|CWE|48005-3^Amino acid change p.HGVS^LN|2a|
   p.Arg204Ter^p.Arg439Ter^HGVS.p|

OBX|22|CWE|48019-4^DNA change type^LN|2a|LA6690-
   7^Substitution^LN|

OBX|23|CWE|48006-1^Amino acid change type^LN|2a|LA6699-
   8^Nonsense^LN|

Genomic specification (HGVS code and VCF-like representation)

OBX|24|CWE|81290-9^Genomic DNA change (gHGVS)^LN|2a|
   NC_000019.9^NC_000019.9^RefSeq-G|

OBX|25|ST|69547-8^Genomic ref allele^LN|2a|G|

OBX|26|NR|81254-5^Genomic allele start-end^LN|2a|
   50367462^50367462|

OBX|27|ST|69551-0^Genomic alt allele^LN|2a|A|
```

Other variables

OBX|28|CNE|81255-2^**dbSNP ID**^LN|**2a**|rs796052850^**rs796052850**^dbSNP|

OBX|29|CWE|48001-2^**Cytogenetic (chromosome) location**^LN|**2a**|19q13.33^**19q13.33**^Chrom-Loc|

OBX|30|CNE|48002-0^**Genomic source class**^LN|**2a**|LA6683-2^**Germline**^LN|

Interpretations

OBX|31|CNE|53037-8^**Genetic variation clinical significance**^LN|**2a**| LA6668-3^**Pathogenic**^LN|

OBX|32|CNE|69548-6^**Genomic variant assessment**^LN|**2a**|LA9633-4^**Present**^LN|

OBX|33|CWE|81259-4^**Probable associated phenotype**^LN|**2a**|CN218420^**Developmental delay AND/OR other significant developmental or morphological phenotypes**^MedGen-Dis|

Allelic state/phase information

OBX|34|CNE|53034-5^**Allelic state**^LN|**2a**|LA6706-1^**Heterozygous**^LN|

Attributes of Second Simple Genetic Variants: Report Section 2

OBX|35|CNE|83005-9^**Variant Category**^LN|**2a**|LA26801-3^**Simple Variant**^LN|

OBX|36|CNE|81252-9^**Discrete genetic variant**^LN|**2b**|130039^**NM_145239.2(PRRT2):c.67G>A(p.Glu23Lys)**^ClinVar-V|

Transcript Specification Variables

OBX|37|CWE|48018-6^**Gene studied**^LN|**2b**|30500^**PRRT2**^HGNC-Symb|

OBX|38|CWE|51958-7^**Transcript RefSeq ID**^LN|**2b**|NM_145239.2^**NM_145239.2**^RefSeq-T|

OBX|39|CWE|41103-3^**Transcript DNA Change (cHGVS)**^LN|**2b**|c.67G>A^**c.67G>A**^HGVS.c|

OBX|40|CWE|48005-3^**Amino acid change p.HGVS**^LN|**2b**|p.Glu23Lys^**p.Glu23Lys**^HGVS.p|

OBX|41|CWE|48019-4^**DNA change type**^LN|**2b**|LA6690-7^**Substitution**^LN|

Genomic specification (HGVS code and VCF-like representation)

OBX|42|CWE|81290-9^**Genomic DNA change (gHGVS)**^LN|**2b**|NC_000016.9^**NC_000016.9**^RefSeq-G|

OBX|43|ST|69547-8^**Genomic ref allele**^LN|**2b**|**G**|

```
OBX|44|NR|81254-5^Genomic allele
   location^LN|2b|29824442^29824442|

OBX|45|ST|69551-0^Genomic alt allele^LN|2b|A|

Other variables

OBX|46|CNE|81255-2^dbSNP
   ID^LN|2b|rs140383655^rs140383655^dbSNP|

OBX|47|CWE|48001-2^Cytogenetic (chromosome) location^LN|2b|
   16p11.2^16p11.2^Chrom-Loc|

OBX|48|CNE|48002-0^Genomic source class^LN|2b|LA6683-
   2^Germline^LN|

Interpretations

OBX|49|CNE|53037-8^Genetic variation clinical
   significance^LN|2b| LA6671-7^Uncertain Significance^LN|

OBX|50|CNE|69548-6^Genomic variant assessment^LN|2b|LA9633-
   4^Present^LN|

OBX|51|CWE|81259-4^Probable associated phenotype^LN|2b|
   C1510586^Autism spectrum disorders^MedGen-Dis|

Allelic state/phase information

OBX|52|CNE|53034-5^Allelic state^LN|2b|LA6706-
   1^Heterozygous^LN|

Attributes of Third Discrete Genetic Variants: Report Section
   2

OBX|53|CNE|83005-9^Variant Category^LN|2c|LA26801-3^Simple
   Variant^LN|

OBX|54|CNE|81252-9^Discrete genetic variant^LN|2c|
   205776^NM_001193466.1(KANSL1):c.727C>A(p.Gln243Lys)^ClinVa
   r-V|

Transcript Specification Variables

OBX|55|CWE|48018-6^Gene studied^LN|2c|24565^KANSL1^HGNC-Symb|

OBX|56|CWE|51958-7^Transcript RefSeq ID^LN|2c|
   NM_001193466.1^NM_001193466.1^RefSeq-T|

OBX|57|CWE|41103-3^Transcript DNA Change(cHGVS)^LN|2c|
   c.727C>A^c.727C>A^HGVS.c|

OBX|58|CWE|48005-3^Amino acid change p.HGVS^LN|2c|
   p.Gln243Lys^p.Gln243Lys^HGVS.p|

OBX|59|CWE|48019-4^DNA change type^LN|2c|LA6690-
   7^Substitution ^LN|

OBX|60|CWE|48006-1^Amino acid change type^LN|2c|LA6698-
   0^Missense^LN|
```

Genomic specification (HGVS code and VCF-like representation)

OBX|61|CWE|81290-9^**Genomic DNA change (gHGVS)**^LN|**2c|**
NC_000017.10^**NC_000017.10**^RefSeq-G|

OBX|62|ST|69547-8^**Genomic ref allele**^LN|**2c|G|**

OBX|63|NR|81254-5^**Genomic allele location**^LN|**2c|44248783^44248783|**

OBX|64|ST|69551-0^**Genomic alt allele**^LN|**2c|T|**

Other variables

OBX|65|CNE|81255-2^**dbSNP ID**^LN|**2c|**rs142096969^**rs142096969**^dbSNP|

OBX|66|CWE|48001-2^**Cytogenetic (chromosome) location**^LN|**2c|**17q21.31^**17q21.31**^Chrom-Loc|

OBX|67|CNE|48002-0^**Genomic source class**^LN|**2c|**LA6683-2^**Germline**^LN|

Interpretations

OBX|68|CNE|53037-8^**Genetic variation clinical significance**^LN|**2c|** LA6674-1^**Likely Benign**^LN|

OBX|69|CNE|69548-6^**Genomic variant assessment**^LN|**2c|**LA9633-4^**Present**^LN|

Allelic state/phase information

OBX|70|CNE|53034-5^**Allelic state**^LN|**2c|**LA6706-1^**Heterozygous**^LN|

Attributes of Fourth Discrete Genetic Variants: Report Section 2

OBX|71|CNE|83005-9^**Variant Category**^LN|**2d|**LA26801-3^**Simple Variant**^LN|

OBX|72|CNE|81252-9^**Discrete genetic variant**^LN|**2d|**
159792^**NM_007254.3(PNKP):c.188C>T(p.Ala63Val)**^ClinVar-V|

Transcript Specification Variables

OBX|73|CWE|48018-6^**Gene studied**^LN|**2d|**9154^**PNKP**^HGNC-Symb|

OBX|74|CWE|51958-7^**Transcript RefSeq ID**^LN|**2d|**
NM_007254.3^**NM_007254.3**^RefSeq-T|

OBX|75|CWE|41103-3^**Transcript DNA Change (cHGVS)**^LN|**2d|**
c.188C>T^**c.188C>T**^HGVS.c|

OBX|76|CWE|48005-3^**Amino acid change p.HGVS**^LN|**2d|**
p.Ala63Val^**p.Ala63Val**^HGVS.p|

OBX|77|CWE|48019-4^**DNA change type**^LN|**2d|**LA6690-7^**Substitution** ^LN|

```
OBX|78|CWE|48006-1^Amino acid change type^LN|2d|LA6698-
   0^Missense^LN|

Genomic specification (HGVS code and VCF-like representation)

OBX|79|CWE|81290-9^Genomic DNA change
   (gHGVS)^LN|2d|NC_000019.9^NC_000019.9^RefSeq-G|

OBX|80|ST|69547-8^Genomic ref allele^LN|2d|G|

OBX|81|NR|81254-5^Genomic allele
   location^LN|2d|50369666^50369666|

OBX|82|ST|69551-0^Genomic alt allele^LN|2d|A|

Other variables

OBX|83|CNE|81255-2^dbSNP ID^LN|2d|rs3739173^rs3739173^dbSNP|

OBX|84|CWE|48001-2^Cytogenetic (chromosome)
   location^LN|2d|19q13.33^19q13.33^Chrom-Loc|

OBX|85|CNE|48002-0^Genomic source class^LN|2d|LA6683-
   2^Germline^LN|

Interpretations

OBX|86|CNE|53037-8^Genetic variation clinical
   significance^LN|2d| LA6671-7^Uncertain Significance^LN|

OBX|87|CNE|69548-6^Genomic variant assessment^LN|2d|LA9633-
   4^Present^LN|

OBX|88|CWE|81259-4^Probable associated phenotype^LN|2d|
   C3150667^Early infantile epileptic encephalopathy
   10^MedGen-Dis|

Allelic state/phase information

OBX|89|CNE|53034-5^Allelic state^LN|2d|LA6706-
   1^Heterozygous^LN|
```

5.9.1.5 STRUCTURAL VARIANT – WHOLE GENOME STUDY FOR DELETION DUPLICATION

This example report illustrates a whole genome study that found a structural variant that may contribute to a phenotype of intellectual disability. This report uses ISCN nomenclature to report the variant. Because this is a whole genome study, the build can be taken as the reference sequence.

The field LOINC 82155-3 “Copy Number,” reports “3” because the specification requires a number even though real reports may report text, such as “partial trisomy.”

Example 5

```
OBR|1|Acme23469|Gen825750|62375-1^Cytogenomic SNP
   Microarray^LN|R|201608030830|201608091650|

Variables that Apply to Overall Study: Report Section 1
```

```
OBX|1|TX|53577-3^Reason for study^LN|1|Patient has
   encephalopathy|
OBX|2|CWE|51967-8^Genetic disease(s) assessed^LN|1|
   C1843367^Intellectual disability^MedGen-Dis|
OBX|3|TX|81293-3^Description of ranges of DNA sequences
   examined^LN|1|Whole genome.|
OBX|4|CWE|83006-7^Deletion-duplication overall
   interpretation^LN|1| LA26804-7^Deletion and/or duplication
   detected in studied region^LN|
OBX|5|FT|51969-4^Full narrative report^LN|1|Genetic Results:
   The cytogenomic microarray analysis indicated that there
   was a gain involving chromosome 16 (1.7 Mb duplicated)
   within 16p13.11, suggesting partial trisomy for this
   region. This duplication has been reported as a risk
   factor for neurocognitive disorders as it appears to be
   enriched in children with intellectual disabilities, but
   is also observed, at a lower frequency, in normal
   individuals. \.br\\.br\ Method: CHROMOSOMAL MICROARRAY
   ANALYSIS (CMA). \.br\\.br\ Methodology: This CMA was
   performed using Affymetrix(R) Cytogenetics Whole-Genome
   2.7M Array. The array offers a total of 2,141,868 markers
   across the entire genome, including 1,742,975 unique non-
   polymorphic markers, and 398,891 SNP markers.|
OBX|6|ST|81291-7^Structural variant ISCN^LN|1|arr
   16p13.11(14,686,844x2,14776269-
   16486370x3,16,494,405x2)(hg18)^ISCN|
Technical details
OBX|7|CWE|62374-4^Human reference sequence
   assembly^LN|1|LA26805-4^NCBI36^LN|
Discrete genetic variants: Report Section 2
OBX|8|CNE|83005-9^Variant Category^LN|2a|LA26802-1^Structural
   Variant^LN|
OBX|9|CWE|48019-4^DNA change type^LN|2a|LA6686-
   5^Duplication^LN|
OBX|10|CWE|48001-2^Cytogenetic chromosome location^LN|2a|
   16p13.11^16p13.11^Chrom-Loc|
OBX|11|CWE|81304-8^Variant analysis method type^LN|2a|
   LA26399-8^Oligo aCGH^LN|
Structural variant addenda
OBX|12|ST|82155-3^Copy number^LN|2a|3|
```

5.9.1.6 STRUCTURAL VARIANT – EXAMPLE OF WHOLE GENOME STUDY FOR DELETION DUPLICATION

This example illustrates a sample report on a whole genome study that found a structural variant that may contribute to a phenotype of developmental delay, and uses ISCN nomenclature to report the variant.

Note that this is a whole genome study, so the build can be taken as the reference sequence.

Also, as of February 2017, the cytogenetics location table in the LHC Clinical Search Table (described in Section 14) does not include the description of adjacent chromosome locations, such as 4q35.1-q35.2, but they are in development.

As we understand, the source table for NCBI uses dashes to represent the adjacent locations, e.g. 4q35.1-q35.2. Some real reports do not use the dash to separate the locations, e.g. 4q35.1q35.2.

Example 6

```
OBR|1|Acme23469|Gen825750|Sample Orderable Test^SNP
   Microarray Pediatric^LN|R|201608030830|201608091650|

Variables that Apply to Overall Study: Report Section 1

OBX|1|TX|53577-3^Reason for study^LN|1|Patient has
   developmental delay.|

OBX|2|CWE|51967-8^Genetic disease(s) assessed^MedGen-
   Dis|1|CN218420^Developmental delay AND/OR other
   significant developmental or morphological
   phenotypes^MedGen-Dis|

OBX|3|TX|81293-3^Description of ranges of DNA sequences
   examined^LN|1|Whole genome|

OBX|4|CWE|83006-7^Deletion-duplication overall
   interpretation^LN|1|LA26804-7^Deletion and/or duplication
   detected in studied region^LN

OBX|5|FT|51969-4^Full narrative report^LN|1|Microarray
   Result- 6.0 MB Terminal Deletion of 4Q35.1 -> 4QTER; 8.5
   MB Terminal Duplication of XQ27.3 -> XQTER. \.br\\.br\
   Interpretation- The presence of both a significant
   terminal gain and significant terminal loss in a different
   chromosome in the same analysis suggests that the patient
   has inherited a single derivative chromosome from a
   balanced translocation between the two chromosomes. The
   whole genome chromosome SNP microarray copy number
   analysis revealed a terminal 4q deletion [Flanking
   proximal OMIM gene: MIR510] and a terminal gain of Xq
   [Flanking proximal OMIM gene: IRF2] spanning the
   chromosomal segments listed below. These intervals include
   numerous OMIM annotated genes that may contribute to the
   patient phenotype...No other significant DNA copy number
   changes or copy neutral LOH were detected within our
```

```
   present reporting criteria in the 2,695,000 region
   specific SNPs.|
OBX|6|ST|81291-7^Structural variant ISCN^LN|1.a|arr
   4q35.1q35.2 (185, 135, 549-190, 957, 473)x1^ISCN|
OBX|7|ST|81291-7^Structural variant ISCN^LN|1.b|Xq27.3q28
   (146, 734, 447-154, 943, 511)x3^ISCN|
Technical details
OBX|8|CWE|62374-4^Human reference sequence
   assembly^LN|1|LA14029-5^GRCh37^LN|
Discrete Genetic Variants: Report Section 2
OBX|9|CNE|83005-9^Variant Category^LN|2a|LA26802-1^Structural
   Variant^LN|
OBX|10|CWE|48001-2^Cytogenetic (chromosome) location^LN|2a|
   4q35.1-q35.2^4q35.1-q35.2^Chrom-Loc|
OBX|11|CWE|48019-4^DNA change type^LN|2a|LA6692-
   3^Deletion^LN|
OBX|12|CWE|81304-8^Variant analysis method
   type^LN|2a|LA26400-4^SNP Array^LN|
Structural variant addenda
OBX|13|ST|82155-3^Copy number^LN|2a|1|
Discrete Genetic Variants: Report Section 2
OBX|14|CNE|83005-9^Variant Category^LN|2a|LA26802-
   1^Structural Variant^LN|
OBX|15|CWE|48001-2^Cytogenetic (chromosome) location^LN|2b|
   Xq27.3-q28^Xq27.3-q28^Chrom-Loc|
OBX|16|CWE|48019-4^DNA change type^LN|2b|LA6686-
   5^Duplication^LN|
OBX|17|CWE|81304-8^Variant analysis method
   type^LN|2b|LA26400-4^SNP Array^LN|
Structural variant addenda
OBX|18|ST|82155-3^Copy number^LN|2b|3|
```

5.9.1.7 STRUCTURAL VARIANT – EXAMPLE OF STRUCTURAL VARIANT REPORTED AS DBVAR CODE

This example illustrates a sample report on Tay-Sach's Disease, which found a structural variant that shows the patient is a carrier for Tay-Sach's disease. The structural variant is reported as a dbVar code, a NCBI (National Center for Biotechnology Information) database of genomics structural variations.

Example 7

```
OBR|1|Acme23469|Gen825750|76033-0^HEXA gene full mutation
   analysis in Blood or Tissue by Sequencing Narrative
   ^LN|R|201608030830|201608091650|

Variables that Apply to Overall Study: Report Section 1

OBX|1|TX|53577-3^Reason for study^LN|1|Patient may have Tay-
   Sach's Disease|

OBX|2|CWE|51967-8^Genetic disease(s) assessed^MedGen-Dis|1|
   C0039373^Tay-Sachs disease^MedGen-Dis|

OBX|3|CNE|48018-6^Gene(s) assessed^LN||1.1|4878^HEXA^HGNC-
   Symb|

OBX|4|TX|81293-3^Description of ranges of DNA sequences
   examined^LN|1|All coding regions and intron/exon
   boundaries of the HEXA gene.|

OBX|5|CWE|83006-7^Deletion-duplication overall
   interpretation^LN|1|LA26804-7^Deletion and/or duplication
   detected in studied regions^LN|

OBX|6|FT|51969-4^Full narrative report^LN|1|Result Summary-
   Positive. \.br\\.br\ Result- The following structural
   alteration was identified: DNA change: c.—
   2654_253+5128delinsG. Genome change:
   g.2644_10588del7945insG, Classification: PATHOGENIC.
   \.br\\.br\ Interpretation - The c.—2654_253+5128delinsG
   alteration is a known pathogenic mutation. This result
   indicates that this individual is a carrier of Tay Sachs
   disease (TSD). This assumes that this individual is not
   clinically affected with TSD. \.br\\.br\ Method - Bi-
   directional sequence analysis was performed to test for
   the presence of mutations in all coding regions and
   intron/exon boundaries of the HEXA gene.|

Technical details

OBX|7|CWE|62374-4^Human reference sequence
   assembly^LN|1|LA14029-5^GRCh37^LN|

Discrete Genetic Variants: Report Section 2

OBX|8|CNE|83005-9^Variant Category^LN|2a|LA26802-1^Structural
   Variant^LN|

OBX|9|CWE|81252-9^Discrete genetic
   variant^LN|2a|nsv513781^15q23-q24(chr15)(72370592-
   72378536)x1^dbVar-GL|

OBX|10|CWE|48019-4^DNA change type^LN|2a|
   LA9659-9^Insertion/Deletion^LN|
```

```
OBX|11|ST|81290-8 Genomic DNA change (gHGVS)^LN|2a|
   NG_009017.1:g.2644_10588del7945insG^
   NG_009017.1:g.2644_10588del7945insG^HGVS.g|

OBX|12|CWE|48001-2^Cytogenetic chromosome location^LN|2a|
   15q23q24^15q23q24^Chrom-Loc|

OBX|13|CWE|81304-8^Variant analysis method
   type^LN|2a|LA26402-0^Curated^LN|

Structural variant addenda

OBX|14|ST|81287-5^Structural variant start-end^LN|2a|
   72370592^72378536|

OBX|15|NM|81300-6^Structural variant length^LN|2a|7945|
```

5.9.2 COMPLEX VARIANT EXAMPLE MESSAGES

5.9.2.1 COMPLEX VARIANT – EXAMPLE OF NON-PHARMACOGENOMIC COMPLEX VARIANT HAPLOTYPE

This is an example of a non-pharmacogenomics complex variant, which happens to be a haplotype.

This report illustrates a sample report for Gaucher's disease, where complex variant shows the patient is a carrier for the disease.

Example 8

```
OBR|1|Acme23469|Gen825750|46988-2^GBA gene mutations tested
   for in Blood or Tissue by Molecular genetics method
   Nominal ^LN||R|201608030830|201608091650|

Variables that Apply to Overall Study: Report Section 1

OBX|1|TX|53577-3^Reason for study^LN|1|Patient may have
   Gaucher's disease.|

OBX|2|CWE|51967-8^Genetic disease(s) assessed^MedGen-Dis|1|
   C0017205^Gaucher disease^MedGen-Dis|

OBX|3|CWE|51958-7^Transcript reference sequence
   [Identifier]^LN|1| NM_000157^ NM_000157^RefSeq-T|

OBX|4|TX|81293-3^Description of ranges of DNA sequences
   examined^LN|1|Bi-directional sequence analysis was
   performed to test for the presence of mutations in all
   coding regions and intron/exon boundaries of the GBA
   gene.|

OBX|5|CNE|48018-6^Gene(s) assessed^LN|1|4177^GBA^HGNC-Symb|

OBX|6|CNE|51968-6^Discrete variation analysis overall
   interpretation^LN|1|LA6576-8^Positive^LN|

OBX|7|FT|51969-4^Full narrative report^LN|1|Result Summary-
   Positive \.br\\.br\ Result - The following haplotype
```

```
   heterozygous alteration was identified: Amino Acid
   changes: p.Ala495Pro, p.Val499=, p.Leu483Pro. DNA change:
   c.1483G>C (g.14481), c.1497G>C (g.14495),
   c.1448T>C (g.14446), Classification: PATHOGENIC \.br\\.br\
   Interpretation - The haplotype 1483G>C (p.Ala495Pro),
   c.1497G>C (p.Val499=), c.1448T>C (p.Leu483Pro) alteration
   is a known pathogenic mutation. This result indicates that
   this individual is a carrier of Gaucher disease. This
   assumes that this individual is not clinically affected
   with Gaucher disease. While the clinical presentation
   associated with Gaucher disease can be variable, the
   p.Ala495Pro, p.Val499=, p.Leu483Pro haplotype mutation is
   associated with Gaucher's disease, type 1, Acute
   neuronopathic Gaucher's disease, Subacute neuronopathic
   Gaucher's disease, and Gaucher disease, perinatal lethal.
   \.br\\.br\ Method - Bi-directional sequence analysis was
   performed to test for the the presence of mutations in all
   coding regions and intron/exon boundaries of the GBA gene.

Technical details

OBX|8|CWE|62374-4^Human reference sequence assembly^LN|1|
   LA14029^GRCh37^LN|

OBX|9|NM|82115-7^dbSNP version^LN|1|147|

Complex Variant: Report Section 5

OBX|10|CWE|81260-2^Complex variant ID^LN|3a|
   4297^NM_001005741.2(GBA):c.[1448T>C;1483G>C;1497G>C] -
   Haplotype^ClinVar-V|

OBX|11|CNE|81263-6^Complex variant type^LN|3a|
   LA26218-0^Haplotype^LN|

OBX|12|CWE|81259-4^Associated
   phenotype^LN|3a|C0017205^Gaucher disease^MedGen-Dis|

OBX|13|CNE|53037-8^Genetic variation clinical
   significance^LN|3a| LA6668-3^Pathogenic^LN|

OBX|14|CNE|53034-5^Allelic state^LN|3a|LA6706-
   1^Heterozygous^LN|

Attributes of First Discrete Variant within the complex
   variant

OBX|15|CNE|83005-9^Variant Category^LN|3a.1a|LA26801-3^Simple
   Variant^LN|

OBX|16|CNE|81252-9^Discrete variant^LN|
   3a.1a|93450^NM_001005741.2(GBA):c.1483G>C
   (p.Ala495Pro)^ClinVar-V|

Transcript Specification Variables
```

```
OBX|17|CWE|48018-6^Gene studied^LN|3a.1a|4177^GBA^HGNC-Symb|
OBX|18|CWE|51958-7^Transcript RefSeq ID^LN|3a.1a|
   NM_001005741.2^NM_001005741.2^H|
OBX|19|CWE|41103-3^Transcript DNA Change
   (cHGVS)^LN|3a.1a|c.1483G >C^c.1483G>C^HGVS.c|
OBX|20|CWE|48005-3^Amino acid change p.HGVS^LN|
   3a.1a|p.Ala495Pro^p.Ala495Pro^HGVS.p|
OBX|21|CWE|48019-4^DNA change type^LN|3a.1a|
   LA6690-7^Substitution^LN|
OBX|22|CWE|48006-1^Amino acid change type^LN|3a.1a|
   LA6698-0^Missense^LN|
Genomic specification (HGVS code and VCF-like representation)
OBX|23|CWE|48013-7^Genomic reference sequence^LN|3a.1a|
   NG_009783.1:g.14481G>C^NG_009783.1:g.14481G>C^RefSeq-G|
OBX|24|CWE|81290-9^Genomic DNA change (gHGVS)^LN|3a.1a|
   NC_000001.10^NC_000001.10^HGVS.g|
OBX|25|ST|69547-8^Genomic ref allele^LN|3a.1a|C|
OBX|26|NR|81254-5^Genomic allele start-end^LN|3a.1a|
   155205008^155205008|
OBX|27|ST|69551-0^Genomic alt allele^LN|3a.1a|G|
Other variables
OBX|28|CNE|81255-2^dbSNP ID^LN|3a.1a|rs368060^rs368060^dbSNP|
OBX|29|CWE|48001-2^Cytogenetic (chromosome)
   location^LN|3a.1a| 1q22^1q22^Chrom-Loc|
OBX|30|CNE|48002-0^Genomic source class^LN|3a.1a|
   LA6683-2^Germline^LN|
Interpretations
OBX|31|CNE|53037-8^Genetic variation clinical
   significance^LN|3a.1a|LA6675-8^Benign^LN|
Allelic state/phase information
OBX|32|CWE|82120-7^Allelic phase [Type]^LN|3a.1a|LA6112-2^1st
   set of variants in CIS relation to each other^LN|
OBX|33|CNE|82309-6^Basis for allelic phase^LN|3a.1a|
   LA26426-9^Directly measured^LN|
Attributes of Second Discrete Genetic Variant within the
   complex variant
OBX|34|CNE|83005-9^Variant Category^LN|3a.1b|LA26801-3^Simple
   Variant^LN|
```

```
OBX|35|CNE|81252-9^Discrete genetic variant^LN|3a.1b|
   93451^NM_001005741.2(GBA):c.1497G>C (p.Val499=)^ClinVar-V|
```

Transcript Specification Variables

```
OBX|36|CWE|48018-6^Gene studied^LN|3a.1b|4177^GBA^HGNC-Symb|

OBX|37|CWE|51958-7^Transcript RefSeq ID^LN|3a.1b|
   NM_001005741.2^NM_001005741.2^RefSeq-T|

OBX|38|CWE|41103-3^Transcript DNA Change (cHGVS)^LN|3a.1b|
   c.1497G>C^c.1497G>C^HGVS.c|

OBX|39|CWE|48005-3^Amino acid change p.HGVS^LN|3a.1b|
   p.Val499=^p.Val499=^HGVS.p|

OBX|40|CWE|48019-4^DNA change type^LN|3a.1b|
   LA6690-7^Substitution^LN|
```

Genomic specification (HGVS code and VCF-like representation)

```
OBX|41|CWE|48013-7^Genomic reference sequence^LN|3a.1b|
   NG_009783.1:g.14495G>C^NG_009783.1:g.14495G>C^RefSeq-G

OBX|42|CWE|81290-9^Genomic DNA change (gHGVS)^LN|3a.1b|
   NC_000001.10^NC_000001.10^RefSeq-G|

OBX|43|ST|69547-8^Genomic ref allele^LN|3a.1b|C|

OBX|44|NR|81254-5^Genomic allele start-
   end^LN|3a.1b|155204994^155204994|

OBX|45|ST|69551-0^Genomic alt allele^LN|3a.1b|G|
```

Other variables

```
OBX|46|CNE|81255-2^dbSNP
   ID^LN|3a.1b|rs1135675^rs1135675^dbSNP|

OBX|47|CWE|48001-2^Cytogenetic (chromosome)
   location^LN|3a.1b| 1q22^1q22^Chrom-Loc|

OBX|48|CNE|48002-0^Genomic source class^LN|3a.1b|
   LA6683-2^Germline^LN|
```

Interpretations

```
OBX|49|CNE|53037-8^Genetic variation clinical
   significance^LN|3a.1b|LA6675-8^Benign^LN|
```

Allelic state/phase information

```
OBX|50|CWE|82120-7^Allelic phase [Type]^LN|3a.1b|LA6112-2^1st
   set of variants in CIS relation to each other^LN

OBX|51|CNE|82309-6^Basis for allelic phase^LN|3a.1b|
   LA26426-9^Directly measured^LN|
```

Attributes of Third Discrete Genetic Variant within the complex variant

```
OBX|52|CNE|83005-9^Variant Category^LN|3a.1c|LA26801-3^Simple
   Variant^LN|

OBX|53|CNE|81252-9^Discrete genetic variant^LN|3a.1c|
   4288^NM_000157.3(GBA):c.1448T>C (p.Leu483Pro)^ClinVar-V|

Transcript Specification Variables

OBX|54|CWE|48018-6^Gene studied^LN|3a.1c|4177^GBA^HGNC-Symb|

OBX|55|CWE|51958-7^Transcript RefSeq ID^LN|3a.1c|
   NM_000157.3^NM_000157.3^RefSeq-T|

OBX|56|CWE|41103-3^Transcript DNA Change (cHGVS)^LN|3a.1c|
   c.1448T>C^c.1448T>C^HGVS.c|

OBX|57|CWE|48005-3^Amino acid change p.HGVS^LN|3a.1c|
   p.Leu483Pro^p.Leu483Pro^HGVS.p|

OBX|58|CWE|48019-4^DNA change type^LN|3a.1c|
   LA6690-7^Substitution^LN|

OBX|59|CWE|48006-1^Amino acid change type^LN|3a.1c|
   LA6698-0^Missense^LN|

Genomic specification (HGVS code and VCF-like representation)

OBX|60|CWE|48013-7^Genomic reference sequence^LN|3a.1c|
   NG_009783.1:g.14496T>C^NG_009783.1:g.14496T>C^RefSeq-G|

OBX|61|CWE|81290-9^Genomic DNA change (gHGVS)^LN|3a.1c|
   NC_000001.10^NC_000001.10^RefSeq-G|

OBX|62|ST|69547-8^Genomic ref allele^LN|3a.1c|A|

OBX|63|NR|81254-5^Genomic allele location^LN|3a.1c|
   155205043^155205043|

OBX|64|ST|69551-0^Genomic alt allele^LN|3a.1c|G|

Other variables

OBX|65|CNE|81255-2^dbSNP ID^LN|3a.1c|rs421016^rs421016^dbSNP|

OBX|66|CWE|48001-2^Cytogenetic (chromosome)
   location^LN|3a.1c| 1q22^1q22^Chrom-Loc|

OBX|67|CNE|48002-0^Genomic source class^LN|3a.1c|
   LA6683-2^Germline^LN|

Interpretations

OBX|68|CNE|53037-8^Genetic variation clinical
   significance^LN|3a.1c|LA6668-3^Pathogenic^LN|

OBX|69|CWE|81259-4^Probable associated
   phenotype^LN|3a.1c|C0017205^Gaucher disease^MedGen-Dis|

Allelic state/phase information
```

```
OBX|70|CWE|82120-7^Allelic phase [Type]^LN|3a.1c|LA6112-2^1st
   set of variants in CIS relation to each other^LN

OBX|71|CNE|82309-6^Basis for allelic phase^LN|3a.1c|LA26426-
   9^Directly measured^LN|
```

5.9.2.2 COMPLEX VARIANT, EXAMPLE OF PHARMACOGENOMICS STUDY THAT DETAILS RESULTS FOR EACH ALLELE

This example illustrates a pharmacogenomics report on a complex variant, which happens to be a haplotype. Note that this example uses the allele ID in the LOINC 81252-9 "Simple Variant" field for the simple variants inside the complex variant instead of the variant ID, because some alleles are submitted with a complex variant as one package and do not have variant IDs.

Example 9

```
OBR|1|Acme23469|Gen825750|47403-1^CYP2D6 gene targeted
   mutation analysis in Blood or Tissue by Molecular genetics
   method Narrative^LN|R|201608030830|201608091650|

Variables that Apply to Overall Study: Report Section 1

OBX|1|TX|53577-3^Reason for study^LN|1|Patient drug not
   responding|

OBX|2|CWE|51958-7^Transcript reference sequence
   [Identifier]^LN|1| NM_000106.5^NM_000106.5^RefSeq-T|

OBX|3|CNE|48018-6^Gene(s) assessed^LN|1|2625^CYP2D6^HGNC-
   Symb|

OBX|4|CWE|36908-2^Gene mutations tested^LN|1|
   16895^[NM_000106.5(CYP2D6):c.886C>T(p.Arg296Cys)][NM_00010
   6.5(CYP2D6):c.1457G>C (p.Ser486Thr)]^ClinVar-V|

OBX|5|CNE|51968-6^Discrete variation analysis overall
   interpretation^LN|1|LA6576-8^Positive^LN|

Technical details

OBX|6|CWE|62374-4^Human reference sequence assembly^LN|1|
   LA14029-6^GRCh37^LN|

OBX|7|NM|82115-7^dbSNP version^LN|1|147|

Complex Variant: Report Section 5

OBX|8|CWE|81260-2^Complex variant^LN|3a|
   16895^NM_000106.5(CYP2D6):c.[886C>T;457G>C]-
   Haplotype^ClinVar-V|

OBX|9|ST|81262-8^Complex variant HGVS name^LN|3a|
   c.[886C>T;457G>C]^c.[886C>T;457G>C]^HGVS.c|

OBX|10|CNE|81263-6^Complex variant type^LN|3a|
   LA26218-0^Haplotype^LN|
```

```
OBX|11|CWE|81259-4^Associated phenotype^LN|3a|
   C1837157^Debrisoquine, ultrarapid metabolism of^MedGen-
   Dis|

OBX|12|CNE|53034-5^Allelic state^LN|3a|LA6706-
   1^Heterozygous^LN|

Attributes of First Simple Variant within the complex variant

OBX|13|CNE|83005-9^Variant Category^LN|3a.1a|LA26801-3^Simple
   Variant^LN|

OBX|14|CNE|81252-9^Simple variant^LN|3a.1a|
   31934^NM_000106.5(CYP2D6):c.886C>T(p.Arg296Cys)^ClinVar-V|

Transcript Specification Variables

OBX|15|CWE|48018-6^Gene studied^LN|3a.1a|2625^CYP2D6^HGNC-
   Symb|

OBX|16|CWE|51958-7^Transcript RefSeq ID^LN|3a.1a|
   NM_000106.5^NM_000106.5^RefSeq-T|

OBX|17|CWE|41103-3^Transcript DNA Change (cHGVS)^LN|3a.1a|
   c.886C>T^c.886C>T^HGVS.c|

OBX|18|CWE|48005-3^Amino acid change p.HGVS^LN|3a.1a|
   p.Arg296Cys^p.Arg296Cys^HGVS.p|

OBX|19|CWE|48019-4^DNA change type^LN|3a.1a|
   LA6690-7^Substitution^LN|

OBX|20|CWE|48006-1^Amino acid change type^LN|3a.1a|
   LA6698-0^Missense^LN|

Genomic specification (HGVS code and VCF-like representation)

OBX|21|CWE|48013-7^Genomic reference sequence^LN|3a.1a|
   NG_032843.1:g.5578C>T^NG_032843.1:g.5578C>T^RefSeq-G|

OBX|22|CWE|81290-9^Genomic DNA change (gHGVS)^LN|3a.1a|
   NC_000022.10^NC_000022.10^HGVS.g|

OBX|23|ST|69547-8^Genomic ref allele^LN|3a.1a|A|

OBX|24|NR|81254-5^Genomic allele start-end^LN|3a.1a|
   42523943^42523943|

OBX|25|ST|69551-0^Genomic alt allele^LN|3a.1a|A|

Other variables

OBX|26|CNE|81255-2^dbSNP ID^LN|3a.1a|rs16947^rs16947^dbSNP|

OBX|27|CWE|48001-2^Cytogenetic (chromosome)
   location^LN|3a.1a| 22q13.2^22q13.2^Chrom-Loc|

OBX|28|CNE|48002-0^Genomic source class^LN|3a.1a|
   LA6683-2^Germline^LN|

Interpretations
```

```
OBX|29|CNE|69548-6^Genomic variant assessment^LN|3a.1a|
   LA9633-4^Present^LN|
```

Attributes of Second Discrete Genetic Variant

```
OBX|30|CNE|83005-9^Variant Category^LN|3a.1b|
   LA26801-3^Simple Variant^LN|
OBX|31|CNE|81252-9^Discrete genetic variant^LN|3a.1b|
   38485^NM_000106.5(CYP2D6):c.1457G>C(p.Ser486Thr)^ClinVar-
   V|
```

Transcript Specification Variables

```
OBX|32|CWE|48018-6^Gene studied^LN|3a.1b|38485^CYP2D6^HGNC-
   Symb|
OBX|33|CWE|51958-7^Transcript RefSeq ID^LN|3a.1b|
   NM_000106.5^NM_000106.5^RefSeq-T|
OBX|34|CWE|41103-3^Transcript DNA Change (cHGVS)^LN|3a.1b|
   c.1457G>C^c.1457G>C^HGVS.c|
OBX|35|CWE|48005-3^Amino acid change p.HGVS^LN|3a.1b|
   p.Ser486Thr^p.Ser486Thr^HGVS.p|
OBX|36|CWE|48019-4^DNA change type^LN|3a.1b|
   LA6690-7^Substitution^LN|
OBX|37|CWE|48006-1^Amino acid change type^LN|3a.1b|
   LA6698-0^Missense^LN|
```

Genomic specification (HGVS code and VCF-like representation)

```
OBX|38|CWE|48013-7^Genomic reference sequence^LN|3a.1b|
   NG_008376.3:g.8381G>C^NG_008376.3:g.8381G>C^RefSeq-G|
OBX|39|CWE|81290-9^Genomic DNA change (gHGVS)^LN|3a.1b|
   NC_000022.10^NC_000022.10^HGVS.g|
OBX|40|ST|69547-8^Genomic ref allele^LN|3a.1b|G|
OBX|41|NR|81254-5^Genomic allele start-end^LN|3a.1b|
   42522613^42522613|
OBX|42|ST|69551-0^Genomic alt allele^LN|3a.1b|G|
```

Other variables

```
OBX|43|CNE|81255-2^dbSNP
   ID^LN|3a.1b|rs1135840^rs1135840^dbSNP|
OBX|44|CWE|48001-2^Cytogenetic (chromosome)
   location^LN|3a.1b| 22q13.2^22q13.2^Chrom-Loc|
OBX|45|CNE|48002-0^Genomic source class^LN|3a.1b|
   LA6683-2^Germline^LN|
```

Interpretations

```
OBX|46|CNE|69548-6^Genomic variant assessment^LN|3a.1b|
   LA9633-4^Present^LN|
```

5.9.3 PHARMACOGENOMICS EXAMPLE MESSAGE

5.9.3.1 EXAMPLE OF PHARMACOGENOMICS STUDY OF 4 GENES WITH GUIDANCE ABOUT SELECTED DRUGS NESTED IN RESULTS FOR EACH GENE

This is an example of a pharmacogenomics report, showing a report that tests for several drug responses.

Example 10

```
OBR|1|Acme23469|Gen825750|Sample Orderable Test^Multiple CYP
   genes & VKORC1 gene Pharmacogenomic Analysis^LN|R|
   201608030830|201608091650|
Variables that Apply to Overall Study: Report Section 1
OBX|1|TX|53577-3^Reason for study^LN|1|Patient not responding
   to drug.|
OBX|2|CWE|51963-7^Medications assessed^RxT-Ingrd|1.a|
   4493^Fluoxetine^RxT-Ingrd|
OBX|3|CWE|51963-7^Medications assessed^RxT-Ingrd|1.b|
   83367^atorvastatin^RxT-Ingrd|
OBX|4|CWE|51963-7^Medications assessed^RxT-Ingrd|1.c|
   7258^Naproxen^RxT-Ingrd|
OBX|5|CWE|51963-7^Medications assessed^RxT-Ingrd|1.d|
   11289^Warfarin^RxT-Ingrd|
OBX|6|CWE|51963-7^Medications assessed^RxT-Ingrd|1.e|
   6754^Meperidine^RxT-Ingrd|
OBX|7|CNE|48018-6^Gene(s) assessed^LN|1.a|2623^CYP2C9^HGNC-
   Symb|
OBX|8|CNE|48018-6^Gene(s) assessed^LN|1.b|2637^CYP3A4^HGNC-
   Symb|
OBX|9|CNE|48018-6^Gene(s) assessed^LN|1.c|2638^CYP3A5^HGNC-
   Symb|
OBX|10|CNE|48018-6^Gene(s) assessed^LN|1.d|23663^VKORC1^HGNC-
   Symb|
OBX|11|CNE|48018-6^Gene(s) assessed^LN|1.e|2625^CYP2D6^HGNC-
   Symb|
OBX|12|CNE|48018-6^Gene(s) assessed^LN|1.f|2621^CYP2C19^HGNC-
   Symb|
OBX|13|FT|51969-4^Full narrative report^LN|1|Results – Genes
   CYP2C9, CYP2C9/VKORC1, and CYP3A4/CYP3A5 have abnormal
   drug responses. CYP2C9 is a Poor Metabolizer for
```

```
   Fluoxetine and Naproxen; CYP2C9/VKORC1 is a Poor
   Metabolizer with High Sensitivity for Warfarin;
   CYP3A4/CYP3A5 is an Increased Metabolizer for
   Atorvastatin. Genes CYP2C19 and CYP2D6 have normal
   responses. \.br\\.br\ Method - Genomic DNA was extracted
   from the submitted specimen and amplified by the
   polymerase chain reaction (PCR) using consensus
   oligonucleotide primers specific for the following genes:
   CYP2C9, VKORC1, CYP3A4, CYP3A5, Factor II, Factor V
   Leiden, and MTHFR; assay may also include CYP2C19 and/or
   CYP2D6. Clinically relevant genetic variants were detected
   after amplification using the Luminex 100/200 Instrument|

Pharmacogenomics: Report Section 4

Results for first gene in the study

OBX|14|CWE|48018-6^Gene(s) studied^LN|4a.a|2623^CYP2C9^HGNC-
   Symb|

OBX|15|CWE|48018-6^Gene(s) studied^LN|4a.b|23663^VKORC1^HGNC-
   Symb|

OBX|16|ST|47998-0^Genotype display name^LN|4a.a|*2/*5|

OBX|17|ST|47998-0^Genotype display name^LN|4a.b|*A/*A|

OBX|18|CWE|53040-2^Genetic variation's effect on drug
   metabolism interp^LN|4a|LA9657-3^Poor metabolizer^LN|

Medication usage implications panel

OBX|19|CWE|51963-7^Medication assessed^LN|4a.1a|
   11289^Warfarin^RxT-Ingrd|

OBX|20|CWE|82116-5^Medication usage suggestion
   [type]^LN|4a.1a| LA26425-1^Use Caution^LN|

OBX|21|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4a.1a|Consider 0.5-2 mg/day to achieve
   therapeutic INR using the warfarin product insert approved
   by the USFDA.|

Results for second gene in the study

OBX|22|CWE|48018-6^Gene(s) studied^LN|4b|2623^CYP2C9^HGNC-
   Symb|

OBX|23|ST|47998-0^Genotype display name^LN|4b|*2/*5|

OBX|24|CWE|53040-2^Genetic variation's effect on drug
   metabolism interp^LN|4b|LA9657-3^Poor metabolizer^LN|

Medication usage implications panel

OBX|25|CWE|51963-7^Medication assessed^LN|4b.1a|
   4493^Fluoxetine^RxT-Ingrd|
```

```
OBX|26|CWE|82116-5^Medication usage suggestion
   [type]^LN|4b.1a| LA26421-0^Consider Alternative
   Medication^LN|

OBX|27|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4b.1a|Monitor for inhibition of other
   drugs. Fluoxetine is a strong 2D6 inhibitor and is known
   to effect drugs which use the CYP 2D6 pathway.|

Medication usage implications panel

OBX|28|CWE|51963-7^Medication
   assessed^LN|4b.1b|7258^Naproxen^RxT-Ingrd|

OBX|29|CWE|82116-5^Medication usage suggestion
   [type]^LN|4b.1b| LA26424-4^Use Caution^LN|

OBX|30|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4b.1b|Consider Dosage reduction. Monitor
   for Gastrointestinal Bleeding.|

Results for third gene in the study

OBX|31|CWE|48018-6^Gene(s) studied^LN|4c.a|2637^CYP3A4^HGNC-
   Symb|

OBX|32|CWE|48018-6^Gene(s) studied^LN|4c.b|2638^CYP3A5^HGNC-
   Symb|

OBX|33|ST|47998-0^Genotype display name^LN|4c.a|*1/*1|

OBX|34|ST|47998-0^Genotype display name^LN|4c.b|*1/*1|

OBX|35|CWE|53040-2^Genetic variation's effect on drug
   metabolism interp^LN|4.3|LA25390-8^Rapid metabolizer^LN|

Medication usage implications panel

OBX|36|CWE|51963-7^Medication assessed^LN|
   4c.1a|83367^atorvastatin^RxT-Ingrd|

OBX|37|CWE|82116-5^Medication usage suggestion
   [type]^LN|4c.1a| LA26423-6^Increase Dose^LN|

OBX|38|TX|83010-9 ^Medication usage suggestion
   [narrative]^LN|4c.1a|Monitor for efficacy.|

Results for fourth gene in the study

OBX|38|CWE|48018-6^Gene(s) studied^LN|4d|2625^CYP2D6^HGNC-
   Symb|

OBX|40|ST|47998-0^Genotype display name^LN|4d|*1/*1|

OBX|41|CWE|53040-2^Genetic variation's effect on drug
   metabolism interp^LN|4d|LA25391-6^Normal metabolizer^LN|

Medication usage implications panel
```

```
OBX|42|CWE|51963-7^Medication assessed^LN|4d.1a|
   4493^Fluoxetine^RxT-Ingrd|
OBX|43|CWE|82116-5^Medication usage suggestion
   [type]^LN|4d.1a| LA26425-1^Normal Response Expected^LN|
OBX|44|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4d.1a|Monitor for inhibition of other
   drugs. Fluoxetine is a strong 2D6 inhibitor and is known
   to effect drugs which use the CYP 2D6 pathway.|
Results for fifth gene in the study
OBX|45|CWE|48018-6^Gene(s) studied^LN|4e|2621^CYP2C19^HGNC-
   Symb|
OBX|46|ST|47998-0^Genotype display name^LN|4e|*1/*1|
OBX|47|CWE|53040-2^Genetic variation's effect on drug
   metabolism interp^LN|4e|LA25391-6^Normal metabolizer^LN|
Medication usage implications panel
OBX|48|CWE|51963-7^Medication assessed^LN|4e.1a|
   6754^Meperidine^RxT-Ingrd|
OBX|49|CWE|82116-5^Medication usage suggestion
   [type]^LN|4e.1a|LA26425-1^Normal Response Expected^LN|
OBX|50|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4e.1a|Follow label dosing and
   administration information. No change needed.|
```

5.9.3.2 GLOSSARY FOR REPORTING HAPLOTYPES

This glossary would give the genetic details to the star alleles that the above example pharmacogenomics report tests for.

Example 11

```
Haplotype Definition Panel
OBX|1|CWE|48018-6^Gene(s) Studied^LN|5a|2623^CYP2C9^HGNC-
   Symb|
OBX|2|CWE|48008-7^Allele Name^LN|5a|^^^^^^^^*2|
Attributes of First Genetic Discrete Variant
OBX|3|CNE|81255-2^dbSNP ID^LN|5a.1a|8409^rs1799853^dbSNP|
OBX|4|ST|69551-0^Genomic alt allele^LN|5a.1a|T|
Haplotype Definition Panel
OBX|5|CWE|48018-6^Gene(s) Studied^LN|5b|2623^CYP2C9^HGNC-
   Symb|
```

```
OBX|6|CWE|48008-7^Allele Name^LN|5b|^^^^^^^^*5|
Attributes of Second Discrete Genetic Variant
OBX|7|CNE|81255-2^dbSNP ID^LN|5b.1a|227774^rs28371686^dbSNP|
OBX|8|ST|69551-0^Genomic alt allele^LN|5b.1a|G|
Haplotype Definition Panel
OBX|9|CWE|48018-6^Gene(s) Studied^LN|5c|23663^VKORC1^HGNC-
   Symb|
OBX|10|CWE|48008-7^Allele Name^LN|5c|^^^^^^^^*A|
Attributes of First Genetic Discrete Variant
OBX|11|CNE|81255-2^dbSNP ID^LN|5c.1a|2211^rs9923231^dbSNP|
OBX|12|ST|69551-0^Genomic alt allele^LN|5c.1a|T|
Haplotype Definition Panel
OBX|13|CWE|48018-6^Gene(s) Studied^LN|5d|2637^CYP3A4^HGNC-
   Symb|
OBX|14|CWE|48008-7^Allele Name^LN|5d|*1B|
Attributes of First Discrete Genetic Variant
OBX|15|CNE|81255-2^dbSNP ID^LN|5d.1a|31955^rs2740574^dbSNP|
OBX|16|ST|69551-0^Genomic alt allele^LN|5d.1a|T|
Haplotype Definition Panel
OBX|17|CWE|48018-6^Gene(s) Studied^LN|5e|2638^CYP3A5^HGNC-
   Symb|
OBX|18|CWE|48008-7^Allele Name^LN|5e|^^^^^^^^*1D|
Attributes of First Discrete Genetic Variant
OBX|19|CNE|81255-2^dbSNP ID^LN|5e.1a|15524^rs15524^dbSNP|
OBX|20|ST|69551-0^Genomic alt allele^LN|5e.1a|T|
```

5.9.3.3 PHARMACOGENOMICS EXAMPLE

This example illustrates a pharmacogenomics report testing for Thiopurine S-Methyltransferase (TPMT) deficiency.

Example 12

```
OBR|1|Acme23469|Gen825750|80738-8^TPMT gene targeted mutation
   analysis^LN|R|201608030830|201608091650|
Variables that Apply to Overall Study: Report Section 1
OBX|1|TX|53577-3^Reason for study^LN|1|Patient not responding
   to drug.|
```

```
OBX|2|CWE|51963-7^Medications assessed^RxT-Ingrd|1.a|
   103^Mercaptopurine^RxT-Ingrd|

OBX|3|CWE|51963-7^Medications assessed^RxT-Ingrd|1.b|
   1256^Azathriopine^RxT-Ingrd|

OBX|4|CWE|51963-7^Medications assessed^RxT-Ingrd|1.c|
   10485^Thioguanine^RxT-Ingrd|

OBX|6|CNE|48018-6^Gene(s) assessed^LN|1|12014^TPMT^HGNC-Symb|

OBX|7|FT|51969-4^Full narrative report^LN|1|Results - This
   individual most likely has intermediate TPMT activity.
   Individuals with intermediate TPMT activity can be treated
   with thiopurine drugs with fewer side effects by reducing
   the initial dose. Subsequent dose adjustments should be
   based on the degree of myelosuppression and according to
   published guidelines. \.br\\.br\ Method - Direct analysis
   of the following TPMT (Genbank # NM_000367.2, build hg19)
   alleles is performed by a polymerase chain reaction (PCR)-
   based 5'-nuclease assay using fluorescently labeled
   detection probes: *2 (c.238G>C), *3A (c.460G>A and
   c.719A>G), *3B (c.460G>A), *3C (c.719A>G,) *4
   (c.626-1G>A), *5 (c.146T>C), *8 (c.644G>A), and *12
   (c.374C>T)|

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Results for first gene in the study

OBX|8|CNE|48018-6^Gene(s) assessed^LN|4a|12014^TPMT^HGNC-
   Symb|

OBX|9|CNE|47998-0^Genotype display name^LN|4a|^^^^^^^^*1/*3A|

OBX|10|CWE|53040-2^Genetic variation's effect on drug
   metabolism interp^LN|4a|LA10317-8^Intermediate
   metaboliser^LN|

Medication usage implications panel

OBX|11|CWE|51963-7^Medications assessed^RxT-Ingrd|4a.1a|
   103^Mercaptopurine^RxT-Ingrd|

OBX|12|CWE|82116-5^Medication usage suggestion
   [type]^LN|4a.1a| LA26422-8^Decrease dose and titrate to
   response^LN|

OBX|13|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4a.1a|Start at 30-70% of the normal
   starting dose - Adjust dose based on myelosuppression and
   disease-specific guidelines - Allow 2-4 weeks to reach
   steady state after each dose adjustment - Eventually, up
   to 65% of patients with intermediate TPMT function may
   tolerate full doses of mercaptopurine.|
```

```
Medication usage implications panel
OBX|14|CWE|51963-7^Medications assessed^RxT-Ingrd|4a.1b|
   1256^Azathriopine^RxT-Ingrd|
OBX|15|CWE|82116-5^Medication usage suggestion
   [type]^LN|4a.1b| LA26422-8^Decrease dose and titrate to
   response^LN|
OBX|16|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4a.1b|Consider starting at 30-70% of target
   dose if "full doses" are to be used - Titrate doses based
   on tolerance - Allow 2-4 weeks to reach steady state after
   each dose adjustment.|
Medication usage implications panel
OBX|17|CWE|51963-7^Medications assessed^RxT-Ingrd|4a.1c|
   10485^Thioguanine^RxT-Ingrd|
OBX|18|CWE|82116-5^Medication usage suggestion
   [type]^LN|4a.1c| LA26422-8^Decrease dose and titrate to
   response^LN|
OBX|19|TX|83010-9^Medication usage suggestion
   [narrative]^LN|4a.1c|Start at 30-50% of the normal
   starting dose - Adjust dose based on myelosuppression and
   disease-specific guidelines - Allow 2-4 weeks to reach
   steady state after each dose adjustment - Eventually, up
   to 65% of patients with intermediate TPMT function may
   tolerate full doses of thioguanine.|
```

5.9.3.4 GLOSSARY FOR REPORTING HAPLOTYPES

This glossary would give the genetic details to the star alleles that the above example pharmacogenomics report tests for.

Example 13

```
Haplotype Definition Panel
OBX|1|CWE|48018-6^Gene(s) Studied^LN|5b|12014^TPMT^HGNC-Symb|
OBX|2|CWE|48008-7^Allele Name^LN|5b|^^^^^^^^*3a|
Attributes of First Genetic Discrete Variant
OBX|3|CNE|81255-2^dbSNP ID^LN|5b.1a|1800460^rs1800460^dbSNP|
OBX|4|ST|69551-0^Genomic alt allele^LN|5a.1a|A|
Attributes of Second Genetic Discrete Variant
OBX|5|CNE|81255-2^dbSNP ID^LN|5b.1b|1142345^rs1142345^dbSNP|
OBX|6|ST|69551-0^Genomic alt allele^LN|5b.1b|G|
```

6 CONFORMANCE TO THIS GUIDE

6.1 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 *HL7 Laboratory US Realm Value Set Companion Guide, Release 1.1, September 2015.*

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

6.2 Profiles and Profile Components

This Implementation Guide defines profile components that are then combined as profiles to define specific conformance requirements. Profile components and profiles can be specific to a very narrow set of requirements for a use case, or broadly defined for use in all US Realm Lab use cases. This latter set is referred to as "domain" profile components in this guide.

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.
- LRI-PH-*xxx* - the component declares behaviors and constraints that apply specifically to reporting to public health
- LRI-NB-*xxx* – the component declares behaviors and constraints that apply specifically to ANY lab testing performed on newborns (up to 28 days old), except dried bloodspot (LRI_NDBS) testing
- LRI-NDBS-*xxx* – the component declares behaviors and constraint that apply specifically to newborn dried blood spot results.

The profile components must be combined to create a valid profile for a particular transaction by populating MSH-21 (Message Profile Identifier) with a valid set of identifiers. Multiple profiles or profile components can be present in MSH-21 provided the combined requirements do not conflict with each other. Additional definitions and guidance for MSH-21 can be found in Section 8.1 MSH – Message Header Segment.

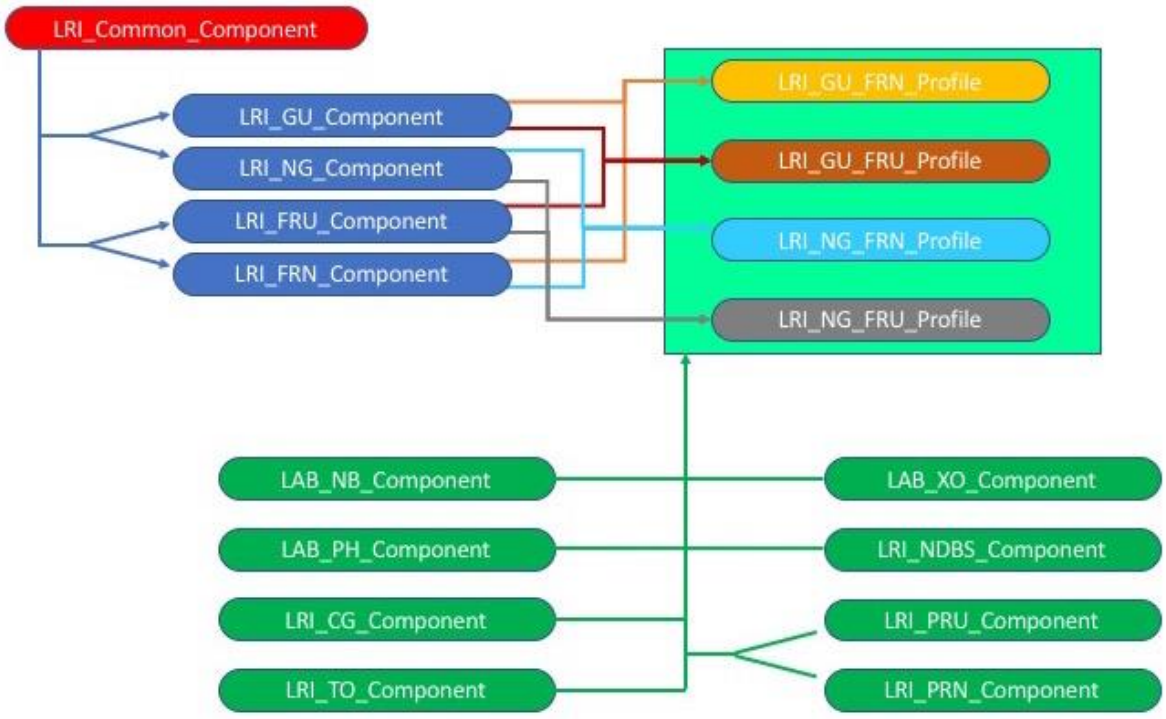


Figure 6-1. Response Profile and Component Architecture

Legend:

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

As of this version a valid profile consists of a minimum of three profile components:

1. The LRI_Common_Component (red) – this component is always present (6.3.1)
2. The LRI_GU_Component **OR** the LRI_NG_Component (dark blue) – at least one of these (6.3.2, 6.3.3)
3. The LAB_FRU_Component **OR** the LAB_FRN_Component (dark blue) – at least one of these (6.3.4, 6.3.5)

Additional components can be provided to further define the message structure and use. This guide defines eight such components (green):

1. The LAB_PRU_Component **OR** the LAB_PRN_Component (6.3.6, 6.3.7)
2. LAB_NB_Component – Newborn (6.3.8)
3. LAB_TO_Component – Time Offset (6.3.9)
4. LAB_XO_Component – Exclusions (6.3.10)
5. LAB_PH_Component – Public Health Reporting (6.3.11)

6. LRI_NDBS_Component – Newborn Dried Blood Spot Screening Results (6.3.12)
7. LRI_CG_Component – Clinical Genomics Results Reporting (6.3.13)

As illustrated above, users must choose which of the four basic profile components (dark blue) they will use, and any optional profile components (green). These can be referenced through pre-coordinated profiles (light green box) as further defined in Section 6.4 Result Profiles.

Additional definitions and guidance for MSH-21 can be found in Section 8.1 MSH – Message Header Segment.

6.3 Result Profile Components

The result profile components that can be assembled into profiles are:

6.3.1 LRI_COMMON_COMPONENT – ID: 2.16.840.1.113883.9.16

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

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

6.3.2 LRI_GU_COMPONENT – ID: 2.16.840.1.113883.9.12

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

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List
- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- ORC-12 – Ordering Provider
- OBR-2 – Placer Order Number
- OBR-3 – Filler Order Number
- OBR-16 – Ordering Provider
- OBR-28 – Result Copies To
- OBR-29 – Parent
- OBX-16 – Responsible Observer
- OBX-23 – Performing Organization Name
- OBX-25 – Performing Organization Medical Director
- SPM-2 – Specimen ID

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

6.3.3 LRI_NG_COMPONENT – ID: 2.16.840.1.113883.9.13

This profile component indicates that the identification method has been negotiated between the trading partners where none or some may use ISO OIDs according to Section 1.4.3 Use of ISO Object Identifier (OID) while others use any of the identification methods allowed through the base standard. Consequently, these identifiers are not guaranteed to be globally unique.

- MSH-3 – Sending Application
- MSH-4 – Sending Facility
- MSH-6 – Receiving Facility
- PID-3 – Patient Identifier List
- ORC-2 – Placer Order Number
- ORC-3 – Filler Order Number
- ORC-4 – Placer Group Number
- ORC-12 – Ordering Provider
- OBR-2 – Placer Order Number
- OBR-3 – Filler Order Number
- OBR-16 – Ordering Provider
- OBR-28 – Result Copies To
- OBR-29 – Parent
- OBX-16 – Responsible Observer
- OBX-23 – Performing Organization Name
- OBX-25 – Performing Organization Medical Director
- SPM-2 – Specimen ID

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

6.3.4 LAB_FRU_COMPONENT (UNIQUE FILLER NUMBER) – ID: 2.16.840.1.113883.9.83

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

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

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

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

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

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

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

6.3.8 LAB_NB_COMPONENT – ID: 2.16.840.1.113883.9.24

This profile component indicates that the data type TS_02 or, when TO_Component is also invoked, TS_03 is used in PID-7 (Date/Time of Birth) to support lab tests that require this precision in the Date/Time of Birth data element.

Note: For the purposes of this guide Newborn is defined as up to 28 days, see Section 16 Glossary.

6.3.9 LAB_TO_COMPONENT – ID: 2.16.840.1.113883.9.22

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

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

Listed datatype in field	becomes	datatype when TO is applied:
TS_02		TS_03
TS_06		TS_07
TS_08		TS_09
TS_10		TS_11
TS_12		TS_13

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

- MSH-7 – Date/Time of Message
- PID-7 – Date/Time of Birth
- ORC-9 – Date/Time of Transaction
- OBR-7 – Observation Date/Time
- OBR-8 – Observation End Date/Time

- OBR-22 – Results Rpt/Status Chng – Date/Time
- TQ1-7 – Start Date/Time
- TQ1-8 – End Date/Time
- OBX-5 – Observation Value (when OBX-2 is “TM”)
- OBX-14 – Date/Time of the Observation
- OBX-19 – Date/Time of the Analysis
- SPM-17 – Specimen Collection Date/Time
- IN1-18 – Insured’s Date of Birth

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

6.3.10 LAB_XO_COMPONENT – ID: 2.16.840.1.113883.9.23

One of the basic premises of this guide is to enable senders to compose transactions that may satisfy multiple purposes, e.g., multiple Implementation Guides that share the same required fields and vocabulary. They therefore may populate any of the fields/components marked ‘O’ (optional). At the same time this Implementation Guide wants to expressly reinforce that if data is sent in optional fields/segments, the receiver can completely ignore those. Therefore, the usage code ‘X’ (Not Supported) 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 according to the definition of ‘X’ per the base standard "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’ are now considered to be marked with an ‘X’. Its use yields, in combination with the other profile components, a fully implementable profile in accordance with Chapter 2B. Note though that this profile component is strictly voluntary and its use cannot be mandated by either trading partner to enable a successful results transaction.

6.3.11 LRI_PH_COMPONENT – ID: 2.16.840.1.113883.9.195.3.5

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

Note: The LRI_PH_Component gives no choice on the minimally required components: it may only be used with the LRI_Common_Component (2.16.840.1.113883.9.16), the GU_component (2.16.840.1.113883.9.12) and FRU_Component (2.16.840.1.113883.9.83) or by using the precoordianted LRI_GU_FRU_Component (2.16.840.1.113883.9.195.3.1).

6.3.12 LRI_NDBS_COMPONENT – ID: 2.16.840.1.113883.9.195.3.6

This profile component is used to convey results specific to newborn dried blood spot (NDBS) screening. It can be used with any of the base profiles.

6.3.13 LRI_CG_COMPONENT – ID: 2.16.840.1.113883.9.195.3.8

This profile component is used to convey results specific to clinical genomics result reporting. It can be used with any of the base profiles.

6.4 Result Profiles (Pre-Coordinated Components)

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

6.4.1 LRI_GU_FRU_PROFILE – ID: 2.16.840.1.113883.9.195.3.1

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_GU_Component and the LAB_FRU_Component as defined within this Guide.

6.4.2 LRI_GU_FRN_PROFILE – ID: 2.16.840.1.113883.9.195.3.2

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_GU_Component, and the LAB_FRN_Component as defined within this Guide.

6.4.3 LRI_NG_FRU_PROFILE – ID: 2.16.840.1.113883.9.195.3.3

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_NG_Component, and the LAB_FRU_Component as defined within this Guide.

6.4.4 LRI_NG_FRN_PROFILE – ID: 2.16.840.1.113883.9.195.3.4

This profile component is used to identify an ORU that is conformant to the combined constraints of the LRI_Common_Component, the LRI_NG_Component, and the LAB_FRN_Component as defined within this Guide.

Note that the PRN, PRU, TO, XO and NB profile components are not included in the pre-coordinated profiles; rather they should also be declared in MSH-21 when applicable, e.g., the LAB_NB_Component would be included to support the level of precision a Newborn use case requires on time-related data elements.

6.5 Response Components

6.5.1 LRI_ACCEPT_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.9

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

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

6.5.2 LRI_APPLICATION_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.195.3.10

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

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

6.5.3 LRI_GU_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.21

This profile component is used to identify an ACK that is constrained for the profiles defined within this Guide in response to the ORU message where MSH-21.3 contains '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile), OR '2.16.840.1.113883.9.195.3.2' (LRI_GU_FRN_Profile), OR '2.16.840.1.113883.9.12' (LRI_GU_Component).

6.5.4 LRI_NG_ACKNOWLEDGEMENT_COMPONENT – ID: 2.16.840.1.113883.9.25

This profile component is used to identify an ACK that is constrained for the profiles defined within this Guide in response to the ORU message where MSH-21 contains '2.16.840.1.113883.9.195.3.3' (LRI_NG_FRU_Profile), **OR** '2.16.840.1.113883.9.195.3.4' (LRI_NG_FRN_Profile), **OR** '2.16.840.1.113883.9.13' (LRI_NG_Component).

6.6 Response Profiles (Pre-Coordinated Components)

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

6.6.1 LRI_ACCEPT_GU_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.11

This profile pre-coordinates the use of the LRI_Accept_Acknowledgement_Component and LRI_GU_Acknowledgement_Component.

6.6.2 LRI_ACCEPT_NG_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.12

This profile pre-coordinates the use of the LRI_Accept_Acknowledgement_Component and Lab_NG_Acknowledgement_Component.

~~**6.6.3 LRI_GU_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.28**~~

~~This profile pre-coordinates the use of the LRI_Acknowledgement_Component and LRI_GU_Acknowledgement_Component.~~

~~**6.6.4 LRI_NG_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.27**~~

~~This profile pre-coordinates the use of the LRI_Acknowledgement_Component and LRI_NG_Acknowledgement_Component.~~

6.6.5 LRI_APPLICATION_GU_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.13

This profile pre-coordinates the use of the LRI_ Application_Acknowledgement_Component and LRI_GU_Acknowledgement_Component.

6.6.6 LRI_APPLICATION_NG_RESPONSE_PROFILE – ID: 2.16.840.1.113883.9.14

This profile pre-coordinates the use of the LRI_Application_Acknowledgement_Component and Lab_NG_Acknowledgement_Component.

7 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 optional with a cardinality of up to 1, while this Implementation Guide defines the segment in the Usage column as R thus a cardinality of [1..1].

7.1 ORU^R01^ORU_R01

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

TABLE 7-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX

Segment	Name	Usage	Cardinality	Description
MSH	Message Header	R	[1..1]	The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
[{SFT}]	Software Segment	Varies		LRI_PH_Component Usage: 'R', Cardinality: [1..*]. Usage for all other components: 'O'
{	***PATIENT_RESULT Begin***	R	[1..1]	
[	***PATIENT Begin***	R	[1..1]	
PID	Patient Identification	R	[1..1]	The patient identification (PID) segment is used to provide basic demographics regarding the subject of the testing. The subject shall be a person except when LRI_PH_Component is invoked.
[PD1]	Additional Demographics	O		
[{NTE}]	Notes and Comments for PID	Varies	[0..*]	LRI_PH_Component Usage: 'RE' All other profiles Usage: 'O'
[{NK1}]	Next of Kin/Associated Parties	Varies	Varies	LRI_PH_Component Usage: 'RE'; Cardinality: [0..*] LRI_NDBS_Component Usage: 'R'; Cardinality: [1..*] Usage for all other components: 'O'
[	***VISIT Begin***	Varies	Varies	LRI_NDBS_Component Usage: 'X' LRI_PH_Component Usage: 'RE'; Cardinality: [0..1] Usage for all other components: 'O'

TABLE 7-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
PV1	Patient Visit	R	[1..1]	HL7 requires that the patient visit (PV1) segment be present if the VISIT group is present.
[PV2]	Patient Visit – Additional Information	O		
]	***VISIT End***			
]	***PATIENT End***			
{	***ORDER_OBSERVATION Begin***	R	[1..*]	The ORDER_OBSERVATION is required and can repeat.
[ORC]	Order Common	R	[1..1]	The common order (ORC) segment identifies basic information about the order for testing of the specimen. This segment includes identifiers of the order, who placed the order, when it was placed, what action to take regarding the order, etc.
OBR	Observations Request	R	[1..1]	The observation request (OBR) segment is used to capture information about one test being performed on the specimen. Most importantly, the OBR identifies the type of testing to be performed on the specimen, and ties that information to the order for the testing.
[{NTE}]	Notes and Comments for OBR	RE	[0..*]	
[{	***TIMING_QTY Begin***	RE	[0..1]	
TQ1	Timing/Quantity	R	[1..1]	
[{TQ2}]	Timing/Quantity Order Sequence	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
}]	***TIMING_QTY End***			
[CTD]	Contact Data	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
[{	***OBSERVATION Begin***	C(R/O)	[0..*]	Condition Predicate: If OBR-25 (Result Status) is valued 'A', 'C', 'F', 'P', or 'M'. Multiple Observation groups, each containing a single OBX and a potentially repeating NTE, may be associated with a single order.
OBX	Observation related to OBR	R	[1..1]	The observation/result (OBX) segment contains information regarding a single observation (analyte) result. This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc.
[{NTE}]	Notes and Comments	RE	[0..*]	
}]	***OBSERVATION End***			
[{FT1}]	Financial Transaction	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'

TABLE 7-1. ORU^R01^ORU_R01 ABSTRACT MESSAGE SYNTAX				
Segment	Name	Usage	Cardinality	Description
{[CTI]}	Clinical Trial Identification	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
[{	***SPECIMEN Begin***	Varies	[0..*]	LRI_PH_Component: C(R/RE), Condition Predicate: If OBR-29 (Parent) is valued. Usage for all other components: 'RE' The specimen group is required if known in the ORU and is used to carry specimen information that is no longer contained in the OBR segment. Each specimen group documents a single sample.
SPM	Specimen Information related to OBR	R	[1..1]	The specimen information (SPM) segment describes the characteristics of a single sample. The SPM segment carries information regarding the type of specimen, where and how it was collected, and some basic characteristics of the specimen.
[{OBX}]	Observation related to Specimen	O	[0..*]	
}]	***SPECIMEN End***			
}	***ORDER_ OBSERVATION End***			
}	***PATIENT_RESULT End***			
[DSC]	Continuation Pointer	X		Excluded for this Implementation Guide, see Section 1.3.1.

Usage Notes

LRI_PH_Component

SFT Segment – The first repeat (i.e., the Laboratory Result Sender actor that generated the message) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. Just being "HL7 aware" is not enough to put in SFT. They actually have to manipulate the data in the transaction beyond routing.

NTE Segment – Notes and comments (NTE) segment should contain notes or comments pertaining to the information in the segment immediately preceding it; it should not contain results.

NK1 Segment – The next of kin (NK1) segment can be used to document the patient's next of kin, employer, guardian, etc. Particular jurisdictions may require the NK1 segment to contain parent/guardian information when reporting lead testing results for children. When reporting results of animal testing (for example testing animals for rabies) the NK1 segment can be used to identify the owner of the animal.

LRI_NDBS_Component

NK1 Segment – This segment is required for the mother (NK1-3.1 = 'MTH'). Additional repeats for information about the father (NK1-3.1 = 'FTH'), the caregiver in a foster situation (NK1-3.1 = 'CGV') or the guardian in the case of adoption (NK1-3.1 = 'GRD') are supported in some jurisdictions.

LRI_CG_Component

SPM Segment/Group – The use of this group is encouraged for non-germline studies, but is typically not essential for germline studies. The usage therefore kept at RE for the Specimen Group to encourage such inclusion where specimen data is available.

7.2 Acknowledgements

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

The diagram in Figure 7-1 summarizes the flow of Acknowledgements from the results sender (LIS) to the results receiver (e.g., EHR-S) and back through the different gateways.

The numbers for R = Result indicate the step in the respective flow. For example the step marked R2 indicates that for the flow of the Result message – the solid green arrow labeled ORU and its related Accept ACK, the dotted black arrow between Gateway 2 and Gateway 1 – would be step 2.

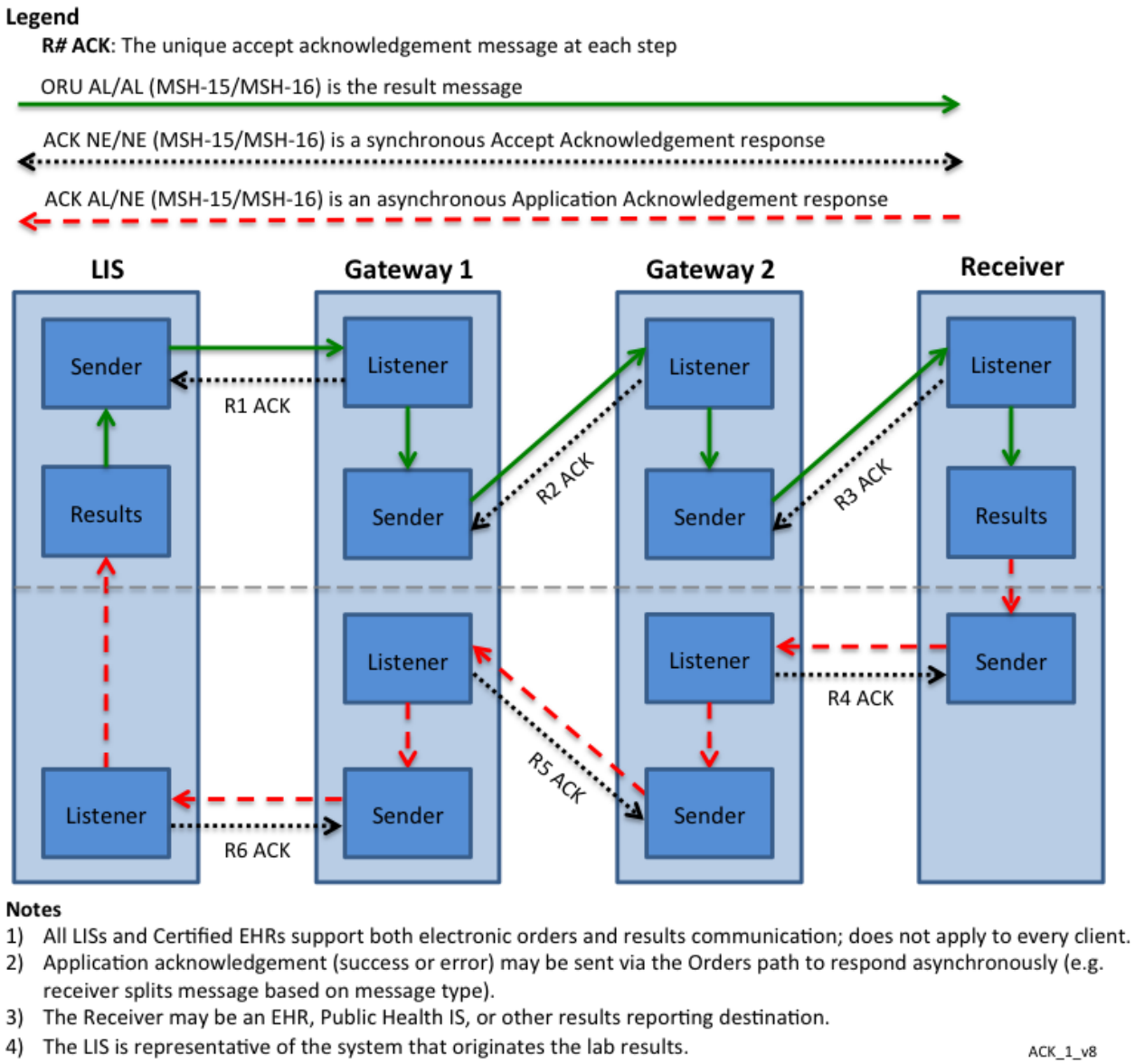


Figure 7-1. LRI Message and Guaranteed Delivery Notification Flow

7.2.1 ACKNOWLEDGEMENT CHOREOGRAPHY APPLIED

The acknowledgement choreography starts with the initial Results message ORU^R01^ORU_R01 indicating in MSH-15 and MSH-16 how the receiving system is to respond.

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

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

TABLE 7-2. ORU ACKNOWLEDGEMENT CODES

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

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

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

TABLE 7-3. ORU ACKNOWLEDGEMENT CODES

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

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

All other values and combinations are NOT allowed.

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

7.2.2 ACK^R01^ACK: RESULTS MESSAGE – ACCEPT ACKNOWLEDGEMENT

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

1: Acknowledgement Code. Note that due to the ACK^R01^ACK message being used for both the Accept Level and Application Level acknowledgements, the only way to distinguish whether this is an Accept Level message is the value of MSA-1.

TABLE 7-4. ACK^R01^ACK ABSTRACT MESSAGE SYNTAX

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

Usage Notes

LRI_PH_Component

SFT Segment – The first repeat (i.e., the Laboratory Result Receiver actor that generated the message) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. Just being "HL7 aware" is not enough to put in SFT. They actually have to manipulate the data in the transaction beyond routing.

This message is only used between nodes that the messages travel along per Figure 7-1. The message is sent only to the immediately preceding sender. This applies to intermediaries between a Laboratory Result Sender and an EHR-S such as HIEs and interface engines, as well as to the final EHR-S destination.

To avoid this acknowledgement from generating a response back to the originating node of the Accept Level Acknowledgement message and effectively start a never-ending series or accept acknowledgement messages between two nodes, the originating node must use the Accept Acknowledgement message (ACK^R01^ACK) with the following code combinations:

TABLE 7-5. ACCEPT ACKNOWLEDGEMENT CODES

Requirement	MSH-15	MSH-16
SHALL support	NE	NE

All other values and combinations are NOT allowed.

7.2.3 ACK^R01^ACK: RESULTS MESSAGE – APPLICATION ACKNOWLEDGEMENT

Based on the actual values in the ORU^R01^ORU_R01 MSH-15 and MSH-16 values, the receiver shall send an Application Level Acknowledgement message using the following message syntax and must use the appropriate response profiles or component in MSH-21, while using either “AA”, “AE”, or “AR in MSA-1: Acknowledgement Code. Note that due to the ACK^R01^ACK message being used for both the Accept Level and Application Level acknowledgements, the only way to distinguish whether this is an Accept Level message is the value of MSA-1.

TABLE 7-3. ACK^R01^ACK ABSTRACT MESSAGE SYNTAX

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

Usage Notes

LRI_PH_Component

SFT Segment – The first repeat (i.e., the Laboratory Result Sender actor that generated the message) is required. Any other application that transforms the message must add an SFT segment for that application. Other applications that route or act as a conduit may add an SFT but are not required to do so. Just being "HL7 aware" is not enough to put in SFT. They actually have to manipulate the data in the transaction beyond routing.

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

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

TABLE 7-6. APPLICATION ACKNOWLEDGMENT CODES

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

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

All other values and combinations are NOT allowed.

7.3 HL7 Batch Protocol

Transmission of LRI_PH_Component messages using batch protocol is optional and not a requirement. Details such as the frequency of batch transmissions are left to specific implementations. For further guidance regarding the Batch Protocol refer to Section 2.10.3 HL7 batch protocol in Chapter 2 of the HL7 v2.5.1 Standard.

When using Acknowledgements we strongly encourage the use of enhanced mode to be consistent with individual transactions and as indicated in section 3.6.2, but leave this for now to the implementation trading partners to resolve.

TABLE 7-7. BATCH PROTOCOL

Segment	Name	Usage	Cardinality	Description/Comments
[FHS]	File Header Segment	R	[1..1]	
{	Batch Begin	R	[1..1]	
[BHS]	Batch Header Segment	R	[1..1]	
{[	Message Begin	RE	[0..*]	A batch containing zero HL7 messages may be sent to meet a requirement for periodic submission of batches when there are no messages to send.
MSH	Message Header Segment	R	[1..1]	
...				
[]}	Message End			
[BTS]	Batch trailer Segment	R	[1..1]	
}	Batch End			
[FTS]	File Trailer Segment	R	[1..1]	

8 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, e.g., constraint statements will be required to use the GU or NG profile components, and agreement about which data type flavors to use (e.g., CWE_03 or CWE_01) needs to be reached.

8.1 MSH – Message Header Segment

TABLE 8-1. MESSAGE HEADER SEGMENT (MSH)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Field Separator	ST	R	[1..1]		
2	Encoding Characters	ST	R	[1..1]		
3	Sending Application	Varies	Varies	Varies	HL70361_USL	LRI_PH_Component: Usage: 'R'; Cardinality: [1..1] GU data type: HD_01 All other profiles: Usage: RE'; Cardinality: [0..1] GU data type: HD_01 NG data type: HD_02
4	Sending Facility	Varies	R	[1..1]	HL70362_USL	LRI_PH_Component: Usage: 'R'; Cardinality: [1..1] GU data type: HD_01 All other profiles: Usage: RE'; Cardinality: [0..1] GU data type: HD_01 NG data type: HD_02
5	Receiving Application	Varies	Varies	Varies		GU data type: HD_01 NG data type: HD_02 LRI_NDBS_Component Usage: 'RE'; Cardinality: [0..1] LRI_PH_Component Usage: 'R' Usage for all other components: 'O'

TABLE 8-1. MESSAGE HEADER SEGMENT (MSH)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
6	Receiving Facility	Varies	Varies	Varies	HL70362_USL	GU data type: HD_01 NG data type: HD_02 LRI_NDBS_Component and LRI_PH_Component Usage: 'R'; Cardinality: [1..1] Usage for all other components: 'RE'; Cardinality: [0..1] This facility originates any related acknowledgment message.
7	Date/Time Of Message	Varies	R	[1..1]		LAB_TO_Component Data Type: 'TS_11' All other profiles Data Type: 'TS_10' 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, except as otherwise indicated through the use of the LAB_TO_Component profile as defined in Section 6.3.9 in MSH-21 (Message Profile Identifier).
8	Security		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
9	Message Type	MSG_01	R	[1..1]		
10	Message Control ID	ST	R	[1..1]		String that identifies the message instance from the sending application. Example formats for message control IDs include GUID, timestamp plus sequence number, OID plus sequence number or sequence number. The important point is that care must be taken to ensure that the message control id is unique within the system originating the message. The combination of MSH 10, MSH 3 (sending Application) and MSH 4 (Sending Facility) can be used to make this message globally unique.
11	Processing ID	PT_01	R	[1..1]		
12	Version ID	VID_01	R	[1..1]		HL7 version number used to interpret format and content of the message. Note that receivers must examine MSH-21 (Message Profile Identifier) to understand which message profile the message instance conforms with.
13	Sequence Number		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
14	Continuation Pointer		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
15	Accept Acknowledgment Type	ID	R	[1..1]	HL70155_USL	The value set constraints are described in Sections 7.2.1 for the ORU, 7.2.2 for the Accept Acknowledgement, and 7.2.3 for the Application Acknowledgment.

TABLE 8-1. MESSAGE HEADER SEGMENT (MSH)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
16	Application Acknowledgment Type	ID	R	[1..1]	HL70155_USL	The value set constraints are described in Sections 7.2.1 for the ORU, 7.2.2 for the Accept Acknowledgement, and 7.2.3 for the Application Acknowledgment.
17	Country Code		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
18	Character Set		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
19	Principal Language Of Message		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
20	Alternate Character Set Handling Scheme		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
21	Message Profile Identifier	EI_01	R	[1..*]		The sender asserts that the message conforms to a given profile and/or valid combination of components.

Usage Notes

LRI_PH_Component

MSH-4 - Sending Facility – For laboratories originating messages, the CLIA identifier is allowed for the Universal ID component of the HD_03 data type. Non-laboratory facilities taking on the Laboratory Result Sender actor role will use an OID for this field.

8.1.1 LRI RESULT PROFILE COMBINATIONS

The MSH-21 (Message Profile Identifier) field shall identify exclusively one lab result interface profile and shall not be populated with conflicting LRI profiles or LRI profile components. Additional compatible profiles or components can be present in MSH-21; for example, if an LRI profile or profile component is further constrained.

The sequence of the elements in MSH-21 is not important and cannot be relied on. To improve readability, implementers are encouraged to start with the base lab result ID followed by additional profiles and/or profile component IDs that add constraints.

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

TABLE 8-2. MSH 21 PROFILE COMBINATIONS			
LRI Profile	Pre-Coordinated OID	Profile Component OIDs	Component Name
LRI_GU_FRU_Profile	2.16.840.1.113883.9.195.3.1	2.16.840.1.113883.9.16 2.16.840.1.113883.9.12 2.16.840.1.113883.9.83	LRI_Common_Component LRI_GU_Component LAB_FRU_Component
LRI_GU_FRN_Profile	2.16.840.1.113883.9.195.3.2	2.16.840.1.113883.9.16 2.16.840.1.113883.9.12 2.16.840.1.113883.9.84	LRI_Common_Component LRI_GU_Component LAB_FRN_Component
LRI_NG_FRU_Profile	2.16.840.1.113883.9.195.3.3	2.16.840.1.113883.9.16 2.16.840.1.113883.9.13 2.16.840.1.113883.9.83	LRI_Common_Component LRI_NG_Component LAB_FRU_Component
LRI_NG_FRN_Profile	2.16.840.1.113883.9.195.3.4	2.16.840.1.113883.9.16 2.16.840.1.113883.9.13 2.16.840.1.113883.9.84	LRI_Common_Component LRI_NG_Component LAB_FRN_Component

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

- LAB_TO_Component – 2.16.840.1.113883.9.22
- LAB_XO_Component – 2.16.840.1.113883.9.23
- LAB_NB_Component – 2.16.840.1.113883.9.24
- LAB_PRU_Component – 2.16.840.1.113883.9.82
- LAB_PRN_Component – 2.16.840.1.113883.9.81
- LRI_NDBS_Component – 2.16.840.1.113883.9.195.3.6
- LRI_CG_Component - 2.16.840.1.113883.9.195.3.8

The following additional profile component identifier may be specified only with the LRI_GU_FRU Profile:

- LRI_PH_Component – 2.16.840.1.113883.9.195.3.5

Example: LRI_NG_FRN_Profile Using Component OIDs

```
MSH...|||||LRI_Common_Component^^2.16.840.1.113883.9.16^ISO~LRI_NG_Component^^2.16.
   840.1.113883.9.13^ISO~LAB_FRN_Component^^2.16.840.1.113883.9.84^ISO
```

Example: LRI_NG_FRN_Profile Pre-Coordinated Profile OID

```
MSH...|||||LRI_NG_FRN_Profile^^2.16.840.1.113883.9.195.3.4^ISO
```

Example: LRI_NG_FRN_Profile using Pre-Coordinated Profile OID and the LAB_NB_Component

```
MSH...|||||LRI_NG_FRN_Profile^^2.16.840.1.113883.9.195.3.4^ISO~LAB_NB_Component^^2.
   16.840.1.113883.9.24^ISO
```

Conformance Statements: LRI_Common_Component

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

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

LRI-72: MSH-9.1 (Message Type.Message Code) **SHALL** contain the constant value 'ORU' drawn from the code system HL70076_USL.

LRI-73: MSH-9.2 (Message Type.Event Trigger) **SHALL** contain the constant value 'R01' drawn from the code system HL70003_USL.

LRI-8: MSH-9.3 (Message Type.Message Structure) **SHALL** contain the constant value 'ORU_R01' drawn from the code system HL70354_USL.

LRI-9: MSH-12.1 (Version ID.Version ID) **SHALL** contain the constant value '2.5.1' drawn from code system HL70104_USL.

Conformance Statements: LRI_GU_FRU_Profile

LRI-10: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16 (LRI_Common_Component), '2.16.840.1.113883.9.12' (LRI_GU_Component) and '2.16.840.1.113883.9.83' (LAB_FRU_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22' (LAB_TO_Component), and/or '2.16.840.1.113883.9.23' (LAB_XO_Component), and/or '2.16.840.1.113883.9.24' (LAB_NB_Component) and/or 2.16.840.1.113883.9.195.3.5 (LRI_PH_Component) and/or 2.16.840.1.113883.9.195.3.6 (LRI_NDBS_Component) and/or 2.16.840.1.113883.9.195.3.8 (LRI_CG_Component).

Conformance Statements: LRI_GU_FRN_Profile

LRI-56: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.2' (LRI_GU_FRN_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16 (LRI_Common_Component), '2.16.840.1.113883.9.12' (LRI_GU_Component) and '2.16.840.1.113883.9.84' (LAB_FRN_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22' (LAB_TO_Component), and/or '2.16.840.1.113883.9.23' (LAB_XO_Component), and/or '2.16.840.1.113883.9.24' (LAB_NB_ Component) and/or 2.16.840.1.113883.9.195.3.6 (LRI_NDBS_Component) and/or 2.16.840.1.113883.9.195.3.8 (LRI_CG_Component).

Conformance Statements: LRI_NG_FRU_Profile

LRI-11: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.3' (LRI_NG_FRU_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16' (LRI_Common_Component), '2.16.840.1.113883.9.13' (LRI_NG_Component) and '2.16.840.1.113883.9.83' (LAB_FRU_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22' (LAB_TO_Component), and/or '2.16.840.1.113883.9.23' (LAB_XO_Component), and/or '2.16.840.1.113883.9.24' (LAB_NB_ Component) and/or 2.16.840.1.113883.9.195.3.6 (LRI_NDBS_Component) and/or 2.16.840.1.113883.9.195.3.8 (LRI_CG_Component).

Conformance Statements: LRI_NG_FRN_Profile

LRI-12: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.4' (LRI_NG_FRN_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16' (LRI_Common_Component), '2.16.840.1.113883.9.13' (LRI_NG_Component) and '2.16.840.1.113883.9.84' (LAB_FRN_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with '2.16.840.1.113883.9.81' (LAB_PRN_Component) **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22 (LRI_TO_Component) and/or 2.16.840.1.113883.9.23 (LAB_XO_Component), and/or 2.16.840.1.113883.9.24 (LAB_NB_ Component) and/or 2.16.840.1.113883.9.195.3.6 (LRI_NDBS_Component) and/or 2.16.840.1.113883.9.195.3.8 (LRI_CG_Component).

Conformance Statements: LRI_PH_GU_FRU_Profile

LRI-PH-90: An occurrence of MSH-21 (Message Profile Identifier) **SHALL** be valued with '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile) or three occurrences **SHALL** be valued with '2.16.840.1.113883.9.16 (LRI_Common_Component), '2.16.840.1.113883.9.12' (LRI_GU_Component), '2.16.840.1.113883.9.83' (LAB_FRU_Component) and '2.16.840.1.113883.9.195.3.5' (LRI_PH_Component) in any order.

Note: Additional occurrences of MSH-21 (Message Profile Identifier) may be valued with **OR** '2.16.840.1.113883.9.82' (LAB_PRU_Component) and/or '2.16.840.1.113883.9.22' (LAB_TO_Component), and/or '2.16.840.1.113883.9.23'

(LAB_XO_Component), and/or ‘2.16.840.1.113883.9.24’ (LAB_NB_ Component), and/or '2.16.840.1.113883.9.195.3.8' (LRI_CG_Component).

8.1.2 LRI ACKNOWLEDGEMENT COMPONENTS

When the initial results transaction uses the GU profile in MSH-21 (Message Profile Identifier) this means that a defined set of fields, including MSH-3 (Sending Application), MSH-4 (Sending Facility), and MSH-6 (Receiving Facility), are considered globally unique by the sender. Therefore, when providing an accept acknowledgement to that result transaction and the acknowledgement uses the exact same values from MSH-3, MSH-4, and MSH-6 to populate the appropriate MSH fields in the acknowledgement message and any fields under the control of the acknowledgement transaction sender are also globally unique, then MSH-21 can assert that the GU profile is used.

As long as MSH-3, MSH-4, and/or MSH-6 are echoed back as-is and MSH-21 indicates the use of the GU profile, it is not necessary to validate that MSH-3, MSH-4, and/or MSH-6 are, in fact, unique.

When the acknowledgement sender populates fields referenced by the GU profile without using MSH-3, MSH-4, and MSH-6 originally received then the acknowledgement sender has all the knowledge to determine whether their values are considered globally unique or not and can populate MSH-21 accordingly.

The table below indicates valid MSH-21 combinations for declaring conformance to a particular pre-coordinated LRI acknowledgement profile or its equivalent set of profile components.

TABLE 8-3. MSH 21 ACKNOWLEDGMENT PROFILE COMBINATIONS

LRI Profile	Pre-Coordinated OID	Profile Component OIDs	Component Name
LRI_Accept_GU_Response_Profile	2.16.840.1.113883.9.11	2.16.840.1.113883.9.9 2.16.840.1.113883.9.21	LRI_Accept_Acknowledgement_Component LRI_GU_Acknowledgement_Component
LRI_Accept_NG_Response_Profile	2.16.840.1.113883.9.12	2.16.840.1.113883.9.9 2.16.840.1.113883.9.25	LRI_Accept_Acknowledgement_Component LRI_NG_Acknowledgement_Component
LRI_Application_GU_Response_Profile	2.16.840.1.113883.9.13	2.16.840.1.113883.9.195.3.10 2.16.840.1.113883.9.21	LRI_Application_Acknowledgement_Component LRI_GU_Acknowledgement_Component
LRI_Application_NG_Response_Profile	2.16.840.1.113883.9.14	2.16.840.1.113883.9.195.3.10 2.16.840.1.113883.9.25	LRI_Application_Acknowledgement_Component LRI_NG_Acknowledgement_Component

Conformance Statements: LRI_Accept_Acknowledgement_Component and LRI_Application_Acknowledgement_Component

LRI-13: MSH-1 (Field Separator) **SHALL** contain the constant value ‘|’.

LRI-14: MSH-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

LRI-115: MSH-9.1 (Message Type.Message Code) **SHALL** contain the constant value 'ACK' drawn from the code system HL70076_USL.

LRI-15: MSH-9.2 (Message Type.Trigger Event) **SHALL** contain the constant value 'R01' drawn from the code system HL70003_USL.

LRI-116: MSH-9.3 (Message Type.Message Structure) **SHALL** contain the constant value 'ACK_R01' drawn from the code system HL70354_USL.

LRI-16: MSH-12.1 (Version ID) **SHALL** contain the constant value '2.5.1'.

Conformance Statements: LRI_GU_Acknowledgement_Component

LRI-18: MSH-21 (Message Profile Identifier) SHALL be valued with a) '2.16.840.1.113883.9.28' (LRI_GU_Response_Profile) or b) a combination of '2.16.840.1.113883.9.26' (LRI_Acknowledgment_Profile) and '2.16.840.1.113883.9.21' LRI_GU_Acknowledgment_Profile) when acknowledging ORU GU Profiles where MSH-21 contains '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile), or '2.16.840.1.113883.9.195.3.2' (LRI_GU_FRN_Profile), or '2.16.840.1.113883.9.12' (LRI_GU_Component).

Conformance Statements: LRI_GU_Acknowledgement_Component and LRI_End-To-End_Acknowledgement_Component

LRI-117: MSH-21 (Message Profile Identifier) SHALL be valued with a combination of '2.16.840.1.113883.9.195.3.7' (LRI_End-To-End_Acknowledgement_Component) and '2.16.840.1.113883.9.21' (GU_Acknowledgment_Profile) when acknowledging ORU GU Profiles where MSH-21 contains '2.16.840.1.113883.9.195.3.1' (LRI_GU_FRU_Profile), or '2.16.840.1.113883.9.195.3.2' (LRI_GU_FRN_Profile), or '2.16.840.1.113883.9.12' (LRI_GU_Component).

Conformance Statements: LRI_NG_Acknowledgement_Component

LRI-19: MSH-21 (Message Profile Identifier) SHALL be valued with a) '2.16.840.1.113883.9.27'(LRI_NG_Response_Profile) or b) a combination of '2.16.840.1.113883.9.26' (LRI_Acknowledgment_Profile) and '2.16.840.1.113883.9.25' LRI_NG_Acknowledgment_Profile) when acknowledging ORU NG Profiles where MSH-21 contains '2.16.840.1.113883.9.195.3.3' (LRI_NG_FRU_Profile), or '2.16.840.1.113883.9.195.3.4' (LRI_NG_FRN_Profile), or '2.16.840.1.113883.9.13' (LRI_NG_Component).

Conformance Statements: LRI_NG_Acknowledgement_Component and LRI_End-To-End_Acknowledgement_Component

LRI-118: MSH-21 (Message Profile Identifier) SHALL be valued with a combination of '2.16.840.1.113883.9.195.3.7' (LRI_End-To-End_Acknowledgement_Component) and '2.16.840.1.113883.9.25' LRI_NG_Acknowledgment_Profile) when acknowledging ORU NG Profiles where MSH-21 contains '2.16.840.1.113883.9.195.3.3' (LRI_NG_FRU_Profile), or '2.16.840.1.113883.9.195.3.4' (LRI_NG_FRN_Profile), or '2.16.840.1.113883.9.13' (LRI_NG_Component).

8.2 SFT – Software Segment

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

TABLE 8-4. SFT – SOFTWARE SEGMENT

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Software Vendor Organization	XON	R	[1..1]		
2	Software Certified Version or Release Number	ST	R	[1..1]		
3	Software Product Name	ST	R	[1..1]		
4	Software Binary ID	ST	R	[1..1]		
5	Software Product Information		O			
6	Software Install Date		O			

8.3 MSA – Acknowledgement Segment

TABLE 8-5. ACKNOWLEDGMENT SEGMENT (MSA)

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

8.4 ERR – Error Segment

TABLE 8-6. ERROR SEGMENT (ERR)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Error Code and Location		X			Excluded for this Implementation Guide, see Section 1.3.1.
2	Error Location	ERL_01	RE	[0..1]		To reduce ambiguity, each error will have an individual ERR segment.
3	HL7 Error Code	CWE_02	R	[1..1]	HL70357_USL	Used to identify issues based on conformance profile in message (structure and vocabulary) or to indicate an application error was identified and is communicated in ERR-5 (Application Error Code).
4	Severity	ID	R	[1..1]	HL70516_USL	
5	Application Error Code	CWE_02	C(R/O)	[0..1]	HL70533_USL	Condition Predicate: If ERR-3.1 (Identifier) is valued '999'. Used to indicate error in content; there is nothing wrong with the message structure, but system cannot use the data.
6	Application Error Parameter		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
7	Diagnostic Information	TX	R	[1..1]		Use to help IT personnel fix the error. Gives additional detail to ERR-3 (HL7 Error Code) and ERR-5 (Application Error Code).
8	User Message	TX	R	[1..1]		Use to display error/instructions to user of the system. Information may differ from that in ERR-7 (Diagnostic Information).
9	Inform Person Indicator		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
10	Override Type		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
11	Override Reason Code		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
12	Help Desk Contact Point		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'

Usage Note

ERR-2.2 (Error Location.Segment Sequence)

Identifies the occurrence of the segment identified in ERR-2.1 (Error Location.Segment ID) within the message. The following example illustrates how ERR-2.2 (Error Location.Segment Sequence) is valued '3' since the error occurred in the third occurrence of an NTE segment. Note that this is not the same as the segment's Set ID element.

Example ERL data type:|NTE^3|

```
MSH...
...
ORC|RE|...
OBR|1|...
OBX|1|...
NTE|1|...
NTE|2|...
OBX|2|...
NTE|1|... invalid NTE segment
SPM|1|...
```

Message sent / received

Bold text indicates errors

```
MSH|^~\&#|||LIS^2.16.840.1.113883.19^ISO|||20150901104930||ORU^R01^ORU_R01|12345678
   90|...
PID|1|...
ORC|XY|...
OBR|1|...
OBX|1|...
OBX|2|...
OBX|3|...
ORC|RE|...
OBR|2||12345|abc^^LNC|...
OBX|1|...
OBX|2|...
OBX|3|...
ORC|RE|...
OBR|3|...
OBX|1|...
OBX|2|...
OBX|3|DT|xyz^^LN|...
```

Application Level Response

```
MSH|^~\&#|||EHR^2.16.840.1.113883.20^ISO|||20150901105030||ACK^R01^ACK|9876543210|.
   ..
MSA|AE|1234567890|...
ERR||ORC^1|203^^HL70357|E|||Control code XY is not supported.||
ERR||OBR^2^4|999^^HL70357|E|201^^HL70533||Coding system LNC is not supported.||
ERR||OBX^9^3^^1|999^^HL70357|E|201^^HL70533||xyz was not found|We do not support
   xyz|
```

8.5 PID – Patient Identification Segment

TABLE 8-7. PATIENT IDENTIFICATION SEGMENT (PID)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – PID	SI	R	[1..1]		
2	Patient ID		X			Excluded for this Implementation Guide, see Section 1.3.1.
3	Patient Identifier List	Varies	R	[1..*]		LRI_PH_Component: Cardinality: [1..1] Data type: CX_01 All other profiles: Usage: GU data type: CX_01 NG data type: CX_02
4	Alternate Patient ID – PID		X			Excluded for this Implementation Guide, see Section 1.3.1.
5	Patient Name	CPN_03	R	[1..1]		
6	Mother's Maiden Name	Varies	Varies	Varies		LRI_PH_Component Data Type: 'XPN_01'; Usage: 'RE'; Cardinality [0..1] Usage for all other components: 'O'
7	Date/Time of Birth	Varies	RE	[0..1]		LAB_NB_Component Data Type: TS_02 LRI_NDBS_Component Data Type: TS_06 All other components Data Type: TS_01
8	Administrative Sex	IS	R	[1..1]	HL70001_USL	
9	Patient Alias		X			Excluded for this Implementation Guide, see Section 1.3.1.

TABLE 8-7. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
10	Race	Varies	RE	[0..*]	HL70005_USL	LRI_PH_Component Data Type: 'CWE_03' All other profiles Data Type: 'CWE_02' Note that state and/or national regulations may dictate other behaviors, e.g., may prohibit the collection of this data. The PID-10 (Race) value is provided for demographic/billing purposes, not clinical use.
11	Patient Address	Varies	Varies	[0..*]		LRI_PH_Component Usage: 'RE'; Data Type: 'XAD_01' All other profiles Usage: 'O'
12	County Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
13	Phone Number – Home	Varies	Varies	Varies		LRI_PH_Component Usage: 'RE'; Data Type: 'XTN_01'; Cardinality: [0..*] Usage for all other components: 'O'
14	Phone Number – Business	Varies	Varies	Varies		LRI_NDBS_Component Usage: 'X' LRI_PH_Component Usage: 'RE'; Data Type: 'XTN_01'; Cardinality [0..*] Usage for all other components: 'O'
15	Primary Language		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
16	Marital Status		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
17	Religion		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
18	Patient Account Number		O			
19	SSN Number – Patient		X			Excluded for this Implementation Guide, see Section 1.3.1.
20	Driver's License Number – Patient		X			Excluded for this Implementation Guide, see Section 1.3.1.
21	Mother's Identifier		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
22	Ethnic Group	Varies	Varies	[0..*]	HL70189_USL	LRI_PH_Component Data Type: 'CWE_03'; Usage: 'RE', Value Set: 'HL70189_USL' remove 'HL70189_USL' from column Value set Usage for all other components: 'O'

TABLE 8-7. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
23	Birth Place		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
24	Multiple Birth Indicator	Varies	Varies	Varies		LRI_NDBS_Component Data Type: 'ID'; Usage: 'RE'; Cardinality: [0..1]; Value set: HL70136_USL Usage for all other components: 'O'
25	Birth Order		Varies	Varies		LRI_NDBS_Component Data Type: 'NM'; Usage: 'RE'; Cardinality: [0..1] Usage for all other components: 'O'
26	Citizenship		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
27	Veterans Military Status		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
28	Nationality		X			Excluded for this Implementation Guide, see Section 1.3.1.
29	Patient Death Date and Time	Varies	Varies	[0..1]		LRI_PH_Component Data Type: 'TS_02' Usage: 'C(RE/O)'; Condition Predicate: If PID-30 (Patient Death Indicator) is valued 'Y'.Usage for all other components: 'O'
30	Patient Death Indicator	Varies	Varies	Varies	Varies	LRI_PH_Component Data Type: 'ID'; Usage: 'RE'; Cardinality: [0..1], Value Set: HL70136_USL Usage for all other components: 'O'
31	Identity Unknown Indicator		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
32	Identity Reliability Code		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
33	Last Update Date/Time	Varies	Varies	Varies		LRI_PH_Component Data Type: TS_06; Usage: 'RE'; Cardinality: [0..1] LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
34	Last Update Facility	Varies	Varies	Varies		LRI_NDBS_Component Usage: 'X' LRI_PH_Component Usage: 'C(RE/O)'; Data Type: HD_01; Cardinality: [0..1] Condition Predicate: If PID-33 (Last Update Date/Time) is valued. Usage for all other components: 'O'

TABLE 8-7. PATIENT IDENTIFICATION SEGMENT (PID)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
35	Species Code		Varies	Varies		LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: CWE_03; Usage: 'RE'; Cardinality: [0..1]; Value Set: PHVS_Animal_CDC Usage for all other components: 'O'
36	Breed Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
37	Strain		X			Excluded for this Implementation Guide, see Section 1.3.1.
38	Production Class Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
39	Tribal Citizenship		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'

Usage Note

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

LRI_PH_Component

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

PID-6 - Mother's Maiden Name – May be included for identification purposes. XPN.7 (Name type code) is constrained to the value "M."

PID-7 - Date/Time of Birth – Note that the granularity of the birth date may be important; for a newborn, birth date may be known down to the minute, while for adults it may be known only to the date.

PID-33 - Last Update Date/Time – The intent of this field is to serve as flag for messages with updated demographic information.

PID-34 - Last Update Facility – This is the facility that originated the demographic update.

PID-35 - Species Code – Population of this field supports animal rabies testing by public health laboratories.

LRI_NDBS_Component

PID-25 - Birth Order – If Multiple Birth Indicator (PID-24) is "Y", then enter the number indicating the baby's birth order, with literal value "1" for the first child born, "2" for the second child, and so on. If Multiple Birth Indicator (PID-24) is "N" then leave the field empty or enter the value "1".

Note: It is strongly encouraged that this field be explicitly used to indicate birth order rather than the convention of using the baby's name (e.g. Baby Boy 1, Baby Boy 2, etc).

LRI_NDBS_Component

For the purpose of NDBS, the newborn's birth date/time shall be fully specified to the minute, if known, in PID-7 (Date of Birth).

Conformance Statements: Base Profile

LRI-20: PID-1 (Set ID - PID) **SHALL** be valued with the constant value '1'.

Conformance Statements: LRI_PH_Component

LRI-PH-88: If valued, PID-6.7 (Name Type Code) **SHALL** contain the constant value 'M'.

8.6 NK1 – Next of Kin / Associated Parties Segment

TABLE 8-8. NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - NK1	SI	R	[1..1]		
2	Name	Varies	Varies	[0..1]		Condition Predicate: If NK1-13 (Organization Name – NK1) is not valued. LRI_PH_Component Data Type: 'XPN_01' LRI_NDBS_Component Data Type: 'XPN_02'; Usage: (R/O), Condition Predicate: If NK1-13 Organization Name is not valued. Usage for all other components: 'O'
3	Relationship	Varies	Varies	Varies	Varies	LRI_PH_Component Data Type: 'CWE_03'; Usage: 'RE'; Cardinality: [0..1]; Value Set: HL70063_USL LRI_NDBS_Component Data Type: 'CWE_02'; Usage: 'R'; Cardinality: [1..1]; Value Set: HL70063_USL Usage for all other components: 'O'
4	Address	Varies	Varies	[0..*]		LRI_PH_Component Data Type: 'XAD_01'; Usage: 'RE' LRI_NDBS_Component Data Type: XAD_02; Usage: 'RE' Usage for all other components: 'O'
5	Phone Number	Varies	Varies	[0..*]		LRI_PH_Component Data Type: 'XTN_01'; Usage: 'RE' LRI_NDBS_Component Data Type: 'XTN_02'; Usage: 'RE' Usage for all other components: 'O'
6	Business Phone Number		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'

TABLE 8-8. NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
7	Contact Role	Varies	Varies	[0..1]	Varies	LRI_PH_Component Data Type: 'CWE_03'; Usage: 'RE'; Value Set: HL70131_USL LRI_NDBS_Component Data Type: 'CWE_02'; Usage: 'RE'; Value Set: HL70131_USL Usage for all other components: 'O'
8	Start Date		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
9	End Date		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
10	Next of Kin / Associated Parties Job Title		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
11	Next of Kin / Associated Parties Job Code/Class		O			
12	Next of Kin / Associated Parties Employee Number		Varies			LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
13	Organization Name - NK1	Varies	Varies	Varies	Varies	LRI_PH_Component: Data Type: 'XON_03'; Usage: 'C(R/X)', Condition Predicate: If NK1-2 (Name) is not valued; Cardinality: [0..1]. LRI_NDBS_Component: Data Type: 'XON_01' or 'XON_02'; Usage: 'C(R/X)', Condition Predicate: If NK1-2 (Name) is not valued; Cardinality: [0..1]. Usage for all other components: 'O'
14	Marital Status		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
15	Administrative Sex		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
16	Date/Time of Birth	Varies	Varies	Varies		LRI_NDBS_Component Data Type: 'TS_05'; Usage: 'RE'; Cardinality: [0..1] Usage for all other components: 'O'
17	Living Dependency		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'

TABLE 8-8. NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
18	Ambulatory Status		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
19	Citizenship		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
20	Primary Language		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
21	Living Arrangement		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
22	Publicity Code		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
23	Protection Indicator		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
24	Student Indicator		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
25	Religion		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
26	Mother's Maiden Name		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
27	Nationality		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
28	Ethnic Group		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
29	Contact Reason		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
30	Contact Person's Name	Varies	Varies	Varies		LRI_PH_Component: Data type: XPN_01; Usage: 'C(RE/X)', Condition Predicate: If NK1-13 (Organization Name - NK1) is valued.; Cardinality: [0..1] Usage for all other components: 'O'
31	Contact Person's Telephone Number		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'

TABLE 8-8. NEXT OF KIN / ASSOCIATED PARTIES SEGMENT (NK1)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
32	Contact Person's Address	Varies	Varies	Varies		LRI_PH_Component Data Type: XAD_01, Usage: 'C(RE/X)'; Condition Predicate: If NK1-13 (Organization Name - NK1) is valued.; Cardinality: [0..1] Usage for all other components: 'O'
33	Next of Kin/Associated Party's Identifiers		O			
34	Job Status		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
35	Race		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
36	Handicap		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
37	Contact Person Social Security Number		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
38	Next of Kin Birth Place		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
39	VIP Indicator		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'

Usage Note

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

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

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

LRI_NDBS_Component

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

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

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

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

8.7 PV1 – Patient Visit Information

TABLE 8-9. PV1 – PATIENT VISIT INFORMATION

SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - PV1	SI	R	[1..1]		
2	Patient Class	IS	R	[1..1]	HL70004_USL	A gross identification of the classification of patient's visit.
3	Assigned Patient Location		O			
4	Admission Type	Varies	Varies	Varies	Varies	LRI_PH_Component Data Type: 'IS'; Usage: 'RE'; Cardinality: [0..1]; Value Set: HL70007_USL Usage for all other components: 'O'
5	Preadmit Number		O			
6	Prior Patient Location		O			
7	Attending Doctor		O			
8	Referring Doctor		O			
9	Consulting Doctor		O			
10	Hospital Service		O			
11	Temporary Location		O			
12	Preadmit Test Indicator		O			
13	Re-admission Indicator		O			
14	Admit Source		O			
15	Ambulatory Status		O			
16	VIP Indicator		O			
17	Admitting Doctor		O			
18	Patient Type		O			
19	Visit Number		O			

TABLE 8-9. PV1 – PATIENT VISIT INFORMATION						
SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
20	Financial Class		O			
21	Charge Price Indicator		O			
22	Courtesy Code		O			
23	Credit Rating		O			
24	Contract Code		O			
25	Contract Effective Date		O			
26	Contract Amount		O			
27	Contract Period		O			
28	Interest Code		O			
29	Transfer to Bad Debt Code		O			
30	Transfer to Bad Debt Date		O			
31	Bad Debt Agency Code		O			
32	Bad Debt Transfer Amount		O			
33	Bad Debt Recovery Amount		O			
34	Delete Account Indicator		O			
35	Delete Account Date		O			
36	Discharge Disposition		O			
37	Discharged to Location		O			
38	Diet Type		O			
39	Servicing Facility		O			
40	Bed Status		X			Excluded for this Implementation Guide, see Section 1.3.1.
41	Account Status		O			
42	Pending Location		O			
43	Prior Temporary Location		O			

TABLE 8-9. PV1 – PATIENT VISIT INFORMATION						
SEQ	HL7 Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
44	Admit Date/Time	Varies	Varies	Varies		LRI_PH_Component Data Type: 'TS_06'; Usage: 'RE', Cardinality: [0..1] Usage for all other components: 'O'
45	Discharge Date/Time	Varies	Varies	Varies		LRI_PH_Component Data Type: 'TS_06'; Usage: 'C(RE/O', Condition Predicate: If PV1-4 = 'I'; Cardinality: [0..1] Usage for all other components: 'O'
46	Current Patient Balance		O			
47	Total Charges		O			
48	Total Adjustments		O			
49	Total Payments		O			
50	Alternate Visit ID		O			
51	Visit Indicator		O			
52	Other Healthcare Provider		X			Excluded for this Implementation Guide, see Section 1.3.1.

Conformance Statements: LRI_PH_Component

LRI-PH-91: PV1-1 (Set ID - PV1) **SHALL** contain the constant value '1'.

8.8 ORC – Common Order Segment

TABLE 8-10. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Order Control	ID	R	[1..1]	HL70119_USL	
2	Placer Order Number	Varies	RE	[0..1]		LRI_PH_Component: Data Type: EI_03 All other components: GU data type: EI_01 NG data type: EI_02
3	Filler Order Number	Varies	R	[1..1]		LRI_PH_Component: Data Type: EI_03 All other components: GU data type: EI_01 NG data type: EI_02

TABLE 8-10. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
4	Placer Group Number	Varies	RE	[0..1]		LRI_PH_Component Data Type: EI_03 All other components: GU data type: EI_01 NG data type: EI_02
5	Order Status		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
6	Response Flag		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
7	Quantity/Timing		X			Excluded for this Implementation Guide, see Section 1.3.1.
8	Parent		Varies	Varies		LRI_PH_Component: Data Type: EI_03 All other components: LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
9	Date/Time of Transaction		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
10	Entered By		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
11	Verified By		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
12	Ordering Provider	Varies	R	[1..1]		Providers should be identified using their NPI. LRI_PH_Component Data Type: XCN_01 All other components: GU data type: XCN_01 NG data type: XCN_02
13	Enterer's Location		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
14	Call Back Phone Number	Varies	Varies	Varies		LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: XTN_01; Usage: 'RE'; Cardinality: [0..2] Usage for all other components: 'O'

TABLE 8-10. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
15	Order Effective Date/Time		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
16	Order Control Code Reason		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
17	Entering Organization		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
18	Entering Device		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
19	Action By		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
20	Advanced Beneficiary Notice Code		X			Excluded for this Implementation Guide, see Section 1.3.1.
21	Ordering Facility Name	Varies	Varies	Varies		LRI_NDBS_Component Usage: 'RE'; Cardinality: [0..1], GU Data Type: XON_01 NG Datatype: XON_02 LRI_PH_Component Data Type: XON_03; Usage: 'RE'; Cardinality: [0..1] Usage for all other components: 'O'
22	Ordering Facility Address	Varies	Varies	Varies		LRI_PH_Component Data Type: XAD_01; Usage: 'R'; Cardinality: [1..1] Usage for all other components: 'O'
23	Ordering Facility Phone Number	Varies	Varies	Varies		LRI_PH_Component Data Type: XTN_01; Usage: 'R'; Cardinality: [1..1] Usage for all other components: 'O'
24	Ordering Provider Address	Varies	Varies	Varies		LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: XAD_01; Usage: 'R'; Cardinality: [1..*] Usage for all other components: 'O'
25	Order Status Modifier		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
26	Advanced Beneficiary Notice Override Reason		C(X/X)			Excluded for this Implementation Guide, see Section 1.3.1.
27	Filler's Expected Availability Date/Time		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'

TABLE 8-10. COMMON ORDER SEGMENT (ORC)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
28	Confidentiality Code		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
29	Order Type		O			
30	Enterer Authorization Mode		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
31	Parent Universal Service Identifier	Varies	Varies	[0..1]		Contains the universal service identifier of the parent order. PRU and FRU, or FRU only – Usage: 'O'; PRU and FRN, or PRN and FRU, or PRN and FRN, or FRN only – Usage: 'C(R/X)'. Condition Predicate: If OBR-29 (Parent) is valued. Data type: CWE_01

Usage Note

ORC-4 (Placer Group Number) - A result message may have an ORC-4 (Placer Group Number) populated, even when the ORC-2 (Placer Order Number) is blank. Two examples of result message that may meet this situation are reflex results, and Add-on orders. Reflex results by their nature, are not an order from the placer, and therefore have no ORC-2 (Placer Order Number); however ORC-4 (Placer Group Number) can be derived from the parent result. Add-on orders can be submitted in a variety of ways. When called in, the order placer may not have access to a placer order number at time of the order. Because the result is part of a group, the resulting system may be able to accurately identify and apply ORC-4 (Placer Group Number), even when the ORC-2 (Placer Order Number) is unavailable.

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

LRI_PH_Component

ORC-14 - Call Back Phone Number – This should be a phone number or other contact information associated with the ordering provider referenced in OBR-16/ORC-12.

ORC-21 - Ordering Facility Name – This field should contain the name of the facility where the order was placed by the provider (even if a sample is being referred by the filler lab to another lab) referenced in OBR-16/ORC-12. If the order was placed in a single provider office, the facility name in this field may be the same as the provider name in ORC-12.

ORC-24 - Ordering Provider Address – This should be the address associated with the ordering provider identified in OBR-16/ORC-12.

Conformance Statements: Base Profile

LRI-23: The value of ORC-2 (Placer Order Number) **SHALL** be identical to the value of OBR-2 (Placer Order Number) within the same Order_Observation Group instance.

LRI-24: The value of ORC-3 (Filler Order Number) **SHALL** be identical to the value of OBR-3 (Filler Order Number) within the same Order_Observation Group instance.

LRI-25: The value of ORC-12 (Ordering Provider) **SHALL** be identical to the value of OBR-16 (Ordering Provider) within the same Order_Observation Group instance.

Conformance Statements: LAB_FRN Profile

LRI-26: The value of ORC-31 (Parent Universal Service Identifier) **SHALL** be identical to the value of OBR-50 (Parent Universal Service Identifier) within the same Order_Observation Group instance.

Conformance Statements: LAB_FRU Profile

LRI-28: The value of ORC-3 (Filler Order Number), excluding those in the Prior Result group(s), **SHALL NOT** be valued identical to another instance of ORC-3 (Filler Order Number) in the same message.

Note: The conformance statements for ORC-2 do not apply when either of those fields is empty.

Conformance Statements: LRI_PH_Component

LRI-PH-93: ORC-14 (Call Back Phone Number) **SHALL** be the same value as OBR-17 (Call Back Phone Number) within same Order_Observation Group.

8.9 OBR – Observation Request Segment

TABLE 8-11. OBSERVATION REQUEST SEGMENT (OBR)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - OBR	SI	R	[1..1]		
2	Placer Order Number	Varies	RE	[0..1]		LRI_PH_Component Data Type: EI_03 All other components: GU data type: EI_01 NG data type: EI_02
3	Filler Order Number	Varies	R	[1..1]		LRI_PH_Component Data Type: EI_03 All other components: GU data type: EI_01 NG data type: EI_02

TABLE 8-11. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
4	Universal Service Identifier	CWE_01	R	[1..1]	LOINC	LOINC shall be used as the standard vocabulary to identify the ordered test in OBR-4 (Universal Service Identifier) when an applicable LOINC code is available and provided by the laboratory. When no valid orderable LOINC code exists, the local code may be the only code sent.
5	Priority – OBR		X			Excluded for this Implementation Guide, see Section 1.3.1
6	Requested Date/Time		X			Excluded for this Implementation Guide, see Section 1.3.1
7	Observation Date/Time	Varies	R	[1..1]		LRI_NDBS_Component Data Type: 'TS_08' All others Data Type: TS_12 This reflects the specimen collection date/time when the test involves a specimen. Since a test may also involve drawing specimens at different times, e.g., tolerance tests, this date/time only covers the draw of the first specimen. All other specimen collection date/times, including the first one, are communicated in the SPM segment For unknown collection date/time use "0000".
8	Observation End Date/Time	TS_06	Varies	[0..1]		Sender Usage: 'O' Receiver Usage: 'RE' **Note:** Future versions of this guide will constrain the usage of this element to 'RE'.
9	Collection Volume		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
10	Collector Identifier		O			
11	Specimen Action Code	ID	RE	[0..1]	HL70065_USL	
12	Danger Code		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
13	Relevant Clinical Information	CWE_02	RE	[0..1]	HL70916_USL	This field pre-adopts the V2.7.1 definition. Constrained to indicate Fasting only.
14	Specimen Received Date/Time		X			Excluded for this Implementation Guide, see Section 1.3.1
15	Specimen Source		X			Excluded for this Implementation Guide, see Section 1.3.1

TABLE 8-11. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
16	Ordering Provider	Varies	R	[1..1]		Providers should be identified using their NPI. Note that ORC-12 Ordering Provider is constrained to contain the same value as this field. LRI_PH_Component: Data type: XCN_01 All other components: GU data type: XCN_01 NG data type: XCN_02
17	Order Call-back Phone Number		Varies	Varies		LRI_NDBS_Component: Usage: 'X' LRI_PH_Component: Data Type: XTN_01; Usage: 'RE'; Cardinality: [0..2] LRI_PH_Component: This should be a phone number or other contact information associated with the original ordering provider Usage for all other components: 'O'
18	Placer Field 1		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
19	Placer Field 2		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
20	Filler Field 1		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
21	Filler Field 2		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
22	Results Rpt/Status Chng - Date/Time	TS_10	R	[1..1]		
23	Charge to Practice		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
24	Diagnostic Service Sect ID		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
25	Result Status	ID	R	[1..1]	HL70123_USL	The value of OBR-25 is derived from the OBX-11 values that follow the OBR as outlined in section 8.9.3 below.
26	Parent Result	PRL_01	C(R/RE)	[0..1]		Condition Predicate: If OBR-11 (Specimen Action Code) is valued "G".
27	Quantity/Timing		X			Excluded for this Implementation Guide, see Section 1.3.1.

TABLE 8-11. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
28	Result Copies To	Varies	C(R/X)	[0..*]		Condition Predicate: If CWE_03.1 (Identifier) or CWE_03.4 (Alternate Identifier) of at least one occurrence of OBR-49 (Result Handling) is valued 'CC' or 'BCC' LRI_PH_Component: Data Type: XCN_01 All other components: GU Profile: XCN_01 NG Profile: XCN_02
29	Parent	Varies	C(R/RE)	[0..1]		Condition Predicate: If OBR-11 (Specimen Action Code) is valued "G". LRI_PH_Component: Data Type: EI_03 All other components: GU Profile: EIP_01 NG Profile: EIP_02 See Section 12.1.1 Parent/Child Linking, of this document for more information on linking parent/child results.
30	Transportation Mode		Varies	Varies		LRI_NDBS_Component: Usage: 'X' Usage for all other components: 'O'
31	Reason for Study	Varies	Varies	Varies	Varies	LRI_PH_Component: Data Type: CWE_03; Usage: 'RE'; Cardinality: [0..*], Value Set: ICD-9CM or ICD-10-CM and/or CORE Problem List Subset of SNOMED CT. Usage for all other components: 'O'
32	Principal Result Interpreter	Varies	Varies	Varies		LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: NDL_01; Usage: 'RE'; Cardinality: [0..1] LRI_PH_Component: Used for pathology results. Usage for all other components: 'O'
33	Assistant Result Interpreter		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
34	Technician		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
35	Transcriptionist		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'

TABLE 8-11. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
36	Scheduled Date/Time		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
37	Number of Sample Containers		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
38	Transport Logistics of Collected Sample		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
39	Collector's Comment		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
40	Transport Arrangement Responsibility		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
41	Transport Arranged		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
42	Escort Required		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
43	Planned Patient Transport Comment		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
44	Procedure Code		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
45	Procedure Code Modifier		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
46	Placer Supplemental Service Information		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
47	Filler Supplemental Service Information	CWE_02	RE	[0..*]	HL70411_USL	As defined in this guide, this field is used with the values from the table to indicate the type of test result structure being sent, i.e, the use of the 'MIC' value indicates the subsequent data will be structured as microbiology results.
48	Medically Necessary Duplicate Procedure Reason		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
49	Result Handling	CWE_04	RE	[0..3]	HL70507_USL	

TABLE 8-11. OBSERVATION REQUEST SEGMENT (OBR)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
50	Parent Universal Service Identifier	Varies	Varies	[0..1]		Contains the universal service identifier of the parent order. PRU and FRU, or PRU only, or FRU only – Usage: 'O'; PRU and FRN, or PRN and FRU, or PRN and FRN, or PRN only, or FRN only – Usage: 'C(R/X) Condition Predicate: If OBR-29 (Parent) is valued. Data type: CWE_01

Usage Note

OBR-3 (Filler Order Number)

In the circumstance where some of the lab results are generated by the lab but others are performed by a reference lab, the sending lab can choose what filler order number to use in OBR-3. The Filler ID for a single orderable must be the same for all messages for that orderable, e.g., the filler ID must be the same for the ORC/OBR pair reporting a preliminary, final or corrected result. Whichever filler order number is used, the sending lab is expected to be able to trace all the observations in the lab result back to the appropriate source lab based on the filler order number provided in OBR-3 (Filler Order Number).

OBR-13 (Relevant Clinical Information)

Note that CWE has been pre-adopted from V2.7.1.

OBR-7 (Observation Date/Time), OBR-8 (Observation End Date/Time), SPM-17.1 (Range Start Date/Time), SPM-17.2 (Range End Date/Time)

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

OBR-25 (Result Status)

When nothing has been reported under an OBR and the LRI message is used to communicate a cancellation, the reason for cancellation, including wrong patient or wrong specimen, is reported in an NTE under the OBR and the OBR-25 is valued 'X' and follows the cancellation path.

If any result is reported on the OBR it must be issued as a corrected report with OBR-25 valued 'M' or 'C'.

OBR-47 (Filler Supplemental Service Information)

Special handling of parent/child resulting for reflexing as well as micro susceptibility:

1. When a parent is non-micro, but it reflexes to a micro with susceptibilities, the non-micro parent should not have "MIC" in OBR-47 (Filler Supplemental Service Information), however the reflex and all susceptibilities should be valued with "MIC" in OBR-47.

2. When the parent is valued “MIC” in OBR-47, all child OBRs should be flagged as micro via the “MIC” in OBR-47.
3. Child OBRs, should be flagged to match the parent indicator for all susceptibilities.

OBR-50 (Parent Universal Service Identifier) – See LRI-26 for the applicable conformance statement when LAB_FRN Profile is used.

Conformance Statements: Base Profile

LRI-33: If present, OBR-8 (Observation End Date/Time) **SHALL** be equal to or later than OBR-7 (Observation Date/Time).

LRI-34: The value of OBR-1 (Set ID – OBR) **SHALL** be valued sequentially starting with the value ‘1’ across the Order_Observation Groups.

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

```
MSH|...<cr>
PID|...<cr>
// First order group
ORC|NW|...<cr>
OBR|1|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
// end first order group
// Second order group - Microbiology Parent
ORC|NW|...<cr>
OBR|2|...<cr>
SPM|1|...<cr>
// end second order group - Microbiology Parent
// Third order group - Microbiology Child #1
ORC|NW|...<cr>
OBR|3|...<cr>
SPM|1|...<cr>
//end third order group - Microbiology Child #1
```

```
// Fourth order group - Microbiology Child #2
ORC|NW|...<cr>
OBR|4|...<cr>
SPM|1|...<cr>
// end fourth order group - Microbiology Child #2
// Fifth order group
ORC|NW|...<cr>
OBR|5|...<cr>
SPM|1|...<cr>
SPM|2|...<cr>
//end fifth order group
```

Conformance Statements: LAB_FRU Profile

~~**LRI-44: Deprecated as of Aug 18, 2012** OBR-2 (Placer Order Number) when present **SHALL** be unique for each OBR segment in the message.~~

~~**LRI-45: Deprecated as of Aug 18, 2012** OBR-3 (Filler Order Number) **SHALL** be unique for each OBR segment in the message.~~

LRI-40: The value of OBR-3 (Filler Order Number) **SHALL NOT** be valued identical to another instance of OBR-3 (Filler Order Number) in the message.

8.9.1 REPORTING RESULTS WITH A PARENT/CHILD RELATIONSHIP (SUCH AS REFLEX RESULTS AND MICROBIOLOGY CULTURE WITH SUSCEPTIBILITY)

When communicating results with a parent/child relationship, such as microbiology results and reflex tests, the use of the right segments and fields is essential to consistently convey the structure and content of the culture, organisms, and susceptibilities. This guide opted for one of potentially 3-4 ways to communicate these results. The following diagrams summarize the concepts and are followed by the formal conformance statements that implement that.

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

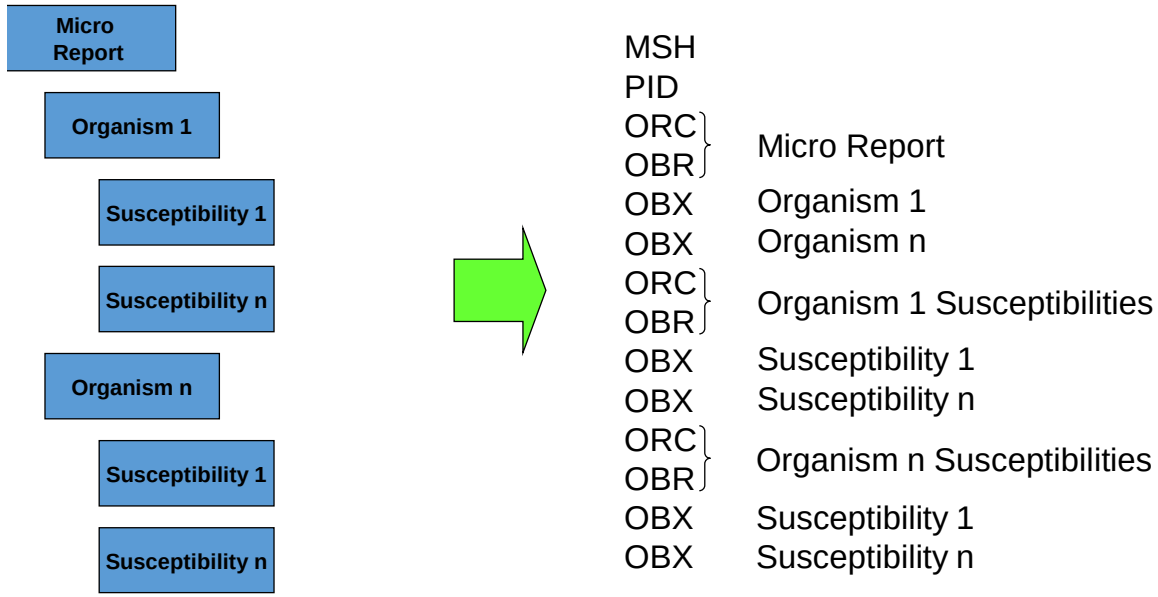


Figure 8-1. Sample Report Structure Represented as Message Structure

Figure 8-1. Sample Report Structure Represented as Message Structure shows the use of the ORC, OBR, and OBX segments. The arrows illustrate how the child Organism refers to value in the parent OBR and OBX to clearly link the child to the parent. (For example the dark blue line illustrates how the value in the child's OBR-26 matches the value of its parents OBX-3 and OBX-4.)

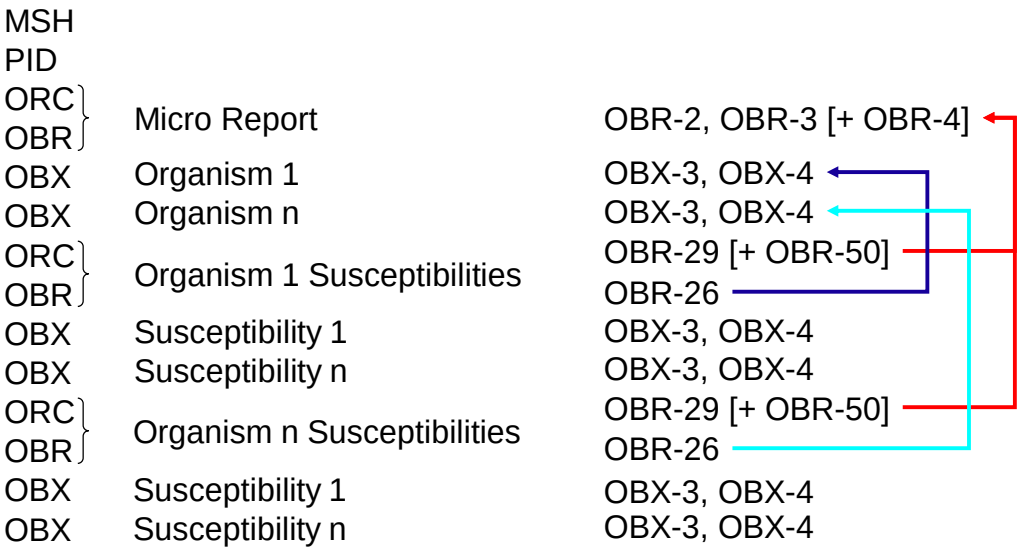


Figure 8-2. Parent-Child Relationships

The following conformance statements express this more formally.

Conformance Statements: LRI_FRU and LRI_PRU Profiles

LRI-43: Results with a Parent/Child relationship (as defined in Section 12.1 Parent/Child Reporting for Reflex and Culture/Susceptibility Testing), such as Microbiology and Reflex Results **MUST** provide proper linking from the Child result to the Parent OBR and OBX as detailed below:

Parent OBR matching: Any OBR with a value of 'G' in OBR-11 (Specimen Action Code) and/or a value in OBR-26 (Parent Result), henceforth referred to as the Child OBR, **SHALL** be successfully matched to a Parent OBR in a previously occurring Order Observation Group in the following ways:

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

AND

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

Parent OBX matching: Any OBR with a value of 'G' in OBR-11 (Specimen Action Code) or a value in OBR-26 (Parent Result), henceforth referred to as the Child OBR, **SHALL** be successfully matched to an OBX segment within the previously identified Parent Order Observation Group in the following ways:

The child OBR-26.1 (Parent Observation Identifier) is valued the same as the Parent OBX-3 value (taking into account the conversion of component delimiters into sub-component delimiters.)

AND

The child OBR-26.2 (Parent Observation Sub-Identifier) is valued the same as the Parent OBX-4 (Observation Sub-Identifier) valuet (taking into account the conversion of component delimiters into sub-component delimiters.)

Conformance Statements: LRI_FRN and LRI_PRN Profiles

LRI-57: Results with a Parent/Child relationship (as defined in section 12.1.1), such as Microbiology and Reflex Results must provide proper linking from the Child result to the Parent OBR and OBX as detailed below:

Parent OBR matching: Any OBR with a value of 'G' in OBR-11 (Specimen Action Code) or a value in OBR-26 (Parent Result), henceforth referred to as the Child OBR, **SHALL** be successfully matched to a Parent OBR in a previously occurring Order Observation Group in the following ways:

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

AND

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

AND

The child OBR-50 (Parent Universal Service Identifier) is valued the same as the Parent OBR-4 value.

Parent OBX matching: Any OBR with a value of "G" in OBR-11 or a value in OBR-26, henceforth referred to as the Child OBR, SHALL be successfully matched to an OBX segment within the previously identified Parent Order Observation Group in the following ways:

The child OBR-26.1 (Parent Observation Identifier) is valued the same as the Parent OBX-3 value (taking into account the conversion of component delimiters into sub-component delimiters.)

AND

The child OBR-26.2 (Parent Observation Sub-Identifier) is valued the same as the Parent OBX-4 (Observation Sub-Identifier) value (taking into account the conversion of component delimiters into sub-component delimiters.)

Examples conforming to **LRI-43** and **LRI-57** can be found in Section 12.2.5 Examples of Culture and Susceptibility Results

8.9.2 RESULTS HANDLING AND RESULT COPIES TO

In this Implementation Guide OBR-28 (Result Copies to) is populated based on the value in OBR-49 (Result Handling) based on two values 'BCC' (Blind copy) and 'CC' (Copy to) in OBR-49. When the order is submitted to the laboratory, the Ordering Provider includes the

identifier (typically the NPI) and the name of the colleagues (up to five[10]) that the provider would like to also receive the patient's results. For information about who is authorized to receive laboratory result reports see Section 13.1.4 Authorized Parties

When the laboratory prepares the report, the one sent back to the original ordering provider will include in OBR-28 all the copy to colleagues that were requested to receive the reports and the flag in OBR-49 will be set as 'CC'.

For all other reports, defined as the blind copy to, the receiving colleague will get the report with OBR-28 containing only the colleague's information and OBR-49 will have 'BCC'.

Example: Physician_1 orders a CBC and Electrolytes for a patient. Because Physician_1 intends to go on vacation starting tomorrow and three other colleagues have agreed to a rotating coverage, Physician_1 requests that the lab also report the results to Colleague_A, Colleague_B and Colleague_C. This will create four reports with unique values in OBR-28 and OBR-49 as noted below:

TABLE 8-12. OBR-16, -28, -49 EXAMPLES

Report	OBR-16	OBR-28	OBR-49
Primary report	Physician_1	Colleague_A, _B, _C	CC
Copy to report to Colleague_A	Physician_1	Colleague_A	BCC
Copy to report to Colleague_B	Physician_1	Colleague_B	BCC
Copy to report to Colleague_C	Physician_1	Colleague_C	BCC

8.9.3 RELATIONSHIP BETWEEN OBR-25 (RESULT STATUS) AND OBX-11 (OBSERVATION RESULTS STATUS)

The OBR-25 (Result Status) is a summary of the OBX-11 statuses that follow the OBR. This is most easily understood in the case where an OBR contains only one OBX with an 'F' (Final), one would naturally expect the OBR-25 value to be 'F' (Final) as well. This guide will prescribe the expected OBR-25 value given multiple and various combinations of OBX-11 values.

Before we can discuss how OBR-25 is derived from the OBX-11 values we must first examine the value set for OBR-25, and understand in what order the values can (or cannot) transition from one value to the same or another value in a series of transactions. That is described in the following section.

8.9.3.1 ALLOWED RESULT STATUS (OBR-25) TRANSITIONS

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

How to Read This Table

[10] More than five recipients can be sent as part of an order see the Laboratory Orders IG - LOI_RC_Component (Results Copies).

First row: An existing OBR-25 valued 'I' (In Process) can take on the following values in a subsequent transaction: 'I' (In Process), 'A' (Partial), 'P' (Preliminary), 'F' (Final) or 'X' (No Results Available, Order Canceled). It cannot be changed to 'M' (Corrected, not final) or 'C' (Corrected, final).

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

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

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

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

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

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

Table Legend

Not Allowed
A=Allowed

TABLE 8-13. ALLOWED OBR-25 TO OBR-25 TRANSITIONS

From OBR-25 (existing result)		To OBR-25						
		I	A	P	F	M (2)	C	X
I	Incomplete	A	A	A	A			A
A	Partial		A	A	A	A	A	
P	Preliminary		A	A	A	A	A	
F	Final				A (1)		A	
M (2)	Corrected, not final					A	A	
C	Corrected, final						A	

TABLE 8-13. ALLOWED OBR-25 TO OBR-25 TRANSITIONS								
From OBR-25 (existing result)		To OBR-25						
		I	A	P	F	M [2]	C	X
X	No Results Available, Order Canceled							A

Notes

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

(2) This value has been added to the HL70123_USL value set.

Example: If an ORC/OBR has been reported with an OBR-25 status of F (Final), then the next time it is reported with any changes, the allowed OBR-25 status may be 'F' or 'C', but not 'I', 'A', 'P', or 'X' – see row 4 for this example.

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

The previous section addressed the transitional state of the OBR-25, this section will prescribe how the OBR-25 is to be valued when multiple and varying OBX-11 values exist under the respective OBR segment.

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

How to Read This Table

1.) The combination of OBX-11 values determines the allowable OBR-25 value.
2.) When viewing the possible OBR-25 values (column), the value is only valid if there is an OBX-11 status that is marked 'R'.
3.) The status of the report is indicated in OBR-25 status. Only certain OBX-11 combinations are allowed for specific OBR-25 values.
    a. For example the OBR-25 value 'M' requires that at least one of the OBX-11 is valued 'C', 'A', or 'B' as well as at least another, that is valued either 'I' or 'P'. If there are multiple OBX segments and their OBX-11 values are limited to only 'P' and 'I', the table below shows that this combination matches the OBR-25 values of 'P' and 'M', but the absence of any OBX-11 valued with 'C', 'A', or 'B' prohibits the use of the value 'M', thus making the correct OBR-25 value 'P'.

First column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where all OBXs have OBX-11 valued 'I'. The status for the order in OBR-25 shall be 'I' indicating work in progress, without available results.

Second column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'F' and the other OBXs have a status of 'I'. None of the OBXs have an OBX-11 status of 'P', 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'A' indicating a partial report.

Third column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'P' and the other OBXs are valued either 'F' or 'I'. None of the OBXs have an OBX-11 status of 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'P' indicating a preliminary report.

Fourth column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'F'. None of the OBXs have an OBX-11 status of 'I', 'P', 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'F' indicating a final report.

Fifth column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI where one or more OBX has OBX-11 valued 'C', 'A', 'B' or 'W'. At least one of the other OBXs has a status indicating either a 'P' or 'I'. The status for the order in OBR-25 shall be 'M', indicating a correction in a partial or preliminary report.

Sixth column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'C', 'A', 'B' or 'W'. **No** OBX has a status indicating either a 'P' or 'I'. The status for the order in OBR-25 shall be 'C' indicating a correction in a final report.

Seventh column: An order (ORC/OBR) with multiple analytes (OBXs) is reported via LRI, where one or more OBX has OBX-11 valued 'N', 'D' or 'X'. None of the OBXs have an OBX-11 status of 'I', 'P', 'F', 'C', 'A', 'B', or 'W'. The status for the order in OBR-25 shall be 'X' indicating a cancelation of the order.

Table Legend

Not Allowed
A=Allowed
R=Required

TABLE 8-14. REQUIRED/ALLOWED OBX-11, AND OBR-25 VALUES IN SAME ORDER

From OBX-11		OBR-25						
		I	A	P	F	M	C	X
		Incomplete	Partial	Preliminary	Final	Corrected, Not Final	Corrected, Final	Results Available, Order Cancelled
I	In Process	R	R	A		R (3)		
P	Preliminary			R		R (3)		
F	Final		A (1)	A	R	A	A	

TABLE 8-14. REQUIRED/ALLOWED OBX-11, AND OBR-25 VALUES IN SAME ORDER								
From OBX-11		OBR-25						
		I	A	P	F	M	C	X
		Incomplete	Partial	Preliminary	Final	Corrected, Not Final	Corrected, Final	Results Available, Order Cancelled
C	Corrected					R (1)	R (1)	
A	Amended					R (1)	R (1)	
B	Appended					R (1)	R (1)	
N (2)	Not Asked		A (1)	A	A	A	A	A
X (2)	Not Possible		A (1)	A	A	A	A	A
D (2)	Delete	A	A	A	A	A	A	A
W	Wrong					R (1)	R (1)	

Notes

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

(2) OBX-11 values 'N', 'X', and 'D' are allowed on several message types but are irrelevant to the determination of OBR-25 unless all OBX-11s consist of a combination of the three. In that case the value of OBR-25 will be 'X'.

(3) Requires at least one of the OBXs present under the OBR to be valued either 'I' or 'P' in OBX-11 to affect the order level result status

Conformance Statements for LRI_Common_Component

Deprecated March 29, 2016

~~**LRI-58:** Any OBR-25 valued 'I' with any related OBX-11 not valued 'I'or 'D' **SHALL** be a hard error.~~

~~**LRI-59:** Any OBR-25 valued 'A' without any related OBX-11 valued 'F', 'N' or 'X' **SHALL** be a hard error.~~

~~**LRI-60:** Any OBR-25 valued 'A' without any related OBX-11 valued 'I' **SHALL** be a hard error.~~

~~**LRI-61:** Any OBR-25 valued 'A' with any related OBX-11 valued 'P', 'C', 'A', 'B' or 'W' **SHALL** be a hard error.~~

~~**LRI-62:** Any OBR-25 valued 'P' without any related OBX-11 valued 'P' **SHALL** be a hard error.~~

~~**LRI-63:** Any OBR-25 valued 'P' with any related OBX-11 valued 'C', 'A', 'B' or 'W' **SHALL** be a hard error.~~

~~**LRI-64:** Any OBR-25 valued 'F' without any related OBX-11 valued 'F' **SHALL** be a hard error.~~

~~**LRI-65:** Any OBR-25 valued 'F' with any related OBX-11 valued 'I', 'P', 'C', 'A', 'B' or 'W' **SHALL** be a hard error.~~

~~**LRI-66:** Any OBR-25 valued 'M' without any related OBX-11 valued 'C', 'A', 'B', or 'W' **SHALL** be a hard error.~~

~~**LRI-67:** Any OBR-25 valued 'M' without any related OBX-11 valued 'I' or 'P **SHALL** be a hard error.~~

~~**LRI-68:** Any OBR-25 valued 'C' without any related OBX-11 valued 'C', 'A', 'B' or 'W' **SHALL** be a hard error.~~

~~**LRI-69:** Any OBR-25 valued 'C' with any related OBX-11 valued 'I' or 'P' **SHALL** be a hard error.~~

~~**LRI-70:** Any OBR-25 valued 'X' with any related OBX-11 value except for 'D', 'N' or 'X' **SHALL** be a hard error.~~

LRI-74: If OBR-25 is valued 'I' then all occurrences of OBX-11 within the same Order-Observation group SHALL be valued 'I'or 'D'.

LRI-75: If OBR-25 is valued 'A' then at least one occurrence of OBX-11 within the same Order-Observation group SHALL be valued 'F', 'N' or 'X'.

LRI-76: If OBR-25 is valued 'A' then at least one occurrence of OBX-11 within the same Order-Observation group SHALL be valued 'I'.

LRI-77: If OBR-25 is valued 'A' then an occurrence of OBX-11 within the same Order-Observation group SHALL NOT be not valued 'P', 'C', 'A', 'B' or 'W'.

LRI-78: If OBR-25 is valued 'P' then at least one occurrence of OBX-11 within the same Order-Observation group SHALL be valued 'P'.

LRI-79: If OBR-25 is valued 'P' then an occurrence of OBX-11 within the same Order-Observation group SHALL NOT be not valued 'C', 'A', 'B' or 'W'.

LRI-80: If OBR-25 is valued 'F' then at least one occurrence of OBX-11 within the same Order-Observation group SHALL be valued 'F'.

LRI-81: If OBR-25 is valued 'F' then an occurrence of OBX-11 within the same Order-Observation group SHALL NOT be not valued 'I', 'P', 'C', 'A', 'B' or 'W'.

LRI-82: If OBR-25 is valued 'M' then at least one occurrence of OBX-11 within the same Order-Observation group SHALL be valued 'C', 'A', 'B', or 'W'

LRI-83: If OBR-25 is valued 'M' then at least one occurrence of OBX-11 within the same Order-Observation group SHALL be valued 'I' or 'P.

LRI-84: If OBR-25 is valued 'C' then at least one occurrence of OBX-11 within the same Order-Observation group SHALL be valued 'C', 'A', 'B' or 'W'.

LRI-85: If OBR-25 is valued 'C' then an occurrence of OBX-11 within the same Order-Observation group SHALL NOT be not valued 'I' or 'P'.

LRI-86: If OBR-25 is valued 'X' then all occurrences of OBX-11 within the same Order-Observation group SHALL be valued 'D', 'N' or 'X'.

8.10 TQ1 – Timing/Quantity Segment

TABLE 8-15. TIMING/QUANTITY SEGMENT FOR ORDER GROUP

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID - TQ1	SI	R	[1..1]		
2	Quantity		O			
3	Repeat Pattern		O			
4	Explicit Time		O			
5	Relative Time and Units		O			
6	Service Duration		O			
7	Start date/time	TS_06	RE	[0..1]		The start date should be the expected date the order should begin or the anticipated date when the order will be fulfilled by the patient arriving at the Patient Service Center (PSC). If this is a future order this should have a date, otherwise it may be empty. A future order is an order with a start date/time where that start date/time indicates the earliest time the specimen can be collected. Leaving this field empty would indicate the earliest available date or when the patient arrives to have specimen drawn.
8	End date/time	TS_06	RE	[0..1]		The latest date and time by which the specimen should be collected.
9	Priority	CWE_02	R	[1..1]	HL70485_USL	
10	Condition text		O			
11	Text instruction		O			
12	Conjunction		X			Excluded for this Implementation Guide, see Section 1.3.1
13	Occurrence duration		O			
14	Total occurrence's		O			

Usage Note

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

Conformance Statements: Base Profile

LRI-44: The value of TQ1-1 (Set ID – TQ1) **SHALL** be valued '1'.

8.11 OBX – Observation/Result Segment

Note: Components 26-30 are pre-adopted from V2.8.2

TABLE 8-16. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – OBX	SI	R	[1..1]		
2	Value Type	ID	C(R/X)	[0..1]	HL70125_USL	Condition Predicate: If OBX-5 (Observation Value) is valued. This field identifies the data type used for OBX-5.
3	Observation Identifier	CWE_01	R	[1..1]	Logical Observation Identification Name and Codes (LOINC)	LOINC shall be used as the standard coding system for this field if an appropriate LOINC code exists, i.e., the LOINC concept is available in the LOINC database, accurately represents the observation, and has a status that allows its use. The status of the LOINC code (i.e. Active, Discouraged, Trial) is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. If a local coding system is in use, a local code should also be sent to help with identification of coding issues. When no valid LOINC exists the local code may be the only code sent. When populating this field with values, this guide does not give preference to the triplet in which the standard (LOINC) code should appear.
4	Observation Sub-ID	Varies	C(R/RE)	[0..1]		LRI_CG_Component Data Type: OG_02 All others data type is OG_01 Condition Predicate: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 (Observation Identifier) values for (OBX-3.1 (Identifier) and OBX-3.3 (Name of Coding System)) or (OBX-3.4 (Alternate Identifier) and OBX-3.6 (Name of Alternate Coding System)). **Note:** The data type is pre-adopted from V2.8.2.
5	Observation Value	Varies	RE	[0..1]		**Note:** If value is coded, ST should not be used. See Section 10.2 SNOMED CT for guidance on how to value this field for Microbiology.
6	Units	CWE_03	Varies	[0..1]		LRI_PH_Component Usage: 'C(R/RE)'; Condition Predicate: If OBX-2 (Value Type) is valued 'NM' or 'SN' and OBX-11 is not valued 'X' or 'N'. **Note:** If there is not a unit of measure available while the Condition Predicate is True, the value "NA" shall be used in CWE_03.1 (Identifier) and "HL70353" in CWE_03.3 (Name of Coding System). Usage for all other components: 'RE' See Section 10.4 UCUM

TABLE 8-16. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
7	References Range	ST	RE	[0..1]		Guidance: It is not appropriate to send the reference range for a result only in an associated NTE segment. It would be appropriate to send additional information clarifying the reference range in an NTE associated with this OBX.
8	Abnormal Flags	Varies	RE	[0..*]	HL70078_USL	LRI_PH_Component Data Type: 'CWE_03'; CWE data type is pre-adopted from HL7 v2.7. All other profiles Data Type: 'IS' LRI_PH_Component Value Set: HL70078_USL (V2.7.1) All other profiles Value Set: Extended HL70078_USL (V2.5.1) This field will be populated from Table 0078 when appropriate. Therefore, if a laboratory populates OBX-8 with a coded interpretation, regardless of the coded interpretation sent, the EHR shall consume and display it. Microbiology example: Ceftazidime susceptibility (LOINC 133-9) value =|<=^1|, units = ug/ml, Abnormal flag = S
9	Probability		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
10	Nature of Abnormal Test		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
11	Observation Result Status	ID	R	[1..1]	HL70085_USL	
12	Effective Date of Reference Range		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
13	User-Defined Access Checks		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
14	Date/Time of the Observation	Varies	RE	[0..1]		LRI_PH_Component Data Type: 'TS_12' LRI_PH_Component: The date/time testing was performed should be reported in OBX-19 (Date/Time of the Analysis) All other components Data Type: 'TS_06' For specimen-based test, if OBX-14 (Date/Time of Observation) is valued it must be the same as SPM-17.1 (Range Start Date/Time). If SPM-17.2 (Range End Date/Time) is present and relates to the same observation, then OBX-14 must be within the DR range.

TABLE 8-16. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
15	Producer's Reference		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
16	Responsible Observer		Varies	Varies		LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
17	Observation Method	Varies	Varies	Varies		LRI_PH_Component Data Type: 'CWE_03'; Usage: 'RE'; Cardinality: [0..1]; Value Set: HL7 V3 Observation Method and/or SNOMED CT Procedure Hierarchy. Usage for all other components: 'O'
18	Equipment Instance Identifier		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
19	Date/Time of the Analysis	TS_08	RE	[0..1]		Be as precise as appropriate and available.
20	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1.
21	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1.
22	Reserved for harmonization with Version 2.6.		X			Excluded for this Implementation Guide, see Section 1.3.1.
23	Performing Organization Name	Varies	C(R/O)	[1..1]		Condition Predicate: If OBX-29 (Observation Type) is valued "RSLT" LRI_PH_Component Data Type: XON_03 All other components: GU data type: XON_01 NG data type: XON_02 The information for producer ID is recorded as an XON data type.
24	Performing Organization Address	XAD_01	C(R/O)	[1..1]		Condition Predicate: If OBX-29 (Observation Type) is valued "RSLT"
25	Performing Organization Medical Director	Varies	C(RE/O)	[0..1]		Condition Predicate: If OBX-29 (Observation Type) is valued "RSLT" LRI_PH_Component: Data type: XCN_01 All other components: GU data type: XCN_01 NG data type: XCN_02

TABLE 8-16. OBSERVATION RESULT SEGMENT (OBX)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
26	Patient Results Release Category		O			
27	Root Cause		O			
28	Local Process Control		O			
29	Observation Type	ID	R	[1..1]	HL70936_USL	**Note:** This field is pre-adopted from v2.8.2.
30	Observation Sub-Type	ID	RE	[0..1]	HL70937_USL	**Note:** This field is pre-adopted from v2.8.2.
31	Action Code	ID	O			
32	Observation Value Absent Reason	CWE_04	C(R,X)	[0..*]	HL70960	**Note:** This field is pre-adopted from V2.9. Condition Predicate: If OBX-11 (Observation Result Status) is valued "X" or "D"

Usage Note

OBX-17 (Observation Method) can further specify information about the specific method to a more granular level than what is defined by the LOINC used in OBX-3 (Observation Identifier). There are two vocabularies available for use at this time, SNOMED CT procedure hierarchy codes and V3 Observation Method codes, and work to make these more complete as well as to provide a cross-map between them is in development.

OBX-30 (Observation Sub-Type) shall be used for every OBX segment:

- Representing an Ask-at-Order Entry or Ask-at-Specimen Collection answers, where OBX-29 is QST.
- Reporting on micro related results (isolates, susceptibilities, and associated observations), where OBX-29 (Observation Type) is RSLT Result.

LRI_PH_Component

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

OBX-3 - Observation Identifier – For Ask at Order Entry (AOE) questions refer to Section 13.3.

OBX-5 - Observation Value – For coded lab test results SNOMED CT shall be used as the standard coding system for this field if an appropriate SNOMED CT code exists. For Ask at Order Entry (AOE) questions refer to Section 13.3.

Conformance Statements: Base Profile

LRI-45: The value of OBX-5 (Observation Value) **SHALL NOT** be truncated.

LRI-46: The value of OBX-1 (Set ID – OBX) **SHALL** be valued sequentially starting the value '1' within a given segment group.

LRI-47: If there are multiple OBX segments associated with the same OBR segment that have the same OBX-3 (Observation Identifier) values for OBX-3.1 (Observation Identifier.Identifier) + OBX-3.3 (Observation Identifier.Name of Coding System) or OBX-3.4 (Observation Identifier.Alternate Identifier) + OBX-3.6 (Observation Identifier.Name of Alternate Coding System), a combination of (OBX-3.1 + OBX3.3) or (OBX-3.4 + OBX-3.6) and OBX-4 **SHALL** create a unique identification under a singl**e** OBR**.**

LRI-48: If OBX-2 (Value Type) is valued, then the data type format for OBX-5 (Observation Value) **SHALL** conform to the corresponding constrained data type identified in the "comment" column of HL70125_USL.

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

Conformance Statements: LRI_PH_Component

LRI-PH-94: OBX-5 (Observation Value) **MUST** be valued if OBX-8 (Abnormal Flags) is empty and OBX-11 (Observation Result Status) is not valued ‘X’ or ‘N’.

LRI-PH-95: OBX-8 (Abnormal Flags) **MUST** be valued If OBX-5 (Observation Value) is empty and OBX-11 (Observation Result Status) is not valued ‘X’ or ‘N’.

LRI-PH-96: OBX-14 (Date/Time of the Observation) For observation related to testing of specimen (OBX's following the OBR), **SHALL** be identical to an occurrence of SPM-17.1 (Range Start Date/Time) value within the same ORDER_OBSERVATION Group.

8.11.1 OBSERVATION IDENTIFIERS, OBSERVATION VALUES, INTERPRETATIONS AND COMMENTS

Laboratory results fall into several broad categories or types of results. The first type of result is a quantitative measure of some property of a specimen and is typically numerical in nature. Often these numeric results are also associated with some sort of interpretation, typically in terms of the normality or abnormality of the measured quantity in relationship to a reference range or normal range. Another type of result is a qualitative result related to the testing of a specimen. This is typically coded or textual in nature. Qualitative results may actually be interpretations of more detailed quantitative measurement (see Section 13.2 CLSI Definitions – Quantitative, Semi-quantitative, Qualitative Results). Both quantitative and qualitative results may have comments associated with them (usually delivered in NTE segments.) These comments may provide additional clarification, information regarding how the result was obtained, etc.

LOINC shall be used as the standard coding system for this field if an appropriate LOINC code exists, i.e., the LOINC concept is available in the LOINC database, accurately represents the observation, and has a status that allows its use. The status of the LOINC code (i.e. Active, Discouraged, Trial) is defined in the LOINC Users' Guide Section 11.2 Classification of LOINC Term Status. LOINC identifiers can easily be classified as quantitative or qualitative. The LOINC scale QN (quantitative) indicates that the LOINC identifier is quantitative. All other LOINC identifiers can be treated as qualitative for the purpose of this discussion. Those OBX’s associated with quantitative LOINC identifiers should be using OBX-5 with either the NM (numeric), SN_01 (structured numeric), TS (timestamp), DT (date) or TM (time) data types. These quantitative results are usually accompanied by a simple interpretation. Coded interpretations should be reported using OBX-8 (abnormal flags) when the values have been drawn from HL70078_USL.

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

a) Ordinal (ORD): OBX-3 observations with qualitative LOINC test codes using ordinal result scales may fully specify the analyte/component measured in OBX-3, thus only requiring a ranked ordered set of answers such as reactive, weakly reactive, non-reactive or a “Presence/Absence” code to fully specify the observation.

b) Nominal (NOM): OBX-3 observations with "presence or identity" LOINC test codes using nominal result scales to fully specify the observation.

    - Bacterial cultures may require a SNOMED CT concept from the "organism" hierarchy

c) Narrative (NAR): OBX-3 observations with narrative LOINC test codes use ST or TX data type in OBX-5.

d) Ordinal or Quantitative (OrdQn): This type is used by Susceptibility tests that may be reported as qualitative (i.e. susceptible, resistant) or as quantitative, numeric results (e.g. Minimum Inhibitory Concentration MIC).

In laboratory test result reporting, the LOINC code in OBX-3 describes what is being tested for and the value (result) in OBX-5 answers either the question of what was found or how much of it. So in chemistry, the serum glucose test answers the how much of it question; telling you how much glucose the serum contains. Microbiology is more interested in the “what was found” kind of questions mostly, what organisms(s) were found. Two different categories of “what was found tests” exist.

The first category of targets only a single organism or species and reports only whether that organism or species was found in the specimen. The name of that target organisms is carried in the analyte part of the LOINC name and the Scale of the LOINC name will be ordinal (ORD). These tests targeted towards identification of a specific organism are typically immuno assays, nucleic acid tests or organism specific cultures and they can only speak to whether the targeted organisms was found or not. So the value of the test would be reported in OBX-5 with SNOMED CT codes of detected/not detected or some analogous SNOMED CT codes. Some ordinal tests may also report codes for equivocal or other such codes between detected and not detected for which SNOMED CT codes should also be used.

The second category carries tests that can detect many different organisms from within a class of organisms and the OBX-5 reports which of these organisms were detected (if any). In this case the analyte part of the LOINC name is at a broader level than individual species, e.g. Bacteria identified, the LOINC scale is “nominal” (NOM), which means, roughly, that the test reports “names” of things. The LOINC name can include further constrains identifying the method and or the system. A good example is the blood culture. The results of blood cultures will be reported as SNOMED CT codes that name the organism(s) that grew in the blood culture, or “no growth” (or something similar), when nothing grew as the final results. We have oversimplified a bit in this example, because blood cultures will report preliminary results such as “no organisms detected after 24 hours”, and early indications of the kinds of organisms that are growing, e.g., gram positive cocci; these findings would also be reported using appropriate SNOMED CT codes.

The above discussion has focused on actual clinical findings, whether they are quantitative or qualitative. Often, additional clarifying documentation is sent along with the clinical findings. Depending on the content, these should be handled either as additional OBX segments grouped together or as comments, conveyed in one or more NTE segment(s) following the OBX in question.

Additional OBXs can cover coded information:

- Ask at Order entry questions needed to properly interpret the result

- Reference Sequences used in genetic testing

Comments typically fall into the following categories:

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

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

TABLE 8-17. OBSERVATION IDENTIFIERS

Testing Situation Discussion	OBX-2 Observation Type	OBX-3 Observation Identifier: LOINC part = scale	OBX-5 Observation value	OBX-6 Units	OBX-7 Reference Range	NTE Segment
Numeric result	NM	QN	number	Should be populated.	Should be populated	May be populated with comments, not clinical findings.
Numerical intervals, ratios, inequalities	SN	QN	structured numeric	May be populated.	May be populated	May be populated with comments, not clinical findings.
Time like quantitative result	TM, DT, DTM	QN	timestamp, time or date	May be empty.	May be populated	May be populated with comments, not clinical findings.
Conveys ordinal value	CWE	ORD	Ordinal as a code using CWE_01. For receivers: SNOMED CT SHALL be supported when received. For senders: SNOMED CT SHOULD be used for Microbiology results at a minimum, and other coded results as negotiated with trading partners; otherwise a local code.	Should be empty.	May be populated	May be populated with comments, not clinical findings.
Conveys ordinal value	SN	ORD	Ordinal as structured numeric	May be populated.	Required	May be populated with comments, not clinical findings.

TABLE 8-17. OBSERVATION IDENTIFIERS						
Testing Situation Discussion	OBX-2 Observation Type	OBX-3 Observation Identifier: LOINC part = scale	OBX-5 Observation value	OBX-6 Units	OBX-7 Reference Range	NTE Segment
Conveys observation	CWE	NOM	Coded observation using CWE_01. For receivers: SNOMED CT SHALL be supported when received. For senders: SNOMED CT SHOULD be used for Microbiology results at a minimum, and other coded results as negotiated with trading partners; otherwise a local code.	Empty	May be populated	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	NAR	Text LRI_PH_Component senders: do not use string or text for results that are capable of being represented as SNOMED-CT coded values.	Empty	May be populated	May be populated with comments, not clinical findings.
Conveys numeric or ordinal value	NM	ORDQN	Number	May be populated.	May be populated	May be populated with comments, not clinical findings.

TABLE 8-17. OBSERVATION IDENTIFIERS						
Testing Situation Discussion	OBX-2 Observation Type	OBX-3 Observation Identifier: LOINC part = scale	OBX-5 Observation value	OBX-6 Units	OBX-7 Reference Range	NTE Segment
Conveys numeric or ordinal value	CWE	ORDQN	Ordinal as a code using CWE_01. For receivers: SNOMED CT SHALL be supported when received. For senders: SNOMED CT SHOULD be used for Microbiology results at a minimum, and other coded results as negotiated with trading partners; otherwise a local code.	Empty	May be populated	May be populated with comments, not clinical findings.
Conveys observation	FT, TX or ST	MULTI	text	Empty	May be populated	May be populated with comments, not clinical findings.
Conveys imbedded object (ED) or pointer to object (RP)	ED, RP	*	Object pointer or imbedded object	Empty	[empty]	May be populated with comments, not clinical findings.

Usage Note

This guide **recommends** the use of SNOMED CT for senders, with a reminder, that a future release of this guide will require the use of SNOMED CT for result reporting.

If either OBX-3.3 or OBX-3.6 is 'LN' (LOINC) then the data type identified in OBX-2 should be drawn from Table 8-18. Data Types for LOINC Scale Part based on the LOINC Scale Part of the code in OBX-3.1 or OBX-3.4, except when OBX-11 equals 'X' or 'N'.

* At this time it is not yet clear how LOINC supports inclusion of documents. We anticipate having clarity by the time this document is moved to a normative state.

TABLE 8-18. DATA TYPES FOR LOINC SCALE PART	
LOINC Scale Part	OBX-2 Value Type
QN - Quantitative	NM, SN, TS, TM, DT
ORD - Ordinal	CWE, SN
NOM – Nominal	CWE
NAR – Narrative	ED, FT, TX or ST
ORDQN - Quantitative or Ordinal	NM, SN, TS, TM, DT, CWE
MULTI - Multi	FT, TX or ST
DOC	ED

The scale of the LOINC code used in OBX-3 (Observation Identifier) prescribes what kinds of values are expected to be used in OBX-5 (Observation Value). For each instance OBX-2 (Value Type) will be populated with the respective code drawn from value set HL70125_USL. The data type flavor to be used in OBX-5 (Observation Value), if not the one defined by the base standard, is specified in the comment column of that value set table.

LRI_PH_Component

For coded test results SNOMED CT **shall** be used, if a suitable code exist.

8.11.2 GROUPING OF RELATED OBX SEGMENTS

Groups are a specific collection of OBX segments that are reported in a pre-determined sequence for display or processing order within the Group. Starting with V2.8.2 a new OG (Observation Grouper) data type was created and OBX-4 (Observation Sub-ID) data type was changed from ST to OG to enable improved structured grouping of observation segments. This IG is pre-adopting this data type for use in OBX-4 (Observation Sub-ID) as the OG_01 flavor.

Group Identification – where grouping is important, a unique identifier (in OBX-4) that declares membership in a group.

- OG_01-1 remains the ST data type for backwards compatibility.
- OG_01-2 (NM) identifies the group and sequence within the OBR.
- OG_01-3_01 (NM) Sequence within a Group – Individual OBXs within the group should have the means to declare an unambiguous sequence in which they should be processed, validated, displayed or for any other reason the sender and receiver may have negotiated.
- OG_01-4_01 (NM) An optional identifier to a result component. For example, an isolate identifier in a microbiology message.

Uniqueness – OBX-4 is the location to declare a unique identifier, OG_01.2 and OG_01.3 plus OBX-3.1 will provide uniqueness.

In addition to the grouping structure, OBX-29 Observation Type and as needed OBX-30 Observation Sub-Type can further clarify the purpose of the OBX in such a structure (although we note that both OBX-29 and as needed OBX-30 are used outside grouping as well). The following example will include that aspect as well.

Example: Grouping with sequence declared and isolates identified using the OG_01 data type in OBX-4.

Note: For an example showing the parent child structure in more detail see Section 12.1.1 Parent/Child Linking.

Test: Culture, Respiratory with antibiotic sensitivities

Specimen: Sputum

Gram Stain: Many WBCs

Moderate Gram Positive Rods

Moderate Gram Positive Cocci in chains

Many Gram Negative Rods

Many Gram Positive Cocci in Clusters

Culture Result: Moderate Growth Normal Respiratory Flora

Isolate 1: Heavy Growth

Klebsiella pneumonia

Sensitive to Ampicillin, Ciprofloxacillin and Gentamicin

Isolate 2: Heavy Growth

Staphylococcus aureus

Sensitive to Ampicillin, Ciprofloxacillin and Gentamicin

```
...(Parent Respiratory Culture ORC/OBR Group)
OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM
   STAIN|^1^1|MNY^Many^99LAB^...|RSLT|MSS|
OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM
   STAIN|^1^2|WBCS^WBCS^99LAB^...|RSLT|MSS|
OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM
   STAIN|^2^1|MOD^Moderate^99LAB^...|RSLT|MSS|
```

```
OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM STAIN|^2^2|GPR^Gram Positive
  Rods^99LAB^ 83514008^ Gram-positive bacillus (organism)^SCT^...|RSLT|MSS|
OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM
  STAIN|^3^1|MOD^Moderate^99LAB^...|RSLT|MSS|
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM STAIN|^3^2|GPCCH^Gram Positive
  Cocci in chains^99LAB^61609004^Gram-positive cocci in chains (finding)^SCT^...|RSLT|MSS|
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM
  STAIN|^4^1|MNY^Many^99LAB^...|RSLT|MSS|
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM STAIN|^4^2|GNR^Gram Negative
  Rods^99LAB^...|RSLT|MSS|
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM
  STAIN|^5^1|MNY^Many^99LAB^...|RSLT|MSS|
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^99LAB^^^GRAM STAIN|^5^2|GPCCL^Gram Positive
  Cocci in clusters^99LAB^...|RSLT|MSS|
OBX|11|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^6^1|263812008^Moderate
  growth^SCT^...|RSLT|MIG|
OBX|12|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^6^2|23506009^Normal flora^SCT^...|RSLT|MCS|
OBX|13|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^7^1^1|655938018^Heavy
  growth^SCT^...|RSLT|MIC|
OBX|14|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^7^2^1|56415008^Klebsiella
  pneumonia^SCT^...|RSLT|MIN|
OBX|15|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^8^1^2|655938018^Heavy
  growth^SCT^...|RSLT|MIG|
OBX|16|CWE|624-7^Bacteria Spt Resp Cul^LN^...|^8^2^2|3092008^Staphylococcus
  aureus^SCT^...|RSLT|MIN|
...(Child Klebsiella Sensitivity ORC/OBR Group)
OBX|1|SN|28-1^ Ampicillin Islt MIC ^LN^...|^1^1^1|<^0.06|ug/mL^^UCUM^...|RSLT|SUR|
OBX|2|SN|185-9^ Ciprofloxacin Islt MIC ^LN^...|^1^2^1|<^0.05|ug/mL^^UCUM^...|RSLT|SUR|
OBX|3|SN|267-5^Gentamicin Islt MIC^LN^...|^1^3^1|<^0.05|ug/mL^^UCUM^...|RSLT|SUR|
...(Child Staphylococcus Sensitivity ORC/OBR Group)
```

```
OBX|1|SN|28-1^ Ampicillin Islt MIC ^LN^...|^1^1^2|<^0.06|ug/mL^^UCUM^...|RSLT|SUR|
OBX|2|SN|185-9^ Ciprofloxacin Islt MIC ^LN^...|^1^2^2|<^0.05|ug/mL^^UCUM^...|RSLT|SUR|
OBX|3|SN|267-5^Gentamicin Islt MIC^LN^...|^1^3^2|<^0.05|ug/mL^^UCUM^...|RSLT|SUR|
```

8.11.3 ALLOWED OBX-11 TRANSITIONS

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

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

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

How to Read This Table

First row: An existing OBX-11 valued 'I' can take on the following values in a subsequent transaction: 'I', 'P', 'F', 'N', 'X', 'D' or 'W'. It cannot be changed to 'C', 'A' or 'B'.

Second row: An existing OBX-11 valued 'P' can take on the following values in a subsequent transaction: 'P', 'F' or 'W'. It cannot be changed to 'I', 'C', 'A', 'B', 'N', 'X' or 'D'.

Third row: An existing OBX-11 valued 'F' can take on the following values in a subsequent transaction: 'F', 'C', 'A', 'B' or 'W'. It cannot be changed to 'I', 'P', 'N', 'X' or 'D'.

Fourth row: An existing OBX-11 valued 'C' can take on the following values in a subsequent transaction: 'C' or 'W'. It cannot be changed to 'I', 'P', 'F', 'A', 'B', 'N', 'X' or 'D'.

Fifth row: An existing OBX-11 valued 'A' can take on the following values in a subsequent transaction: 'C', 'A' or 'W'. It cannot be changed to 'I', 'P', 'F', 'B', 'N', 'X' or 'D'.

Sixth row: An existing OBX-11 valued 'B' can take on the following values in a subsequent transaction: 'C', 'A', B' or 'W'. It cannot be changed to 'I', 'P', 'F', 'N', 'X' or 'D'.

Seventh row: An existing OBX-11 valued 'N' can take on the following values in a subsequent transaction: 'N' or 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'X' or 'D'.

Eighth row: An existing OBX-11 valued 'X' can take on the following values in a subsequent transaction: 'X' or 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'N' or 'D'.

Ninth row: An existing OBX-11 valued 'D' can take on the following values in a subsequent transaction: 'D' or 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'X' or 'N'.

Ninth row: An existing OBX-11 valued 'W' can ONLY remain 'W'. It cannot be changed to 'I', 'P', 'F', 'C, 'A', 'B', 'X', 'N' or 'D'.

Table Legend

Not Allowed
A=Allowed

TABLE 8-19. ALLOWED OBX-11 TRANSITIONS

OBX-11 (existing result)		To OBX-11 (new result)									
		I	P	F	C	A	B	N	X	D	W
I	In Process	A	A	A				A	A	A	A
P	Preliminary		A	A							A
F	Final			A	A	A	A				A
C (1)	Corrected				A						A
A	Amended				A	A	A				A
B	Appended				A	A	A				A
N	Not Asked							A			A
X	Not Possible								A		A
D	Delete									A	A
W	Wrong										A

Notes

(1) Once Corrected, always Corrected – 'C' status can only progress to 'W'.

8.12 SPM – Specimen Segment

TABLE 8-20. SPECIMEN SEGMENT (SPM)

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

TABLE 8-20. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
2	Specimen ID	Varies	R	[1..1]		LRI_NDBS_Component: GU data type: EIP_04; NG data type: EIP_03 LRI_PH_Component: Data type: EIP_05. All other components: GU data type: EIP_01 NG data type: EIP_02
3	Specimen Parent IDs	Varies	RE	[0..*]		GU data type: EIP_01 NG data type: EIP_02
4	Specimen Type	CWE_03	R	[1..1]	SNOMED_CT_USL and/or HL70487_USL	Codes from either HL70487_USL or SNOMED_CT_USL Specimen hierarchy codes may be used. It should be noted that in the future SNOMED CT Specimen hierarchy may become the only recommended value set so trading partners should consider moving in that direction. LRI_NDBS_Component Value Set Fixed to: '440500007^Blood spot specimen^SCT'
5	Specimen Type Modifier	Varies	Varies	Varies	Varies	LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: 'CWE_03'; Usage: 'C(RE/X)'; Condition Predicate: If SPM-4.3 (Name of Coding System) or SPM-4.6 (Alternate Coding System ID) is valued 'SCT'.; Cardinality: [0..*]; Value Set: SNOMED_CT_USL Usage for all other components: 'O'
6	Specimen Additives	Varies	Varies	Varies	Varies	LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: 'CWE_03'; Usage: 'RE'; Cardinality: [0..*]; Value Set: SNOMED_CT_USL and/or HL70371_USL Usage for all other components: 'O'
7	Specimen Collection Method	Varies	Varies	Varies	Varies	LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: 'CWE_03'; Usage: 'RE'; Cardinality: [0..1]; Value Set: SNOMED_CT_USL and/or HL70488_USL. Usage for all other components: 'O'
8	Specimen Source Site	Varies	Varies	Varies	Varies	LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: CWE_03; Usage: 'RE'; Cardinality: [0..1]; Value Set: SNOMED_CT_USL. Usage for all other components: 'O'

TABLE 8-20. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
9	Specimen Source Site Modifier	Varies	Varies	Varies	Varies	LRI_NDBS_Component Usage: 'X' LRI_PH_Component Data Type: CWE_03; Usage: 'C(RE/X)'; Condition Predicate: If SPM-8.3 (Name of Coding System) or SPM-8.6 (Alternate Coding System ID) is valued 'SCT'.; Cardinality: [0..*]; Value Set: SNOMED_CT_USL Usage for all other components: 'O'
10	Specimen Collection Site		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
11	Specimen Role		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
12	Specimen Collection Amount		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
13	Grouped Specimen Count		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
14	Specimen Description		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
15	Specimen Handling Code		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
16	Specimen Risk Code		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
17	Specimen Collection Date/Time	DR_01	Varies	Varies		SPM-17.1 must use TS_12 for the data type definition. SPM-17.2 must use TS_06 for the data type definition. For specimen-based test, if only SPM-17.1 (Range Start Date/Time) is valued it must be the same as OBX-14 (Date/Time of the Observation). If both SPM-17.1 and SPM-17.2 (Range End Date/Time) are present and relates to the same observation, then OBX-14 must be within this DR_01 range. LRI_PH_Component Usage: 'R' Cardinality: [1..1] Usage for all other components: 'RE', Cardinality: [0..1]
18	Specimen Received Date/Time		Varies			LRI_PH_Component Data Type: 'TS_06'; Usage: 'R' Cardinality: [1..1] Usage for all other components: 'O'
19	Specimen Expiration Date/Time		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'

TABLE 8-20. SPECIMEN SEGMENT (SPM)						
SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
20	Specimen Availability		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
21	Specimen Reject Reason	CWE_03	RE	[0..*]	HL70490_USL	SPM-21 should not be interpreted as the cancel reason.
22	Specimen Quality		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
23	Specimen Appropriateness		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
24	Specimen Condition	CWE_03	RE	[0..5]	HL70493_USL	
25	Specimen Current Quantity		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
26	Number of Specimen Containers		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
27	Container Type		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
28	Container Condition		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
29	Specimen Child Role		Varies			LRI_NDBS_Component Usage: 'X' Usage for all other components: 'O'
30	Accession ID		O			**Note:** This field is pre-adopted from V2.7.1
31	Other Specimen ID	Varies	Varies	Varies		**Note:** This field is pre-adopted from V2.7.1. NDBS_Component: Datatype: CX_01 or CX_02, Usage: RE Cardinality: 0..*, Comment: When the State assigned Bloodspot card number is sent here SPM-31.5, drawn from HL70203 will be valued 'SNBSN'. Usage for all other components: O

Usage Note

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

LRI_NDBS_Component

SPM-2 - Specimen ID – SPM-2.1 corresponds to the State printed on filter paper card [Identifier] in NBS card (LOINC 57716-3). SPM-2.2 corresponds to the Lab Internal Identifier.

LRI_PH_Component

SPM-2 - Specimen ID – Unique identifier for the specimen as referenced by the Placer application, the Filler application, or both. Note that the specimen ID is not the same thing as the placer/filler order number. Order numbers identify the specific test to be performed on a specimen. A particular specimen may be associated with multiple orders (and multiple placer/filler order numbers). The specimen ID may be the same as an accession number, depending on how the particular lab assigns accession numbers.

SPM-4 - Specimen Type – The standard vocabulary for this field should be based upon the SNOMED CT Specimen hierarchy. Although it is not required to send information about the original specimen, when sending information, the original clinical specimen type/source (e.g. Stool) in SPM.4 is preferred over reporting a derivative of the specimen (e.g. an isolate, DNA, or RNA).

SPM-5 - Specimen Type Modifier – Modifiers or qualifiers for Specimen type. This allows use of post-coordinated expressions for specimen type.

SPM-8 - Specimen Source Site – Source from which the specimen was obtained. For biological samples, it represents the anatomical site from which the specimen was collected.

SPM-9 – Specimen Source Site Modifier –Topographical modifier (such as “left” or “right”) for the specimen source site (SPM-8). Only used if SPM-8 is a SNOMED code. This allows use of post-coordinated expression for specimen source site.

Conformance Statements: Base Profile

LRI-50: The value of SPM-1 (Set ID – SPM) **SHALL** be valued sequentially starting the value ‘1’ within a given segment group.

LRI-53: If one or more SPM segments are present for the same OBR, then the earliest SPM-17.1 (Range Start Date/Time) **SHALL** be equal to or before OBR-7 (Observation Date/Time) and OBR-7 (Observation Date/Time) **SHALL** be equal to or before the latest SPM-17.2 (Range End Date/Time).

LRI-54: If one or more SPM segments are present for the same OBR and if OBR-8 (Observation End Date/Time) is present, OBR-8 (Observation End Date/Time) **SHALL** be equal to or before the latest SPM-17.2 (Range End Date/Time).

LRI-71: SPM-2 shall not repeat with in a given order group.

Conformance Statements: LRI_NDBS_Component

LRI-NDBS-97: SPM-4.1 (Specimen Type.Identifier) **SHALL** contain the value ‘440500007’ drawn from the code system ‘SNOMED CT’.

LRI-NDBS-98: SPM-4.2 (Specimen Type.Text) **SHALL** contain the value ‘Blood spot specimen’ drawn from the code system ‘SNOMED CT’.

LRI-NDBS-99: SPM-4.3 (Specimen Type.Code System) **SHALL** contain the value ‘SCT’ drawn from the code system ‘HL70396’.

8.12.1 GUIDANCE FOR RESULT MESSAGES DESCRIBING SPECIMEN REJECTION REASON AND SPECIMEN CONDITION

SPM-21 can be used for communicating the specimen rejection reason in a codified manner. This IG has identified HL70490_USL as the value set for SPM-21, though the content needs improvement. The SNOMED finding hierarchy also has some appropriate terms, but is not complete. Future work on these vocabularies could expand the content. Disposition of the specimen is a CLIA requirement which needs to be retained and displayed in the patient record and incorporated into any type of report regardless of the medium of that report (paper, display on screen).

Use of SPM-24 can be very useful for communicating specimen condition information that does not meet the laboratory’s standard for acceptability (HL70493_USL). The SNOMED CT finding hierarchy also has some appropriate terms, but is not complete. Future work on these vocabularies could expand the content.

Since changes are needed to expand the current vocabularies and since SPM-21 and SPM-24 are only sufficient for conveying the cancelation reason when all analytes are cancelled for a single specimen related reason and only one specimen is present for the order, it will be necessary to use OBX-5 and NTE segment(s), which follow the same display/report rules as SPM-21, to convey the specimen rejection information.

If a test is not performed OBX-11 (Observation Result Status) MUST be valued 'X' (Results cannot be obtained) or 'N' (Not asked). OBX-5 (Observation Value) must contain either a code to indicate that the test could not be performed – for example SNOMED: 373121007^Test not done (qualifier value)^SCT, a flavor of null, or a string. OBX-32 (Observation Value Absent Reason) must contain the reason, which may be used to display instead of, or in addition to the OBX-5 (Observation Value) value. Note that the OBR -25 (Observation Status) value is dependent on all the OBX-11 values in the ORC/OBR pair.

The NTE immediately following that OBX may further describe the reason the test could not be performed.

Example cancellation message using OBX-32, the NTE segment, as well as SPM-21

```
MSH...
PID...
ORC...
OBR|1|15810^H_Dx_2_0|16699480030^MB|123^Erythrocyte sedimentation
  rate^L|||20110331150551-
  0800|||||||||^Smith^John||15810||008847||20110615102200|||F||||
OBX|1|NM|30341-2^Erythrocyte sedimentation rate^LN|||||||X|||20110331140551-
  0800||33445566^Levin^Henry^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^EN|||2011033115
  0551-0800||||Century Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|2070
  Test Park^^Los
```

```
   Angeles^CA^90067^^B|2343242^Knowsalot^Phil^J.^III^Dr.^^^&2.16.840.1.113883.3.72.5.30.1
   &ISO^L^^^DN||||RSLT|||373121007^Test not done^SCT^TNP^test not performed^L|
NTE|1||Blood in tube was clotted, resulting in a rejection of the specimen and leaving
   the lab unable to perform this test. Please resubmit a new specimen, if test is still
   desired.
SPM|1|S-2015-66&GoodHealthC_EHR&2.16.840.1.113883.3.72.5.24&ISO^S-9911-33&NIST Lab
   Filler&2.16.840.1.113883.3.72.5.25&ISO||119297000^BLD^SCT^BldSpc^Blood^99USA^^^Blood
   Specimen||||||||||||20110103143428||||RC^Clotting^HL70490^CLT^Clotted^99USA^^^Blood
   clotted in tube|||CLOT^Clotted^HL70493^CLT^Clotted^99USA^^^clotted blood
```

Example using OBX-32 and NTE segment for the same test, specimen and rejection reason

```
MSH...
PID...
ORC...
OBR|1|15810^H_Dx_2_0|16699480030^MB|123^Erythrocyte sedimentation
   rate^L|||20110331150551-
   0800|||||||||^Smith^John||15810||008847||20110615102200|||F||||
OBX|1|NM|30341-2^Erythrocyte sedimentation rate^LN|||||||X|||20110331140551-
   0800||33445566^Levin^Henry^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^EN|||2011033115
   0551-0800||||Century Hospital^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^XX^^^987|2070
   Test Park^^Los
   Angeles^CA^90067^^B|2343242^Knowsalot^Phil^J.^III^Dr.^^^&2.16.840.1.113883.3.72.5.30.1
   &ISO^L^^^DN||||RSLT|||373121007^Test not done^SCT^TNP^test not performed^L|
NTE|1||Blood in tube was clotted, resulting in a rejection of the specimen and leaving
   the lab unable to perform this test. Please resubmit a new specimen, if test is still
   desired.|
SPM|1|S-2015-66&GoodHealthC_EHR&2.16.840.1.113883.3.72.5.24&ISO^S-9911-33&NIST Lab
   Filler&2.16.840.1.113883.3.72.5.25&ISO||119297000^BLD^SCT^BldSpc^Blood^99USA^^^Blood
   Specimen||||||||||||20110103143428
```

8.13 NTE – Notes and Comments Segment

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

TABLE 8-21. NOTES AND COMMENTS SEGMENT (NTE)

SEQ	Element Name	DT	Usage	Cardinality	Value Set	Description/Comments
1	Set ID – NTE	SI	R	[1..1]		
2	Source of Comment		Varies			LRI_PH_Component Data Type: 'ID'; Usage: 'RE' Cardinality: [0..1]; Value Set: HL70105_USL Usage for all other components: 'O'
3	Comment	FT	R	[1..1]		Comment contained in the segment. **Note:** This Implementation Guide disallows the use of '~', hexadecimal or local escape sequences as a line break indicator.
4	Comment Type	Varies	Varies	Varies	Varies	LRI_NDBS_Component and LRI_PH_Component Data Type: 'CWE_03'; Usage: 'RE'; Cardinality: [0..1]; Value Set: HL70364_USL Usage for all other components: 'O'

Usage Note

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

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

Reports generated by the lab using the LRI message transaction must follow the LRI IG; reports generated by an external lab and received by an EHR via an LIS-LIS interface may contain additional NTEs and OBXs that must be accommodated for some period of time. This must be managed through local trading partner agreements.

Examples of valid formatted text within a single NTE

Option 1:

```
. .
```

```
TE|1||result should be interpreted in conjunction with other laboratory and \.br\ clinical data
 available to the clinician.
TE|2||Identification performed by DLS Laboratories, Aiea, HI.
TE|3||Susceptibility performed by Focus Diagnostics, Inc., Cypress, CA
..
```

Option 2 implies that these are NOT 3 distinct concepts, but rather are to be considered together:

```
..
TE|1||result should be interpreted in conjunction with other laboratory and \.br\ clinical data
 available to the clinician. \.br\ Identification performed by DLS Laboratories, Aiea, HI.
.br\ Susceptibility performed by Focus Diagnostics, Inc., Cypress, CA
..
```

Conformance Statements: Base Profile

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

8.14 FHS – File Header Segment

TABLE 8-22. FHS – FILE HEADER SEGMENT

SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	File Field Separator	ST	[1..1]	R		
2	File Encoding Characters	ST	[1..1]	R		
3	File Sending Application	Varies	Varies	Varies	HL70361_USL	GU data type: HD_01 NG data type: HD_02 LRI_PH_Component Usage: 'R'; Cardinality: [1..1] All other profiles Usage: RE'; Cardinality: [0..1]
4	File Sending Facility	Varies	R	[1..1]	HL70362_USL	GU data type: HD_01 NG data type: HD_02 LRI_PH_Component: HD_03 This facility will receive any related acknowledgment message.

TABLE 8-22. FHS – FILE HEADER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
5	File Receiving Application	Varies	Varies	Varies		GU data type: HD_01 NG data type: HD_02 LRI_NDBS_Component Usage: 'RE'; Cardinality: [0..1] LRI_PH_Component Usage: 'R' Usage for all other components: 'O'
6	File Receiving Facility	Varies	Varies	Varies	HL70362_USL	GU data type: HD_01 NG data type: HD_02 LRI_NDBS_Component and LRI_PH_Component Usage: 'R'; Cardinality: [1..1] Usage for all other components: 'RE'; Cardinality: [0..1] This facility originates any related acknowledgment message.
7	File Creation Date/Time	Varies	[1..1]	R		LAB_TO_Component Data Type: TS_11 Data type for all other components: 'TS_10'
8	File Security			O		
9	File Name/ID			R		
10	File Header Comment			O		
11	File Control ID			O		
12	Reference File Control D			O		

Conformance Statements: LRI_PH_Component

LRI-PH-103: FHS-1 (Field Separator) **SHALL** contain the constant value '|'.

LRI-PH-104: FHS-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

8.15 FTS – File Trailer Segment

TABLE 8-23. FTS – FILE TRAILER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	File Batch Count	NM	[1..1]	R		The number of batches contained in this file. Since this interface is constrained to one batch per file, this number should always be '1'.
2	File Trailer Comment			X		Excluded for this Implementation Guide, see Section 1.3.1

Conformance Statements: LRI_PH_Component

LRI-PH-105: FTS-1 (File Batch Count) SHALL be valued with the constant value '1'.

8.16 BHS – Batch Header Segment

TABLE 8-24. BHS – BATCH HEADER SEGMENT

SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	Batch Field Separator	ST	[1..1]	R		
2	Batch Encoding Characters	ST	[1..1]	R		
3	Batch Sending Application	Varies	Varies	Varies	HL70361_USL	GU data type: HD_01 NG data type: HD_02 LRI_PH_Component Usage: 'R'; Cardinality: [1..1] All other profiles Usage: RE'; Cardinality: [0..1]
4	Batch Sending Facility	Varies	R	[1..1]	HL70362_USL	GU data type: HD_01 NG data type: HD_02 LRI_PH_Component: HD_03 This facility will receive any related acknowledgment message.
5	Batch Receiving Application	Varies	Varies	Varies		GU data type: HD_01 NG data type: HD_02 LRI_NDBS_Component Usage: 'RE'; Cardinality: [0..1] LRI_PH_Component Usage: 'R' Usage for all other components: 'O'
6	Batch Receiving Facility	Varies	Varies	Varies	HL70362_USL	GU data type: HD_01 NG data type: HD_02 LRI_NDBS_Component and LRI_PH_Component Usage: 'R'; Cardinality: [1..1] Usage for all other components: 'RE'; Cardinality: [0..1] This facility originates any related acknowledgment message.
7	Batch Creation Date/Time	Varies	[1..1]	R		LAB_TO_Component Data Type: TS_11 Data type for all other components: 'TS_10'
8	Batch Security			X		Excluded for this Implementation Guide, see Section 1.3.1
9	Batch Name/ID/Type			R		
10	Batch Comment			X		Excluded for this Implementation Guide, see Section 1.3.1
11	Batch Control ID			X		Excluded for this Implementation Guide, see Section 1.3.1

TABLE 8-24. BHS – BATCH HEADER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
12	Reference Batch Control D			X		Excluded for this Implementation Guide, see Section 1.3.1

Conformance Statements: LRI_PH_Component

LRI-PH-106: BHS-1 (Field Separator) **SHALL** contain the constant value '|'.

LRI-PH-107: BHS-2 (Encoding Characters) **SHALL** contain the constant value '^~\&' or the constant value '^~\&#'.

8.17 BTS – Batch Trailer Segment

TABLE 8-25. BTS – BATCH TRAILER SEGMENT						
SEQ	HL7 Element Name	DT	Cardinality	Usage	Value Set	Description/Comments
1	Batch Message Count	NM	[1..1]	R		This is the total number of messages contained in the batch.
2	Batch Comment			X		Excluded for this Implementation Guide, see Section 1.3.1
3	Batch Totals			X		Excluded for this Implementation Guide, see Section 1.3.1

9 DATA TYPES

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

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

9.1 CNE – Coded No Exceptions

The CNE data type is used by Clinical Genomics to ensure use of particular code systems within OBX segments. Although Clinical Genomics only will use CNE_02, CNE_01 is included for completeness and avoid confusion. CNE_01 is used in eDOS.

9.1.1 CNE_01 – CODED WITH NO EXCEPTIONS

TABLE 9-1. CODED WITH NO EXCEPTIONS (CNE_01)

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		O		
5	Alternate Text		O		
6	Name of Alternate Coding System		O		
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CNE_01.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID		O		
9	Original Text		O		

9.1.2 CNE_02 – CODED NO EXCEPTIONS; CODE REQUIRED, BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL; CODE SYSTEM OID SUPPORTED

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

TABLE 9-2. CODED NO EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL (CNE_02)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		
2	Text	ST	RE		It is strongly recommended that text be sent to accompany any identifier. **Note:** For CG, it is not uncommon to have lengths up to 300 characters or above and that OBX-5 cannot be truncated, see section 1.4.5.

TABLE 9-2. CODED NO EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL (CNE_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CNE_02.14 is not valued.
4	Alternate Identifier		O		
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CNE_02.4 (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 CNE_02.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CNE_02.3 (Name of Coding System) is not an HL7 defined table or user defined.
8	Alternate Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CNE_02.6 (Name of Alternate Coding System) is not an HL7 defined table or user defined.
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System		O		
13	Second Alternate Coding System Version ID		O		
14	Coding System OID		C(R/X)		Condition Predicate: If CNE_02.3 (name of coding system) is not valued.
15	Value Set OID		O		
16	Value Set Version ID		O		
17	Alternate Coding System OID		O		
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID		O		
20	Second Alternate Coding System OID		O		
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID		O		

Usage Note

The CNE_01 data type is used where it is necessary to communicate a code, text, or coding system and the version of the coding system the code was drawn from and alternate codes drawn from another coding system. Many coded fields in this specification identify coding systems or value set attributes that must be used for the field. When populating the CNE_01 data type 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 CNE_01.3 (Name of Coding System) or CNE_01.14 (Code System OID) and, if valued, CNE_01.6 (Alternate Name of Coding System) and, if valued, CNE_01.20 (Second Alternate Name of Coding System) to determine if it recognizes the coding system or value set.

9.2 CNN_01 – Composite ID Number and Name Simplified

TABLE 9-3. COMPOSITE ID NUMBER AND NAME SIMPLIFIED (CNN_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		The ID Number component combined with the Assigning Authority – Universal ID component (component 10) must uniquely identify the associated person. Note - despite the component being named "ID Number" this component is an ST string data type, not numeric, so the component is not limited to just numbers.
2	Family Name	ST	RE		
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof	ST	RE		
5	Suffix (e.g., JR or III)	ST	RE		
6	Prefix (e.g., DR)	ST	RE		
7	Degree (e.g., MD)	IS	O	HL70360_USL	
8	Source Table		C(O/X)		Condition Predicate: If CNN.1 (Identifier) is valued.
9	Assigning Authority – Namespace ID	IS	C(RE/X)	Local	Condition Predicate: If CNN.1 (Identifier) is valued. The coding system for this component is locally managed.
10	Assigning Authority - Universal ID	ST	C(R/X)		Condition Predicate: If CNN.1 (Identifier) is valued.
11	Assigning Authority - Universal ID Type	ID	C(R/X)	HL70301_USL	Condition Predicate: If CNN.10 (Assigning Authority - Universal ID) is valued.

Conformance Statements: LRI_PH_Component

LRI-PH-108: CNN.10 (Assigning Authority - Universal ID) **SHALL** be valued with an ISO-compliant OID.

LRI-PH-109: CNN.11 (Assigning Authority - Universal ID Type) **SHALL** contain the value "ISO".

9.3 CWE – Coded With Exceptions

Display of CWE content is context dependent; the requirements when conveying results derive from CLIA and other sources. The resulting processing, storage, and display requirements are defined in the HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1, US Realm. The generic approach used is listed here to help the sender understand how populating of the CWE data type will affect the receiver, since the equivalent of the Functional Requirements guide for the LRI sender does not yet exist.

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

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

9.3.1 CWE_01 – CODED WITH EXCEPTIONS; CODE REQUIRED

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

TABLE 9-4. CODED WITH EXCEPTIONS; CODE REQUIRED (CWE_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	R		
2	Text	ST	RE		It is strongly recommended that text be sent to accompany any identifier.
3	Name of Coding System	ID	R	HL70396	
4	Alternate Identifier	ST	RE		The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_01.1.
5	Alternate Text	ST	RE		It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_01.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_01.3 (Name of Coding System) is not an HL7 defined table or user defined table.
8	Alternate Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_01.6 (Name of Alternate Coding System) is present and is not an HL7 defined table or user defined table.
9	Original Text	ST	RE		Original Text is used to convey the text that was the basis for coding.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_01.10 is populated and CWE_01.20 is not populated. Both CWE_01.6 and CWE_01.17 may be populated.
13	Second Alternate Coding System Version ID		O		

TABLE 9-4. CODED WITH EXCEPTIONS; CODE REQUIRED (CWE_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
14	Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_01.1 is populated and CWE_01.3 is not populated. Both CWE_01.3 and CWE_01.14 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_01.15 is populated.
17	Alternate Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_01.4 is populated and CWE_01.6 is not populated. Both CWE_01.6 and CWE_01.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_01.18 is populated.
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_01.17 is valued, and cannot be valued if CWE_01.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		

TABLE 9-4. CODED WITH EXCEPTIONS; CODE REQUIRED (CWE_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_01.10 is populated and CWE_01.12 is not populated. Both CWE_01.12 and CWE_01.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

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

The CWE_01 data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. Many coded fields in this specification identify coding systems or value sets that must be used for the field. When populating the CWE_01 data types with these values, this guide does not give preference to the triplet in which the standard code should appear.

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

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

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

TABLE 9-5. CODED WITH EXCEPTIONS; CODE REQUIRED, SECOND TRIPLET OPTIONAL (CWE_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_02.10 is populated and CWE_02.20 is not populated. Both CWE_02.6 and CWE_02.17 may be populated.
13	Second Alternate Coding System Version ID		O		
14	Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_02.1 is populated and CWE_02.3 is not populated. Both CWE_02.3 and CWE_02.14 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_02.15 is populated.
17	Alternate Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_02.4 is populated and CWE_02.6 is not populated. Both CWE_02.6 and CWE_02.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_02.18 is populated.

TABLE 9-5. CODED WITH EXCEPTIONS; CODE REQUIRED, SECOND TRIPLET OPTIONAL (CWE_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_02.17 is valued, and cannot be valued if CWE_02.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_02.10 is populated and CWE_02.12 is not populated. Both CWE_02.12 and CWE_02.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

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

The CWE_02 data type is used where it is necessary to communicate a code, text, coding system and the version of coding system the code was drawn from. It also allows the communication of an alternate code drawn from another coding system. Many coded fields in this specification identify coding systems or value sets that must be used for the field. When populating the CWE_02 data types with these values, this guide does not give preference to the triplet in which the standard code should appear.

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

Note: Pre-adoption of components 10-22 from V2.7.1

TABLE 9-6. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		

TABLE 9-6. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_03.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, the original text element (CWE_03.9) is used to carry the text, not the text (CWE_03.2) element.
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_03.1 (Identifier) is valued.
4	Alternate Identifier	ST	C(RE/X)		Condition Predicate: If CWE_03.1 (Identifier) is valued. The alternate identifier (from the alternate coding system) should be the closest match for the identifier found in CWE_03.1.
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_03.4 (Alternate Identifier) is valued. It is strongly recommended that alternate text be sent to accompany any alternate identifier.
6	Name of Alternate Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_03.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_03.3 (Name of Coding System) is not an HL7 defined table or user defined table.
8	Alternate Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_03.6 (Name of Alternate Coding System) is not an HL7 defined table or user defined table.
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_03.1 (Identifier) is not valued. Original Text is used to convey the text that was the basis for coding. If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_03.10 is populated and CWE_03.20 is not populated. Both CWE_03.6 and CWE_03.17 may be populated.
13	Second Alternate Coding System Version ID		O		

TABLE 9-6. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
14	Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_03.1 is populated and CWE_03.3 is not populated. Both CWE_03.3 and CWE_03.14 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_03.15 is populated.
17	Alternate Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_03.4 is populated and CWE_03.6 is not populated. Both CWE_03.6 and CWE_03.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_03.18 is populated.
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_03.17 is valued, and cannot be valued if CWE_03.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		

TABLE 9-6. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY (CWE_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_03.10 is populated and CWE_03.12 is not populated. Both CWE_03.12 and CWE_03.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

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

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

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

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

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

TABLE 9-7. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL (CWE_04)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_04.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, CWE_04.9 (Original Text Element) is used to carry the text, not CWE_04.2 (Text) element.
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_04.1 (Identifier) is valued.
4	Alternate Identifier		O		
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_04.4 (Alternate Identifier) is valued. It is strongly recommended that alternate text be sent to accompany any alternate identifier.

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

TABLE 9-7. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL (CWE_04)					
SEQ	Component Name	DT	Usage	Value Set	Comments
17	Alternate Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_04.4 is populated and CWE_04.6 is not populated. Both CWE_04.6 and CWE_04.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_04.18 is populated.
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_04.17 is valued and cannot be valued if CWE_04.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_04.10 is populated and CWE_04.12 is not populated. Both CWE_04.12 and CWE_04.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

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

(Alternate Name of Coding System) and, if valued, CWE_04-20 (Second Alternate Name of Coding System) to determine if it recognizes the coding system or value set.

9.3.5 CWE_05 – CODED WITH EXCEPTIONS; CODE REQUIRED, BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL; CODE SYSTEM OID SUPPORTED

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

TABLE 9-8. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL (CWE_05)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Identifier	ST	RE		
2	Text	ST	C(RE/X)		Condition Predicate: If CWE_05.1 (Identifier) is valued. It is strongly recommended that text be sent to accompany any identifier. When a coded value is not known, CWE_05.9 (Original Text Element) is used to carry the text, not CWE_05.2 (Text) element. **Note:** For CG, it is not uncommon to have lengths up to 300 characters or above and that OBX-5 cannot be truncated, see section 1.4.5
3	Name of Coding System	ID	C(R/X)	HL70396	Condition Predicate: If CWE_05.1 (Identifier) is valued and CWE_05.14 is not valued.
4	Alternate Identifier		O		
5	Alternate Text	ST	C(RE/X)		Condition Predicate: If CWE_05.4 (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_05.4 (Alternate Identifier) is valued.
7	Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_05.3 (Name of Coding System) is not an HL7 defined table or user defined table.
8	Alternate Coding System Version ID	ST	C(RE/O)		Condition Predicate: If CWE_05.6 (Name of Alternate Coding System) is not an HL7 defined table or user defined table.
9	Original Text	ST	C(R/RE)		Condition Predicate: If CWE_05.1 (Identifier) and CWE_05.4 (Alternate Identifier) are not valued. Original Text is used to convey the text that was the basis for coding. If neither the first or second triplet has values, this contains the text of the field.
10	Second Alternate Identifier		O		
11	Second Alternate Text		O		
12	Second Name of Alternate Coding System	ID	C(R/O)	HL70396	Condition Predicate: This component is required when CWE_05.10 is populated and CWE_05.20 is not populated. Both CWE_05.6 and CWE_05.17 may be populated.

TABLE 9-8. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL (CWE_05)					
SEQ	Component Name	DT	Usage	Value Set	Comments
13	Second Alternate Coding System Version ID		O		
14	Coding System OID	ST	C(R/X)		Condition Predicate: If CWE_05.1 (Identifier) is valued and CWE_05.3 (name of coding system) is not valued. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
15	Value Set OID		O		
16	Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required if CWE_05.15 is populated.
17	Alternate Coding System OID	ST	C(R/O)		Condition Predicate: This component is required when CWE_05.4 is populated and CWE_05.6 is not populated. Both CWE_05.6 and CWE_05.17 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined code systems the OID registered in the HL7 OID registry SHALL be used.
18	Alternate Value Set OID		O		
19	Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: Value set version ID is required if CWE_05.18 is populated.
20	Second Alternate Coding System OID	ST	C(O/X)		Condition Predicate: This component is optional when CWE_05.17 is valued, and cannot be valued if CWE_05.17 is empty. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.
21	Second Alternate Value Set OID		O		

TABLE 9-8. CODED WITH EXCEPTIONS; CODE REQUIRED BUT MAY BE EMPTY; SECOND TRIPLET OPTIONAL (CWE_05)					
SEQ	Component Name	DT	Usage	Value Set	Comments
22	Second Alternate Value Set Version ID	ID	C(R/O)		Condition Predicate: This component is required when CWE_05.10 is populated and CWE_05.12 is not populated. Both CWE_05.12 and CWE_05.20 may be populated. The value for this component is 2.16.840.1.113883.12.#### where "####" is to be replaced by the HL7 table number in the case of an HL7 defined or user defined table. For externally defined value sets, the OID registered in the HL7 OID registry SHALL be used.

Usage Note

The CWE_05 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_05 data type 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_05.3 (Name of Coding System) and, if valued, CWE_04-6 (Alternate Name of Coding System) and, if valued, CWE_05-20 (Second Alternate Name of Coding System) to determine if it recognizes the coding system or value set.

9.4 CX – Extended Composite ID with Check Digit

The CX_01 and CX_02 data types are used to carry identifiers. Although the Identifier Type Code component is required in this Implementation Guide, it is not a part of the actual identifier. Rather, it is metadata about the identifier. The ID Number and Assigning Authority component, together, constitute the actual identifier. The Assigning Authority represents the identifier's name space, e.g., Healthy Hospital Medical Record Numbers, or Healthy Hospital Order Numbers. Consequently, the Identifier Type Code is technically not necessary. However, due to various naming practices, organizational mergers, and other challenges, it is not always clear through the Assigning Authority OID what identifier type is being indicated by the identifier name space (note that it is highly recommended that this detail be associated with the OID in the registry metadata about the OID). Therefore, to maintain forward compatibility with V3, while recognizing the current practical challenges with understanding the identifier type/namespace at hand, this guide opted to keep the Identifier Type Code component as required.

9.4.1 CX_01 – EXTENDED COMPOSITE ID WITH CHECK DIGIT; GLOBALLY UNIQUE

TABLE 9-9. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	R		
2	Check Digit		O		
3	Check Digit Scheme		O		

TABLE 9-9. EXTENDED COMPOSITE ID WITH CHECK DIGIT (CX_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
4	Assigning Authority	HD_01	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		O		
7	Effective Date		O		
8	Expiration Date		O		
9	Assigning Jurisdiction		O		
10	Assigning Agency or Department		O		

Usage Note

The GU profile requires that assigning authorities accompany all identifiers and that all identifiers carry an identifier type. This method allows the exchange of universally unique identifiers for the associated object across organizational and enterprise boundaries, enabling broad interoperability.

9.4.2 CX_02 – EXTENDED COMPOSITE ID WITH CHECK DIGIT; NON-GLOBALLY UNIQUE

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

Usage Note

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

CX_02.4 Assigning Authority usage is set to RE as sometimes that data is not provided to the sender of the message, e.g., the original order was a paper order.

9.5 DR_01 – Date/Time Range 1; Start And End Dates Required But May Be Empty

TABLE 9-11. DATE/TIME RANGE (DR_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Range Start Date/Time	TS_12	RE		
2	Range End Date/Time	TS_06	RE		

9.6 DTM – Date/Time

It is strongly recommended that the time zone offset always be included in the DTM particularly if the precision includes hours, minutes, seconds, etc. Specific fields in this Implementation Guide may require Date/Time to a specific level of precision, which may require the time zone offset.

For precision only to year, the base DTM is used and is not represented in this document.

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

TABLE 9-12. DATE/TIME 1: PRECISE TO YEAR, POTENTIALLY TO DAY (DTM_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		O		
	MM		O		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		O		

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

TABLE 9-13. DATE/TIME 2: PRECISE TO YEAR, POTENTIALLY TO MINUTE (DTM_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		O		

9.6.3 DTM_03 – DATE/TIME 3: PRECISE TO THE YEAR, POTENTIALLY TO THE MINUTE, TIME ZONE OFFSET REQUIRED WHEN TIME IS SENT

Used when TO Component is invoked.

TABLE 9-14. DATE/TIME 3: PRECISE TO THE YEAR, POSSIBLY TO THE MINUTE (DTM_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		RE		
	DD		RE		
	HH		RE		
	MM		RE		
	[SS[.S[S[S]]]]]		O		
	+/- ZZZZ		C(R/X)		Condition Predicate: When 'HH' is valued.

9.6.4 DTM_05 – DATE/TIME 5: PRECISE TO DAY

TABLE 9-15. DATE/TIME 4: PRECISE TO DAY (DTM_04)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		O		
	MM		O		
	SS		O		
	[.S[S[S]]]]		O		
	+/- ZZZZ		O		

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

TABLE 9-16. DATE/TIME 6: PRECISE TO DAY, POTENTIALLY TO MINUTE (DTM_06)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		RE		
	MM		RE		
	[SS[.S[S[S]]]]]		O		
	+/- ZZZZ		O		

9.6.6 DTM_07 – DATE/TIME 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED WHEN TIME IS SENT

Used when TO Component is invoked.

TABLE 9-17. DATE/TIME 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (DTM_07)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		

TABLE 9-17. DATE/TIME 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (DTM_07)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	MM		R		
	DD		R		
	HH		RE		
	MM		RE		
	[SS[.S[S[S[S]]]]]		O		
	+/- ZZZZ		C(R/X)		Condition Predicate: When 'HH' is valued.

9.6.7 DTM_08 – DATE/TIME 8: PRECISE TO MINUTE

TABLE 9-18. DATE/TIME 8: PRECISE TO MINUTE (DTM_08)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		R		
	MM		R		
	[SS.S[S[S[S]]]]		O		
	+/- ZZZZ		O		

9.6.8 DTM_09 – DATE/TIME 9: PRECISE TO MINUTE; TIME ZONE OFFSET REQUIRED

Used when TO Component is invoked.

TABLE 9-19. DATE/TIME 9: PRECISE TO MINUTE; TIME ZONE OFFSET REQUIRED (DTM_09)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		R		
	MM		R		
	[SS.S[S[S[S]]]]		O		
	+/- ZZZZ		R		

9.6.9 DTM_10 – DATE/TIME 10: PRECISE TO SECOND

TABLE 9-20. DATE/TIME 10: PRECISE TO SECOND (DTM_10)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		

TABLE 9-20. DATE/TIME 10: PRECISE TO SECOND (DTM_10)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	HH		R		
	MM		R		
	SS		R		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		O		

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

Used when TO Component is invoked.

TABLE 9-21. DATE/TIME 11: PRECISE TO THE SECOND; TIME ZONE OFFSET REQUIRED (DTM_11)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY		R		
	MM		R		
	DD		R		
	HH		R		
	MM		R		
	SS		R		
	[.S[S[S[S]]]]		O		
	+/- ZZZZ		R		

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

TABLE 9-22. DATE/TIME 12: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES (DTM_12)					
SEQ	Component Name	DT	Usage	Value Set	Comments
	YYYY	DTM	R		
	MM	DTM	C(R/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	DD	DTM	C(R/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	HH	DTM	C(RE/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	MM	DTM	C(RE/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	[SS[.S[S[S[S]]]]]	DTM	C(O/X)		Condition Predicate: If DTM_12.1 (YYYY) is not valued '0000'.
	+/- ZZZZ	DTM	O		

Usage Note

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

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

Use instead of DTM_12 when LAB_TO_Component is used

TABLE 9-23. DATE/TIME 13: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (DTM_13)

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

Usage Note

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

9.7 ED_01 – Encapsulated Data 1: Data Subtype Required But May Be Empty

TABLE 9-24. ENCAPSULATED DATA (ED_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Source Application	HD	O		
2	Type of Data	ID	R	HL70191_USL	
3	Data Subtype	ID	RE	HL70291_USL	
4	Encoding	ID	R	HL70299_USL	
5	Data	TX	R		

Usage Note

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

9.8 EI – Entity Identifier

9.8.1 EI_01 – ENTITY IDENTIFIER; GLOBALLY UNIQUE

TABLE 9-25. ENTITY IDENTIFIER; GLOBALLY UNIQUE (EI_01)

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_01 data type is used to carry identifiers. The GU profile component 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: LRI_GU Profile

LRI-2: EI_01.3 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

LRI-3: EI_01.4 (Universal ID Type) **SHALL** contain the value "ISO" drawn from the code system HL70301_USL.

9.8.2 EI_02 – ENTITY IDENTIFIER; NON-GLOBALLY UNIQUE

TABLE 9-26. ENTITY IDENTIFIER; NON-GLOBALLY UNIQUE (EI_02)

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

Usage Note

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

9.8.3 EI_03 – ENTITY IDENTIFIER

TABLE 9-27. ENTITY IDENTIFIER; NON-GLOBALLY UNIQUE (EI_03)

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	HL70301_USL	

Usage Note

EI_03 was created to allow use of CLIA as well as OIDs for assigning authority identification because EI_01 is restricted to use of just OIDs (ISO).

9.9 EIP – Entity Identifier Pair

9.9.1 EIP_01 – ENTITY IDENTIFIER PAIR; GLOBALLY UNIQUE, AT LEAST ONE IDENTIFIER IS REQUIRED

TABLE 9-28. ENTITY IDENTIFIER PAIR; GLOBALLY UNIQUE, AT LEAST ONE IDENTIFIER IS REQUIRED (EIP_01)

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

9.9.2 EIP_02 – ENTITY IDENTIFIER PAIR; NON-GLOBALLY UNIQUE, AT LEAST ONE IDENTIFIER IS REQUIRED

TABLE 9-29. ENTITY IDENTIFIER PAIR; NON-GLOBALLY UNIQUE, AT LEAST ONE IDENTIFIER IS REQUIRED (EIP_02)

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

9.9.3 EIP_03 – ENTITY IDENTIFIER PAIR; NON-GLOBALLY UNIQUE, PLACER AND FILLER REQUIRED

TABLE 9-30. ENTITY IDENTIFIER PAIR (EIP_03)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_02	R		
2	Filler Assigned Identifier	EI_02	R		

9.9.4 EIP_04 – ENTITY IDENTIFIER PAIR; GLOBALLY UNIQUE, PLACER AND FILLER REQUIRED

TABLE 9-31. ENTITY IDENTIFIER PAIR (EIP_04)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_01	R		
2	Filler Assigned Identifier	EI_01	R		

9.9.5 EIP_05 – ENTITY IDENTIFIER PAIR; GLOBALLY UNIQUE, PLACER AND FILLER REQUIRED

TABLE 9-32. ENTITY IDENTIFIER PAIR (EIP_05)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Placer Assigned Identifier	EI_03	R		
2	Filler Assigned Identifier	EI_03	R		

9.10 ERL_01 – Error Location; All Required but Field Position and Repetition, Component and Sub-Component Number May Be Empty

TABLE 9-33. ERROR LOCATION (ERL_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Segment ID	ST	R		
2	Segment Sequence	NM	R		Absolute position of this segment in the message (e.g. 3rd NTE in message, regardless of the number or type of intervening segments).
3	Field Position	NM	RE		Not used, when entire segment is referred to
4	Field Repetition	NM	RE		If not specified repetition is assumed 1
5	Component Number	NM	RE		Not used, when entire field is referred to
6	Sub-component Number	NM	RE		Not used, when entire component is referred to

9.11 FN_01 – Family Name; Surname Required

TABLE 9-34. FAMILY NAME (FN_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Surname	ST	R		
2	Own Surname Prefix		O		
3	Own Surname		O		
4	Surname Prefix From Partner/Spouse		O		
5	Surname From Partner/Spouse		O		

9.12 HD – Hierarchic Designator

9.12.1 HD_01 – HIERARCHIC DESIGNATOR; GLOBALLY UNIQUE

TABLE 9-35. HIERARCHIC DESIGNATOR; GLOBALLY UNIQUE (HD_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	RE		The value of HD_01.1 reflects a local code that represents the combination of HD_01.2 and HD_01.3.
2	Universal ID	ST	R		
3	Universal ID Type	ID	R		Fixed to “ISO”.

Usage Note

The HD data type is used directly to identify objects such as applications or facilities. It is used also as a component of other data types, where it is typically an assigning authority for an identifier. Where this capability is used in this specification, the usage is described separately. Note that the HD data type has been constrained to carry an OID identifying an application, a facility, or an assigning authority.

Conformance Statements: LRI_GU Profile

LRI-4: HD_01.2 (Universal ID) **SHALL** be valued with an ISO-compliant OID.

LRI-5: HD_01.3 (Universal ID Type) **SHALL** contain the value “ISO” drawn from the code system HL70301_USL.

9.12.2 HD_02 – HIERARCHIC DESIGNATOR; NON-GLOBALLY UNIQUE

TABLE 9-36. HIERARCHIC DESIGNATOR; NON-GLOBALLY UNIQUE (HD_02)

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

Usage Note

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

The HD_02 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.

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

Example

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

9.12.3 HD_03 – HIERARCHIC DESIGNATOR; GLOBALLY UNIQUE, OID OR CLIA ID ALLOWED

TABLE 9-37. HIERARCHIC DESIGNATOR; GLOBALLY UNIQUE, OID OR CLIA ID ALLOWED (HD_03)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Namespace ID	IS	RE		The value of HD_03.1 reflects a local code that represents the combination of HD_03.2 and HD_03.3
2	Universal ID	ST	R		
3	Universal ID Type	ID	R		LRI_PH_Component: HL70203_USL.

Conformance Statement: LRI_PH_Component

~~**LRI-PH-110:** HD_03.3 (Universal ID Type) If element is in MSH-4 (Sending Facility), then HD_03.3 (Universal ID type) **SHALL** contain the value "ISO" OR "CLIA", else HD_03.3 (Universal ID type) **SHALL** contain the value "ISO".~~

LAB-PH-1: HD_03.3 (Universal ID Type) SHALL contain the value "ISO" OR "CLIA".

~~**LRI-PH-111:** If HD_03.3 (Universal ID type) value is "CLIA", then HD_03.2 (Universal ID) **SHALL** be a valid CLIA identifier format.~~

~~**LRI-PH-112:** If HD_03.3 (Universal ID type) value is "ISO", then HD_03.2 (Universal ID) **SHALL** be a valid ISO OID format.~~

LAB-PH-2: If HD_03.3 (Universal ID type) value is "CLIA", then HD_03.2 (Universal ID) **SHALL** be a valid CLIA identifier format.

LAB-PH-3: If HD_03.3 (Universal ID type) value is "ISO", then HD_03.2 (Universal ID) **SHALL** be a valid ISO OID format.

9.13 MSG_01 – Message Type; US Realm value sets required

TABLE 9-38. MESSAGE TYPE (MSG_01)

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

9.14 NDL_01 - Name With Date And Location, Name Required

TABLE 9-39. NAME WITH DATE AND LOCATION, NAME REQUIRED (NDL_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Name	CNN_01	R		
2	Start Date/time		O		
3	End Date/time		O		
4	Point of Care		O		
5	Room		O		
6	Bed		O		
7	Facility		O		
8	Location Status		O		
9	Person Location Type		O		
10	Building		O		
11	Floor		O		

9.15 OG – Observation Grouper

Note: the OG data type is pre-adopted from V2.8.2.

9.15.1 OG_01 - OBSERVATION GROUPER; GROUP, SEQUENCE, AND IDENTIFIER REQUIRED, IDENTIFIER MAY BE EMPTY

TABLE 9-40. OBSERVATION GROUPER (OG_01)

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

TABLE 9-40. OBSERVATION GROUPER (OG_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
4	Identifier	ST	RE		

9.15.2 OG_02 – OBSERVATION GROUPER; ORIGINAL SUB-IDENTIFIER REQUIRED, ALL OTHERS EXCLUDED

TABLE 9-41. OBSERVATION GROUPER (OG_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Original Sub-Identifier	ST	R		
2	Group	NM	X		
3	Sequence	NM	X		
4	Identifier	ST	X		

9.16 PRL_01 – Parent Result Link; Parent Observation Sub-Identifier required but may be empty

TABLE 9-42. PARENT RESULT LINK (PRL_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Parent Observation Identifier	CWE_01	R		
2	Parent Observation Sub-Identifier	OG_01	RE		
3	Parent Observation Value Descriptor		O		

Usage Note

See Section 12.1.1 Parent/Child Linking for details on how this data type and the EIP data type are used in parent/child result linking. Use of data type CWE_01 for sequence 1 reflects a pre-adoption of *HL7 Version 2.7.1* standard.

9.17 PT_01 – Processing Type; US Realm Value Sets Required

TABLE 9-43. PROCESSING TYPE (PT_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Processing ID	ID	R	HL70103_USL	
2	Processing Mode		O		

9.18 SAD_01 – Street address; Street or Mailing Address Required

TABLE 9-44. STREET ADDRESS (SAD_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street or Mailing Address	ST	R		
2	Street Name		O		
3	Dwelling Number		O		

9.19 SN_01 – Structured Numeric

TABLE 9-45. STRUCTURED NUMERIC (SN_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Comparator	ST	RE		
2	Num1	NM	R		
3	Separator/Suffix	ST	C(R/O)		Condition Predicate: If SN_01.2 (Num1) and SN_01.4 (Num2) are valued.
4	Num2	NM	RE		

Usage Note

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

Conformance Statements: LRI_PH_Component

~~**LRI-PH-113**: SN_01.1 (Comparator) **SHALL** contain the value ">" or "<" or ">=" or "<=" or "=" or "<>".~~

~~**LRI-PH-114**: SN_01.3 (Separator/Suffix) **SHALL** contain the value "-" or "+" or "/" or "." or ":".~~

9.20 TS – Time Stamp

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

TABLE 9-46. TIME STAMP 1- PRECISE TO YEAR, POTENTIALLY TO DAY (TS_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_01	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

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

TABLE 9-47. TIME STAMP 2: PRECISE TO YEAR, POTENTIALLY TO MINUTE (TS_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_02	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

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

TABLE 9-48. TIME STAMP 3: PRECISE TO YEAR, POTENTIALLY TO MINUTE, TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (TS_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_03	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.20.4 TS_05 – TIME STAMP 5: PRECISE TO DAY

TABLE 9-49. TIME STAMP 5: PRECISE TO MINUTE (TS_05)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_05	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

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

TABLE 9-50. TIME STAMP 6: PRECISE TO DAY, POTENTIALLY TO MINUTE (TS_06)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_06	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

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

TABLE 9-51. TIME STAMP 7: PRECISE TO DAY, POTENTIALLY TO MINUTE; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (TS_07)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_07	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.20.7 TS_08 – TIME STAMP 8: PRECISE TO MINUTE

TABLE 9-52. TIME STAMP 8: PRECISE TO MINUTE (TS_08)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_08	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.20.8 TS_09 – TIME STAMP 9: PRECISE TO MINUTE; TIME ZONE OFFSET REQUIRED

TABLE 9-53. TIME STAMP 9: PRECISE TO MINUTE; TIME ZONE OFFSET REQUIRED (TS_09)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_09	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.20.9 TS_10 – TIME STAMP 10: PRECISE TO SECOND,

TABLE 9-54. TIME STAMP 10: PRECISE TO SECOND (TS_10)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_10	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.20.10TS_11 – TIME STAMP 11: PRECISE TO SECOND; TIME ZONE OFFSET REQUIRED

TABLE 9-55. TIME STAMP 11: PRECISE TO SECOND, TIME ZONE OFFSET REQUIRED (TS_11)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_11	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.20.11TS_12 – TIME STAMP 12: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES

TABLE 9-56. TIME STAMP 12: UNKNOWN DATE/TIME IN REQUIRED FIELD, IF YEAR AVAILABLE, MUST BE PRECISE TO DAY, POTENTIALLY TO MINUTES (TS_12)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_12	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.20.12TS_13 – TIME STAMP 13: UNKNOWN DATE/TIME IN REQUIRED FIELD; IF AVAILABLE, PRECISE TO DAY, POTENTIALLY TO MINUTES; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY

TABLE 9-57. TIME STAMP 13: UNKNOWN DATE/TIME IN REQUIRED FIELD; IF AVAILABLE, PRECISE TO DAY, POTENTIALLY TO MINUTES; TIME ZONE OFFSET REQUIRED BUT MAY BE EMPTY (TS_13)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Time	DTM_13	R		
2	Degree of Precision	ID	X		Excluded for this Implementation Guide, see Section 1.3.1.

9.21 VID_01 – Version Identifier; US Realm Value Set Required

TABLE 9-58. VERSION IDENTIFIER (VID_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Version ID	ID	R	HL70104_USL	
2	Internationalization Code		O		
3	International Version ID		O		

9.22 XAD – Extended Address

9.22.1 XAD_01 – EXTENDED ADDRESS

TABLE 9-59. EXTENDED ADDRESS (XAD_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street Address	SAD_01	RE		
2	Other Designation	ST	RE		
3	City	ST	RE		
4	State or Province	ST	RE	USPS_USL	
5	Zip or Postal Code	ST	RE		.

TABLE 9-59. EXTENDED ADDRESS (XAD_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
6	Country Code	ID	RE	HL70399_USL	Use 3-character (alphabetic) form of ISO 3166 for HL7 Table 0399 as defined in HL7 Chapter 2, Section 2.15.9.17.
7	Address Type	ID	RE	HL70190_USL	
8	Other Geographic Designation		O		
9	County/Parish Code	IS	RE	FIPS64_USL	
10	Census Tract		O		
11	Address Representation Code		O		
12	Address Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
13	Effective Date		O		
14	Expiration Date		O		

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

TABLE 9-60. EXTENDED ADDRESS (XAD_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Street Address	SAD_01	R		
2	Other Designation	ST	RE		
3	City	ST	R		
4	State or Province	ST	R	USPS_USL	
5	Zip or Postal Code	ST	R		.
6	Country Code	ID	RE	HL70399_USL	Use 3-character (alphabetic) form of ISO 3166 for HL7 Table 0399 as defined in HL7 Chapter 2, Section 2.15.9.17.
7	Address Type	ID	RE	HL70190_USL	LRI_NDBS_Component: Default value is 'H'.
8	Other Geographic Designation		O		
9	County/Parish Code	IS	Varies	FIPS64_USL	LRI_NDBS_Component: required when NK1-3.1 is valued 'MTH' All other profiles: RE
10	Census Tract		O		
11	Address Representation Code		O		
12	Address Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
13	Effective Date		O		
14	Expiration Date		O		

9.23 XCN – Extended Composite ID Number and Name for Persons

9.23.1 XCN_01 – EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS; GLOBALLY UNIQUE

TABLE 9-61. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		The ID Number component combined with the Assigning Authority (XCN_01.9) must uniquely identify the associated person. **Note:** Despite the component being named "ID Number" this component is an ST string data type, not numeric, so the component is not limited to just numbers.
2	Family Name	FN_01	C(R/RE)		
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof	ST	RE		
5	Suffix (e.g., JR or III)	ST	RE		
6	Prefix (e.g., DR)	ST	RE		
7	Degree (e.g., MD)	IS	X		Excluded for this Implementation Guide, see Section 1.3.1.
8	Source Table		O		
9	Assigning Authority	HD_01	C(R/X)		Condition Predicate: If XCN_01.1 (ID Number) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.
10	Name Type Code	ID	RE	HL70200_USL	
11	Identifier Check Digit		O		
12	Check Digit Scheme	ID	C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
13	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XCN_01.1 (ID Number) is valued.
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
18	Name Assembly Order		O		
19	Effective Date		O		
20	Expiration Date		O		
21	Professional Suffix		O		

TABLE 9-61. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

9.23.2 XCN_02 – EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS; NON-GLOBALLY UNIQUE

TABLE 9-62. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	ID Number	ST	RE		**Note:** Despite the component being named "ID Number" this component is an ST string data type, not numeric, so the component is not limited to just numbers.
2	Family Name	FN_01	C(R/RE)		Condition Predicate: If XCN_02.1 (ID Number) is not valued.
3	Given Name	ST	RE		I.e., first name.
4	Second and Further Given Names or Initials Thereof	ST	RE		
5	Suffix (e.g., JR or III)	ST	RE		
6	Prefix (e.g., DR)	ST	RE		
7	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
8	Source Table		O		
9	Assigning Authority	HD_02	C(RE/X)		Condition Predicate: If XCN_02.1 (ID Number) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID Number in component 1.
10	Name Type Code	ID	RE	HL70200_USL	
11	Identifier Check Digit		O		
12	Check Digit Scheme	ID	C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
13	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XCN_02.1 (ID Number) is valued.
14	Assigning Facility		O		
15	Name Representation Code		O		
16	Name Context		O		
17	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
18	Name Assembly Order		O		
19	Effective Date		O		
20	Expiration Date		O		

TABLE 9-62. EXTENDED COMPOSITE ID NUMBER AND NAME FOR PERSONS (XCN_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
21	Professional Suffix		O		
22	Assigning Jurisdiction		O		
23	Assigning Agency or Department		O		

9.24 XON – Extended Composite Name and Identification Number for Organizations

9.24.1 XON_01 – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; GLOBALLY UNIQUE

TABLE 9-63. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; GLOBALLY UNIQUE (XON_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	RE		
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
4	Check Digit		O		
5	Check Digit Scheme		C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
6	Assigning Authority	HD_01	C(R/X)		Condition Predicate: If XON_01.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10.
7	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XON_01.10 (Organization Identifier) is valued.
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	C(R/RE)		Condition Predicate: If XON_01.1 (Organization Name) is not valued.

Usage Note

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

9.24.2 XON_02 – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; NON-GLOBALLY UNIQUE

TABLE 9-64. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; NON-GLOBALLY UNIQUE (XON_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	RE		

TABLE 9-64. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; NON-GLOBALLY UNIQUE (XON_02)					
SEQ	Component Name	DT	Usage	Value Set	Comments
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
4	Check Digit		O		
5	Check Digit Scheme	ID	C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
6	Assigning Authority	HD_02	C(RE/X)		Condition Predicate: If XON_02.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10.
7	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XON_02.10 (Organization Identifier) is valued.
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	C(R/RE)		Condition Predicate: If XON_02.1 (Organization Name) is not valued.

Usage Note

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

9.24.3 XON_03 – EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; GLOBALLY UNIQUE

TABLE 9-65. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; GLOBALLY UNIQUE (XON_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Organization Name	ST	R		
2	Organization Name Type Code		O		
3	ID Number		X		Excluded for this Implementation Guide, see Section 1.3.1.
4	Check Digit		O		
5	Check Digit Scheme		C(O/X)		Note that the condition predicate will be established when this profile is constrained further.
6	Assigning Authority	HD_01	C(R/X)		Condition Predicate: If XON_01.10 (Organization Identifier) is valued. The Assigning Authority component is used to identify the system, application, organization, etc. that assigned the ID in component 10.

TABLE 9-65. EXTENDED COMPOSITE NAME AND IDENTIFICATION NUMBER FOR ORGANIZATIONS; GLOBALLY UNIQUE (XON_03)					
SEQ	Component Name	DT	Usage	Value Set	Comments
7	Identifier Type Code	ID	C(R/X)	HL70203_USL	Condition Predicate: If XON_01.10 (Organization Identifier) is valued.
8	Assigning Facility		O		
9	Name Representation Code		O		
10	Organization Identifier	ST	RE		

9.25 XPN – Extended Person Name

9.25.1 XPN_01 – EXTENDED PERSON NAME; NAME COMPONENTS REQUIRED BUT MAY BE EMPTY, NAME TYPE CODE REQUIRED

TABLE 9-66. EXTENDED PERSON NAME; NAME COMPONENTS REQUIRED BUT MAY BE EMPTY, NAME TYPE CODE REQUIRED (XPN_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN_01	RE		
2	Given Name	ST	RE		I.e., first name.
3	Second and Further Given Names or Initials Thereof	ST	RE		
4	Suffix (e.g., JR or III)	ST	RE		
5	Prefix (e.g., DR)		O		
6	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
7	Name Type Code	ID	R	HL70200_USL	
8	Name Representation Code		O		
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

Usage Note

To convey ‘unknown’ in PID-3.5 (Patient Name), send 'U' in XPN.7, i.e. '^^^^^^U’.

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

TABLE 9-67. EXTENDED PERSON NAME EXTENDED PERSON NAME; FAMILY NAME REQUIRED, OTHERS REQUIRED BUT MAY BE EMPTY, NAME TYPE CODE REQUIRED BUT MAY BE EMPTY (XPN_03)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Family Name	FN_01	C(R/O)		Condition Predicate: If XPN_03.7 is not valued "U".
2	Given Name	ST	C(RE/O)		I.e., first name. Condition Predicate: If XPN_03.7 is not valued "U".
3	Second and Further Given Names or Initials Thereof	ST	C(RE/O)		Condition Predicate: If XPN_03.7 is not valued "U".
4	Suffix (e.g., JR or III)	ST	C(RE/O)		Condition Predicate: If XPN_03.7 is not valued "U".
5	Prefix (e.g., DR)		O		
6	Degree (e.g., MD)		X		Excluded for this Implementation Guide, see Section 1.3.1.
7	Name Type Code	ID	RE	HL70200_USL	
8	Name Representation Code		O		
9	Name Context		O		
10	Name Validity Range		X		Excluded for this Implementation Guide, see Section 1.3.1.
11	Name Assembly Order		O		
12	Effective Date		O		
13	Expiration Date		O		
14	Professional Suffix		O		

Usage Note

To convey 'unknown' in PID-3.5 (Patient Name), send 'Doe' in XPN.1, i.e., 'Doe^^^^^^U').

9.26 XTN_01 - Extended Telecommunication Number

TABLE 9-68. EXTENDED TELECOMMUNICATION NUMBER (XTN_01)

SEQ	Component Name	DT	Usage	Value Set	Comments
1	Telephone Number		X		Not supported.
2	Telecommunication Use Code	ID	O		
3	Telecommunication Equipment Type	ID	R	HL70202_USL	
4	Email Address	ST	C(R/X)		Condition Predicate: If XTN_01-3 (Telecommunication Equipment Type) is valued 'X.400' or 'Internet'.
5	Country Code	NM	O		

TABLE 9-68. EXTENDED TELECOMMUNICATION NUMBER (XTN_01)					
SEQ	Component Name	DT	Usage	Value Set	Comments
6	Area/City Code	IS	C(R/X)		Condition Predicate: If XTN_01-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX' or 'TDD'.
7	Local Number	NM	C(R/X)		Condition Predicate: If XTN_01-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX'or 'TDD'.
8	Extension	NM	C(RE/X)		Condition Predicate: If XTN_01-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX' or 'TDD'.
9	Any Text	ST	RE		For example: "Regular hours 8 am to 5 pm."
10	Extension Prefix		O		
11	Speed Dial Code		O		
12	Unformatted Telephone number		C(O/X)		Condition Predicate: If XTN_01-3 (Telecommunication Equipment Type) is valued 'PH', 'CP', 'SAT', 'FX' or 'TDD'.

Usage Note

How to populate XTN_01.4 - Email Address and XTN_01.7 - Local Number

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

XTN_01.1 - Telephone Number

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

10 CODE SYSTEMS

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

Every code value passed in a message instance is drawn from a code system that either may have a globally unique identifier, such as an OID, an HL7 identifier (Table 0001), or a locally defined identifier. In general, the coded values allowed in a field (a) may be drawn from more than one code system, and (b) may be a subset of the codes from a given coding system. Combining (a) and (b) makes it possible for the allowed code value to be a combination of multiple subsets drawn from multiple coding systems. In most cases, only subsets of the codes defined in a code system are legal for use in a particular message.

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

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

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

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

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

10.1 LOINC

10.1.1 GENERAL

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

LOINC shall be used as the standard coding system to identify the Resulted Test in the Observation Identifier (OBX-3) if an appropriate LOINC code exists. Appropriate status is defined in the LOINC Manual Section 11.2 Classification of LOINC Term Status. If a local coding system is in use, a local

code should also be sent to help with identification of coding issues. When no valid LOINC exists the local code may be the only code sent.

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

1. If the result is related to a reportable condition and the laboratory provides a LOINC code, Meaningful Use Stage 1 requires the EHR to send the LOINC code to public health.

2. If the LOINC code is the only code sent to the EHR in OBX-3, then the EHR must store and retain that code to satisfy CLIA reporting requirements.

3. LOINC codes may be used for secondary data exchange purposes and other partner exchange agreements.

For further information on LOINC, request codes for new tests, and access to tools, please visit http://loinc.org/.

10.1.2 LRI_NDBS_COMPONENT

The LRI_NDBS_Component provides a general set of specifications for an electronic NDBS laboratory results message. It does not identify, eliminate or override variations in state or local jurisdiction requirements for data collection, reporting, or protection of privacy and security of patient data. This profile seeks to establish a minimum threshold of common identifiers and reporting structure for NDBS screening data, and variations in local laws and practices may result in additional data requirements for NDBS screening.

The LOINC codes referenced in this section are from LOINC version 2.56, released June 2016, and may have been modified since the release of this Implementation Guide. For the latest and most updated NDBS LOINC codes, please go to http://newbornscreeningcodes.nlm.nih.gov/HL7.

LOINC codes are available for all aspects related to reporting the results of NDBS screening, including card data ("ask at order entry" demographic information traditionally written on the NDBS filter paper card), report summary (e.g. reason for test, specimen quality, conditions tested, conditions with positive markers, and conditions with equivocal markers), and analytes/measurements for laboratory tests used for NDBS (to report quantitative measure, interpretation, and a narrative comment specific to the condition or category of conditions).

The LOINC Newborn screening panel - American Health Information Community (AHIC) (LOINC code 54089-8), includes all of the conditions and variables that could be reported by any state is described in Table 15-1. NDBS LOINC Panel Requirements. It should be used as a master template from which each state NDBS program may select the items it uses, based on the screening tests it performs and its reporting policies. The full panel, with comprehensive details, is available at: http://s.details.loinc.org/LOINC/54089-8.html?sections=Comprehensive.

The LOINC Newborn Screening panel includes a number of nested LOINC panels to indicate sections of the message and relationships between sets of LOINC terms. Previous guidance used nested OBR- OBX relationships to represent that nesting in the message, but since the segment order in a message does not have to be preserved a different approach that preserves the hierarchical relationship between the different groups of tests as well as provides a way to identify those groupings has been chosen in this profile. However, several of the grouping LOINC panel codes are not included in the HL7 message, and this approach conforms to the preferences of the Laboratory Results Interface (LRI) Implementation Guide. Instead this profile makes use of the generic parent-child linkage mechanisms (See Section 12.1), even though these are not reflex tests, but always

performed for this order – it is similar to the approach of dealing with convenience panels, where the grouping within the panel is important. Refer to the example of an HL7 message representation; see Section 12 Additional Implementation Guidance – Reflex and Culture/Susceptibility Testing.

We recognize that NDBS laboratories and programs in different states have varied capabilities and policies related to reporting quantitative results and other NDBS information, and therefore tend to designate optionality as loosely as possible to accommodate these variations. However, to better inform health care providers, we encourage NDBS laboratories to send quantitative results for at least all of the screen positive or equivocal conditions to all report receivers. Additionally, to provide opportunities to study and improve NDBS, we encourage NDBS laboratories to report all quantitative and qualitative results to the state newborn screening program, regardless of whether they are positive or negative indicators for the condition.

Note: Definitions/descriptions, related names and example units of measure in computable UCUM format for all numeric NDBS measures are available at http://r.details.loinc.org/LOINC/54089-8.html?sections=Comprehensive

Note: Relationships between the conditions that are targeted by newborn screening and the tests/analytes/measurements that are used as markers for newborn screening conditions, as well as synonyms, and mappings to other code systems including International Classification of Diseases (ICD-9-CM and ICD-10-CM), Enzyme Commission (EC) codes and classifications, Online Mendelian Inheritance in Man® (OMIM®), and Universal Protein Resource (UniProt) are available at: https://newbornscreeningcodes.nlm.nih.gov/

See Section 15 NDBS LOINC Requirements.

10.1.3 LRI_PH_COMPONENT AND LRI_CG_COMPONENT

The LOINC long common name SHOULD be sent in addition to the LOINC code in order to facilitate debugging and message validation between the sender and the public health agency.

10.2 SNOMED CT

For receivers, SNOMED CT is a required vocabulary for Microbiology related results reported as Coded With Exception (CWE) data types in OBX-5 (and identified as CWE in OBX-2). When received, certified EHR technology shall be capable of supporting SNOMED CT codes (Concept ID, and if sent, Description as provided by IHTSDO.)

For senders, SNOMED CT is the recommended vocabulary in this release of the Implementation Guide. It is the intent of this Guide to move toward requiring the use of SNOMED CT on the sender side in a future release. Senders are highly encouraged to implement SNOMED CT support as soon as possible.

For results other than Microbiology, the use of SNOMED CT would need to be negotiated between trading partners, but its use is recommended.

If a SNOMED CT code is not published for a Microbiology coded result, it is acceptable to use an alternate or local coding system (and identified as CWE in OBX-2) by itself.

When SNOMED CT is used in OBX-5, CWE_01.9 or CWE_05.9 (Original Text) shall contain the laboratory's original text which is used for printing and/or display to satisfy CLIA reporting requirements, when it does not match the value in CWE_01.2 or CWE_05.2 (Text) or CWE_01.4 or CWE_05.4 (Alternate Text).

10.2.1 LRI_PH_COMPONENT

Where a SNOMED CT code is available, SNOMED CT SHALL be used for coded reportable laboratory results using CWE with the CWE_01 data type flavor; in OBX-5. Each SNOMED CT Concept has a permanent unique numeric Identifier which is known as the "Concept ID" and only these shall be used for this IG[11]. In other words, SNOMED alphanumeric legacy codes shall not be used for this IG.

The majority of coded results for reportable laboratory results fall into three categories: microorganism names (e.g. 88274000^Trypanosoma cruzi^SCT), presence or absence findings (e.g. 260373001^Detected^SCT), and, less commonly, substances (255835006^Shiga toxin^SCT). When SNOMED CT is used in OBX-5, CWE_01.9 shall contain the laboratory's original text which is used for printing and/or display to satisfy CLIA reporting requirements. The original text may be different than or the same as the text describing the standard and/or local code.

10.2.2 EXAMPLE HL7 MESSAGES

General Format for OBX-2 = CWE (SNOMED CT required when available code is published)

```
OBX|1|CWE|LOINC code^Loinc Longname^LOINC code
   systemID||CWE.1=SNOMED CT
   ConceptID^CWE.2=description^CWE.3=SNOMED CT code
   systemID^CWE.4=alt. code ^CWE.5=alt. description^CWE.6=alt.
   code system^CWE.7=SNOMED CT code system version^CWE.8=alt.
   code system version^CWE.9=original
   text||||||F|||200808151030-0700|||0086^Bacterial
   identification^OBSMETHOD^^^^501-20080815||200808161030-
   0700||||Reliable Labs,
   Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434
   Industrial Loop^^Ann
   Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.84
   0.1.113883.19.4.6&ISO^L^^^NPI
```

SNOMED CT-Specific Format for OBX-2 = CWE (SNOMED CT required for receivers/recommended for senders when available code is published)

Example of organism finding with generic LOINC in Nominal scale:

```
OBX|1|CWE|600-7^Bacteria identified in Blood by
   Culture^LN||112283007^Escherichia coli^SCT^ECO^Escherichia
   coli ^L^20110731^1^Escherichia coli bacteria
   isolated||||||F|||200808151030-0700|||0086^Bacterial
   identification^OBSMETHOD^^^^501-20080815||200808161030-
   0700||||Reliable Labs,
   Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434
   Industrial Loop^^Ann
   Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.84
   0.1.113883.19.4.6&ISO^L^^^NPI
```

[11] From Section 3.1.2. Concept Identifiers SNOMED CT User Guide- July 2012 International Release (US English), (www.snomed.org/ug.pdf).

Example of substance finding with generic LOINC in Nominal scale:

```
OBX|1|CWE|34175-0^Analgesics [Identifier] in Serum or
   Plasma^LN||387494007^Codeine^SCT^COD^Codeine^L^20110731^1^C
   odeine detected||||||F|||200808151030-0700|||0086^Bacterial
   identification^OBSMETHOD^^^^501-20080815||200808161030-
   0700||||Reliable Labs,
   Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434
   Industrial Loop^^Ann
   Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.84
   0.1.113883.19.4.6&ISO^L^^^NPI
```

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

```
OBX|1|CWE|546-2^Streptococcus.beta-hemolytic [Presence] in
   Throat by Organism specific
   culture^LN||46651001^isolated^SCT^ISO^Isolated^
   ^L^20110731^1^beta-hemolytic streptococcus isolated
   ||||||F|||200808151030-0700|||0086^Bacterial
   identification^OBSMETHOD^^^^501-20080815||200808161030-
   0700||||Reliable Labs,
   Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434
   Industrial Loop^^Ann
   Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.84
   0.1.113883.19.4.6&ISO^L^^^NPI
```

General Format for OBX-2 = CWE

```
OBX|1|CWE|546-2^Streptococcus.beta-hemolytic [Presence] in
   Throat by Organism specific culture^LN^^^^||53490009^beta-
   hemolytic streptococcus^SCT^^^^^beta-hemolytic
   streptococcus isolated||||||F|||200808151030-
   0700|||0086^Bacterial identification^OBSMETHOD^^^^501-
   20080815||200808161030-0700||||Reliable Labs,
   Inc^L^^^^CLIA&2.16.840.1.113883.19.4.6&ISO^XX^^^1236|3434
   Industrial Loop^^Ann
   Arbor^MI^99999^USA^B|9876543^Slide^Stan^S^^^^^NPPES&2.16.84
   0.1.113883.19.4.6&ISO^L^^^NPI
```

10.3 Specimen Type

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

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

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

10.3.1 LRI_PH_COMPONENT

SNOMED CT drawn from the specimen hierarchy in SNOMED CT should be used for SPM-4 (Specimen type). A mapping between HL70487 and SNOMED CT is available as an example of the concept map in FHIR: http://hl7.org/fhir/conceptmap-example-specimen-type.html.

10.4 UCUM

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, specifically using case-sensitive abbreviations as the coded value.

For dimensionless units the UCUM representation "{any string}" can be used, e.g., for a titer the UCUM representation is "{titer}^titer^UCUM". Only the string in the curly braces should be considered the "UCUM" unit. To communicate that an analyte has "No units", OBX-6 should be empty.

A table of commonly used example UCUM units for electronic messaging is available here: https://loinc.org/usage/units/.

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

An open source JavaScript tool for validating and converting UCUM units is available at https://lhncbc.github.io/ucum-lhc.

10.4.1 LRI_PH_COMPONENT

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

11 LABORATORY RESULT MESSAGE DEVELOPMENT RESOURCES

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

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

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

The repository is available at https://hl7v2tools.nist.gov/portal/#/.

11.1 Cardinality Testing

As part of testing message elements with unlimited cardinality, minimum testing limits have been established and are defined in a spreadsheet that, in future, will be accessible on the National Institute of Standards and Technologies HIT test support site.

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

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

11.2 Length Testing

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

11.3 Attached File Size Testing

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

12 ADDITIONAL IMPLEMENTATION GUIDANCE – REFLEX AND CULTURE/SUSCEPTIBILITY TESTING

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

Release Note: Revised examples will be provided for this section that are conformant to the statements in the final publication of this Release (D3). The examples in the shaded boxes below are all subject to changes as a result of ballot.

12.1.1 PARENT/CHILD LINKING

This section presents a brief discussion on Parent/Child Linking and how the use of PRU, FRU, PRN, and FRN effect which fields may be required to properly identify the link between parent and child.

12.1.1.1 HIGH LEVEL DESCRIPTION OF PARENT/CHILD LINKING

It must be understood that an observation (test result value) can be the catalyst for additional tests (orders), e.g., reflex tests (orders). When looking at those test orders and results, it is important to understand which is the originator (Parent), and which test orders and results are generated as Children. For example, an order has a result that yields a reflexive test based on the test result value, or an order yields a culture that in turn is identified to contain an organism that yields a specific susceptibility for an identified drug. Note that there is no information in the Parent that indicates the presence of a Child. It is the function of the Child pointing to a Parent that defines the relationship.

Both parent and child(ren) must be in the same message and the parent must precede its child(ren).

12.1.1.2 FRU, FRN, GU AND NG PROFILE COMPONENT CONSIDERATIONS

The specific combination of RU flavor (PRU or FRU), RN flavor (PRN or FRN), GU and NG components impact the specific combination of fields, components and sub-components that must be correctly populated in a message to support linking Child with Parent. As a reminder, the various profile components are repeated here:

- GU - This profile component indicates the use of Globally Unique Identifiers through ISO OID as described in Section 1.4.3 Use of ISO Object Identifier (OID)
- NG - This profile component indicates that the identification method has been negotiated between the trading partners and is not required to guarantee global uniqueness
- PRU and FRU - These profile components indicates that the test can be identified using the placer order number (PRU) or using the filler order number (FRU). No additional information is necessary since either identifier on its own is unique.
- PRN and FRN - These profile components indicates that the test can be only be identified using the placer order number (PRN) or the filler order number (FRN) in combination with the Parent Universal Service Identifier

When using the FRU/PRU Component, because of the uniqueness of the placer order number and/or filler order number, fewer fields are needed to link the Child to its Parent. When the PRN and FRN Components are both used in a single message, the non-unique placer order numbers and filler order numbers require a Parent Universal Service Identifier be used along with the non-unique order number to uniquely link the Child to the Parent. Use of the GU and NG profile components dictates

what data type components must be populated for the EI & EIP data types used to link the Child to its Parent. The following table shows the potential profile component combinations. This section will provide examples illustrating parent/child result linking for each of these combinations.

TABLE 12-1. COMPONENT COMBINATIONS

	FRN	FRU
GU	FRN + GU	FRU + GU
NG	FRN + NG	FRU + NG

12.1.1.3 DETAILED EXPLANATION OF HOW PARENT/CHILD RESULT LINKING WORKS

Order processing of the child is beyond the scope of this document, it is important to note that the Child observations will have its own Common Order (ORC)/Observation Request (OBR) group. The Child's "Parent Result" field (OBR-26), and "Parent" field (OBR-29) are used to link to the Parent as described below.

12.1.1.3.1 OBR-26 – PARENT RESULT

OBR-26 is populated in the Child observations, and this provides a link between the Child OBR, and the OBX in the Parent that generated the new tests. It will contain the two subfields, the first (OBR-26.1) will be valued with the Parent's "Observation Identifier" (OBX-3), and the second (OBR-26.2) will be valued with the Parent's "Observation Sub-ID" (OBX-4).

Note: The Parent's "Observation Identifier" (OBX-3) and Observation Sub-Identifier (OBX-4) component separators will need to be converted to sub-component separators when placed into the Child's OBR.

Note that OBR-26 Parent Result link works the same across each component profile combination. Also note that OBR-26 alone is insufficient to identify the OBR the parent OBX is associated with. OBR-29 (Parent) and potentially OBR-50 (Parent Universal Service Identifier) are needed to identify the specific parent OBR that the parent OBX is associated with.

Parent OBX

```
OBX|1|TX|008847^Urine Culture, Routine^99zzz^630-4^Bacteria
  identified^LN^^^Bacteria identified|^1^1|L-99990^Gram
  negative rods^ORM||||||F|20031013163200||20110615100900|...
```

Child OBR

```
OBR|2|15810^H_Dx_2_0|16699480030^MB|997135^Antimicrobial
  Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay|
  |15810||||20110615102200|||F|008847&Urine Culture,
  Routine&99zzz&630-4&Bacteria identified&LN&&&Bacteria
  identified^&1&1|...
```

12.1.1.3.2 OBR-29 – PARENT

OBR-29 is populated in the Child observations, and this provides a link between the Child OBR, and the Parent OBR. The Child's OBR-29 shall contain two fields the first (OBR-29.1) will be populated with the Parent's OBR-2 value, and the second field (OBR-29.2) will be populated with the Parent's

OBR-3 value. (Please note: The Parent's OBR-2, and OBR-3, component separators will need to be converted to sub-component separators when placed into the Child's OBR.)

Regardless of profile component, OBR-29 is required if OBR-11 (Specimen Action Code) is populated with a 'G' indicating the OBR is associated with a generated or reflex order.

For the messages with either the PRU or FRU component profile, OBR-29 is sufficient to link the child OBR to the correct parent OBR- The two examples below show how OBR-29 is used in the PRU-FRU-NG and PRU-FRU-GU profile combinations.

Example: FRU-NG Profile

Parent OBR

```
OBR|1|15810^H_Dx_2_0|16699480030^MB|008847^Urine Culture,
   Routine^99zzz|||20110614160000||||||^SRC:CL
   CATCH|||^Family^Fay||||||20110615102200|||F|...
```

Child OBR

```
OBR|2|15811^H_Dx_2_0|16699480031^MB|997135^Antimicrobial
   Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay|
   |||||20110615102200|||F|008847&Urine Culture,
   Routine&99zzz^1|||15810&H_Dx_2_0^16699480030&MB|...
```

Example: FRU-GU Profile

Parent OBR

```
OBR|1|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^2.16.
   840.1.113883.19.3.1.2^ISO|008847^Urine Culture,
   Routine^99zzz|||20110614160000||||||^SRC:CL
   CATCH|||^Family^Fay||||||20110615102200|||F|...
```

Child OBR

```
OBR|2|15811^^2.16.840.1.113883.19.3.1.1^ISO|16699480031^^2.16.
   840.1.113883.19.3.1.2^ISO|997135^Antimicrobial
   Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay|
   |||||20110615102200|||F|008847&Urine Culture,
   Routine&99zzz^1|||15810&&2.16.840.1.113883.19.3.1.1&ISO^166
   99480030&&2.16.840.1.113883.19.3.1.2&ISO|...
```

Notes

1) The PRU and FRU profiles require that the OBR be uniquely identified by the OBR-2 (in the case of the PRU) and/or the OBR-3 (in the case of the FRU). This means that use of either the PRU or FRU component provides uniqueness at the OBR level. Remember the Child's result uses the parent's OBR-2 and OBR-3 values for identification, so as long as one of them is unique per OBR, the combination of the two will also be unique.

2) The examples show OBR-2 populated in both the Parent and Child OBR's. In many circumstances, the Child OBR-2 will likely be empty as the placer is unlikely to assign a placer order number for the child result. Since all profiles have OBR-2 listed as RE (required but may be empty) this is not normally a problem. However, use of null OBR-2 would cause problems with matching the Child result to a parent if the profile components where a combination of PRU and FRN. (Filler order number is not unique, and the Placer Order Number is empty, effectively also not unique.) In a situation where the component profiles are PRU and FRN, and the filler can send empty OBR-2 values, then OBR-50 is required, just as if the message where using the PRN and FRN component profiles. (More on this can be found below.)

3) OBR-11 (Specimen Action Code) is valued with G (generated or reflex order) of the second OBR in each example. When OBR-11 is valued G, OBR-29 becomes required.

When the PRN and FRN Components are both used (or PRU and FRN with the possibility of an empty OBR-2 as described above), an additional identifier is needed to overcome the lack of uniqueness in the order numbers and filler order numbers. To obtain the uniqueness that the Child result needs to successfully identify its Parent, the non-unique order number(s) are combined with the Parent's Universal Service Identifier (OBR-4) as described below:

12.1.1.3.3 OBR-50 – PARENT UNIVERSAL SERVICE IDENTIFIER

OBR-50 of the Child is used in combination with the parent's universal service identifier OBR-4 to uniquely identify linking relationship, specifically when working with single requisition identifiers used on multiple ordered tests (the PRN and FRN Components). When the FRU component is used, then OBR-50 is not needed for linking the Child to the Parent OBR, as OBR-26 is sufficient to this task. If PRU is used theoretically OBR-50 would not need to be supported, but as previously noted, in some reflex situations the value of OBR-2 is empty, and as such use of the PRU may not provide the uniqueness required to identify the Parent OBR. In that case OBR-50 becomes required.

Example: FRN-NG

Non-Parent OBR, followed by Parent OBR (single requisition example, as potentially found in RN Component)

```
OBR|1|15810^H_Dx_2_0|16699480030^MB|007204^Amikacin Peak,
   Serum^99zzz|||20110614160000|||||||||^Family^Fay|||||20110
   615102200|||F||||
OBR|2|15810^H_Dx_2_0|16699480030^MB|008847^Urine Culture,
   Routine^99zzz|||20110614160000|||||||||^Family^Fay|||||201
   10615102200|||F||||
```

Child OBR

```
OBR|3|15810^H_Dx_2_0|16699480030^MB|997135^Antimicrobial
   Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay|||
   |||20110615102200|||F|008847&Urine Culture,
   Routine&99zzz^1|||15810&H_Dx_2_0^16699480030&MB||||||||||||||
   |||||||008847^Urine Culture, Routine^99zzz
```

Example: FRN-GU Profile

Non-Parent OBR, followed by Parent OBR (single requisition example, as potentially found in FRN Component):

```
OBR|1|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^
   2.16.840.1.113883.19.3.1.2^ISO|007204^Amikacin Peak,
   Serum^99zzz|||20110614160000|||||||||^Family^Fay||||||20110
   615102200|||F||||
OBR|2|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^
   2.16.840.1.113883.19.3.1.2^ISO|008847^Urine Culture,
   Routine^99zzz|||20110614160000|||||||||^Family^Fay||||||201
   10615102200|||F||||
```

Child OBR

```
OBR|3|15810^^2.16.840.1.113883.19.3.1.1^ISO|16699480030^^2.16.84
   0.1.113883.19.3.1.2^ISO|997135^Antimicrobial
   Susceptibility^99zzz|||20110614160000||||G|||||^Family^Fay|||
   |||20110615102200|||F|008847&Urine Culture,
   Routine&99zzz^1|||15810&&2.16.840.1.113883.19.3.1.1&ISO^16699
   480030&&2.16.840.1.113883.19.3.1.2&ISO||||||||||||||||||||008
   8847 Urine Culture, Routine^99zzz
```

12.1.1.3.4 SPECIMEN INHERITANCE

When reporting child results, the specimen information reported on its parent are not automatically assumed to be inherited by the children. Each child OBR must include the relevant specimen segment(s) for the observations being reported.

12.1.1.3.5 TIMING/QUANTITY INHERITANCE

When the child's timing/quantity is to be exactly the same as the parent's or has no meaning, then the TQ1 segment does not have to be sent along with the child. If not sent, it will inherit the TQ1 values from the parent. If it is sent, the TQ1 on that child is specific to that child only.

12.2 Culture and Susceptibilities Reporting

Section 12.1 describes the general use of parent-child result linking which may apply to any sort of reflex testing. This section focuses on parent/child result linking for the purpose of reporting microbiology culture and susceptibilities.

12.2.1 INTRODUCTION

Culture and sensitivities (e.g., reporting of multi-resistant tuberculosis or drug-resistant gonococcus or pneumococcus) can be reported using the HL7 electronic messaging standard in a number of different ways. Consequently, many vendors and large laboratories use varying methods to account for variations in the systems with which they work while still staying within the standard definitions. To improve consistency when implementing new or upgrading existing laboratory results interfaces, and considering that culture and susceptibilities reporting is a critical component of electronic,

laboratory-based public health reporting, this IG requires a specific approach, using parent-child relationship, when reporting microbiology results for this message profile that shall be supported.

Both parent and child(ren) must be in the same message and the parent must precede its child(ren).

12.2.2 TEMPLATE FOR CULTURE RESULTS

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

Example

```
MSH|...
PID|...
ORC|...
OBR|1|Placer number (OBR-2)|Filler number (OBR-3)|Identifier code
   for the requested test or panel of tests(OBR-4)|...
TQ1|...
OBX|1|CWE|Other identifier (OBX-3)|Sub-id for the first
   observation group (OBX-4)|Observation on the specimen (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type =
   'MOX'(OBX-30)
...
OBX|n|CWE|Specific organism identifier (OBX-3)|Sub-id for the
   first organism (OBX-4)|Description of organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type =
   'MIN'(OBX-30)
OBX|n+1|CWE|Other identifier (OBX-3)|Sub-id for the first
   organism (OBX-4)|Observation on the organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type =
   'MIG'(OBX-30)
OBX|n+2|CWE|Specific organism identifier (OBX-3)|Sub-id for the
   second organism (OBX-4)|Description of organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type =
   'MIN'(OBX-30)
OBX|n+3|CWE|Other identifier (OBX-3)|Sub-id for the second
   organism (OBX-4)|Observation on the Organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type =
   'MIG'(OBX-30)
OBX|n+4|CWE|Specific organism identifier (OBX-3)|Sub-id for the
   third organism (OBX-4)|Description of organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type =
   'MIN'(OBX-30)
OBX|n+5|CWE|Other identifier (OBX-3)|Sub-id for the third
   organism (OBX-4)|Observation on the organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type =
```

```
   'MIG'(OBX-30)
SPM|1|Specimen identifier for the specimen being tested|
```

This report has the MSH (Message Header), the PID (Patient Identification Segment), a single OBR (Observation Request Segment), and six OBX (Observation/Results) segments, and a single SPM (Specimen Segment). Note that the Set ID in the first field of each OBX is sequential, while the Sub-ID in the fourth field of each OBX is not sequential but acts as a link for all of the OBX segments that are reporting information for a related observation. The Sub-ID field in the template above has the words "first," "second" and "third" in **bold** and highlighted in green. This is done to show that the identification of the first organism is the relating observation for the first two OBX segments (*e.g.*, Set-ID numbers 1 and 2). The identification of the second organism is the relating observation for the second two segments (*e.g.*, Set-ID numbers 3 and 4), and so on. An example using the template above is presented below.

12.2.3 EXAMPLES OF CULTURE RESULTS

Example

Note that the use of OBX-4 Sub-ID is independent of the component profile combination. For this example, message details have been omitted to emphasize the salient fields.

```
MSH|...
PID|...
ORC|RE|RP723234^...|250401^...|RGP12356^...
OBR|1|RP723234^...|250401^...|624-7^Bacteria Spt Resp
   Cul^LN^...
TQ1|1|...
OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^1^1|MNY^Many^L^...|...||RSLT|MSS
OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^1^2|WBCS^WBCS^L^...|...||RSLT|MSS
OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^2^1|MOD^Moderate^L^...|...||RSLT|MSS
OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^2^2|GPR^Gram Positive Rods^L^...|...||RSLT|MSS
OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^3^1|MOD^Moderate^L^...|...||RSLT|MSS
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^3^2|GPCCH^Gram Positive Cocci in
   chains^L^...|...||RSLT|MSS
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^4^1|MNY^Many^L^...|...||RSLT|MSS
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^4^2|GNR^Gram Negative Rods^L^...|...||RSLT|MSS
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
```

```
   STAIN|^5^1|MNY^Many^L^...|...||RSLT|MSS
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^5^2|GPCCL^Gram Positive Cocci in
   clusters^L^...|...||RSLT|MSS
OBX|11|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^6^1|263812008^Moderate
   growth^SCT^...|...||RSLT|MIG
OBX|12|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^6^2|23506009^Normal flora^SCT^...|...||RSLT|MCS
OBX|13|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^7^1^1|655938018^Heavy
   growth^SCT^...|...||RSLT|MIG
OBX|14|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^7^2^1|56415008^Klebsiella
   pneumonia^SCT^...|...||RSLT|MIN
OBX|15|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^8^1^2|655938018^Heavy
   growth^SCT^...|...||RSLT|MIMIG
OBX|16|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^8^2^2|3092008^Staphylococcus
   aureus^SCT^...|...||RSLT|MIN
SPM|1|^C448&...||45710003^Sputum specimen^SCT^...|...
```

12.2.4 TEMPLATE FOR CULTURE AND SUSCEPTIBILITY RESULTS

The template and example in Section 12.2 Culture and Susceptibilities Reporting describe a report for a culture. The following template shows how antimicrobial susceptibility results are reported for the culture described in that section. The connection of the culture to the susceptibilities is a "parent-child" relationship, where the culture is the parent result and the susceptibilities are the child results. This means that there can be many child results for a single parent result. In other words, there can be multiple OBR child segments for the single OBR parent segment. The template for the report containing the culture and susceptibilities appears below. The titles in ***Bold Italics*** are given to highlight the individual parent and child segments and are not found in an actual HL7 message transmission. It is important to note that each of the OBR child segment references the parent result. These reference fields are OBR-26 (Parent Result), OBR-29 (Parent Number) and, for the FRN component, ORC-31 and OBR-50 (Parent Universal Service Identifier).

Example

```
Message Header and Patient Identification Segment for the
   Parent-Child Message
MSH|...
PID|...
Parent ORC/OBR Group
ORC|RE|Placer number (OBR-2)|Filler number (OBR-3)|...
```

```
OBR|1|Placer number (OBR-2)|Filler number (OBR-3)|Identifier
   code for the requested test or panel of tests(OBR-4)|...
TQ1|...
```

Parent OBX Segments for Non-Isolate Related Specimen Observations

```
OBX|1|CWE|Other identifier (OBX-3)|Sub-id for the first
   observation group (OBX-4)|Observation on the specimen (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'MOD'(OBX-30)
```

…

Parent OBX Segments for First Organism Identified

```
OBX|n|CWE|Specific organism identifier (OBX-3)|Sub-id for the
   first organism (OBX-4)|Description of organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'MIN'(OBX-30)
OBX|n+1|CWE|Other identifier (OBX-3)|Sub-id for the first
   organism (OBX-4)|Observation on the organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'MIG'(OBX-30)
```

Parent OBX Segments for Second Organism Identified

```
OBX|n+2|CWE|Specific organism identifier (OBX-3)|Sub-id for
   the second organism (OBX-4)|Description of organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'MIN'(OBX-30)
OBX|n+3|CWE|Other identifier (OBX-3)|Sub-id for the second
   organism (OBX-4)|Observation on the Organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'MIG'(OBX-30)
```

Parent OBX Segments for Third Organism Identified

```
OBX|n+4|CWE|Specific organism identifier (OBX-3)|Sub-id for
   the third organism (OBX-4)|Description of organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'MIN'(OBX-30)
OBX|n+5|CWE|Other identifier (OBX-3)|Sub-id for the third
   organism (OBX-4)|Observation on the organism (OBX-
   5)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'MIG'(OBX-30)
```

SPM Segment

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

Child ORC/OBR Group for First Organism identified

```
ORC|RE||Filler number (OBR-3)|...|Parent Universal Service
   Identifier(ORC-31) The parent identifier code for the
```

requested test or panel of tests (OBR-4 of Parent OBR)

OBR|2|Placer number (OBR-2)|Filler order number (OBR-3)|Identifier code for the requested test or panel of tests (OBR-4)|...|Specimen Action Code='G'(OBR-11)|...|Parent Result**(OBR-26) The parent OBX segment that contained the identification of the first organism**|||**Parent(OBR-29) The parent placer and/or filler order numbers for the requested test or panel of tests (OBR-2 and OBR-3 of Parent OBR)**|...|**Parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**|...

Child OBX Segments for Susceptibilities of First Organism Identified

OBX|n|CE|Specific susceptibility identifier for first antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+1|CE|Specific susceptibility identifier for second antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+2|CE|Specific susceptibility identifier for third antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

SPM Segment

SPM|1| Specimen identifier for the specimen being tested(Isolate)|Specimen identifier for the clinical specimen from which the isolate was obtained|Isolate|...

Child ORC/OBR Group for Second Organism identified

ORC|RE||Filler number (OBR-3)|...|Parent Universal Service Identifier(ORC-31) The parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)

OBR|3|Placer number (OBR-2)|Filler order number (OBR-3)|Identifier code for the requested test or panel of tests (OBR-4)|...|Specimen Action Code='G'(OBR-11)|...|Parent Result**(OBR-26) The parent OBX segment that contained the identification of the** second **organism**|||**Parent(OBR-29) The parent placer and/or filler order numbers for the requested test or panel of tests (OBR-2 and OBR-3 of Parent OBR)**|...|**Parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**|...

Child OBX Segments for Susceptibilities of Second Organism Identified

OBX|n|CE|Specific susceptibility identifier for first antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+1|CE|Specific susceptibility identifier for second antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+2|CE|Specific susceptibility identifier for third antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

SPM Segment

SPM|1|Specimen identifier for the specimen being tested||Isolate|...

Child ORC/OBR Group for** Third **Organism identified

ORC|RE||Filler number (OBR-3)|...|Parent Universal Service Identifier(ORC-31) The parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)

OBR|4|Placer number (OBR-2)|Filler order number (OBR-3)|Identifier code for the requested test or panel of tests (OBR-4)|...|Specimen Action Code='G'(OBR-11)|...|Parent Result**(OBR-26) The parent OBX segment that contained the identification of the** third **organism**|||**Parent(OBR-29) The parent placer and/or filler order numbers for the requested test or panel of tests (OBR-2 and OBR-3 of Parent OBR)**|...|**Parent identifier code for the requested test or panel of tests (OBR-4 of Parent OBR)**|...

Child OBX Segments for Susceptibilities of Third Organism Identified

OBX|n|CE|Specific susceptibility identifier for first antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+1|CE|Specific susceptibility identifier for second antimicrobial (OBX-3)|Sub-id (OBX-4)||Susceptibility finding (OBX-5)|||Susceptibility interpretation (OBX-8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-Type = 'SUR'(OBX-30)

OBX|n+2|CE|Specific susceptibility identifier for third


```
   antimicrobial (OBX-3)|Sub-id (OBX-4)|Susceptibility finding
   (OBX-5)|||Susceptibility interpretation (OBX-
   8)|...|Observation type= 'RSLT' (OBX-29)|Observation Sub-
   Type = 'SUR'(OBX-30)
SPM Segment
SPM|1|Specimen identifier for the specimen being
   tested||Isolate|...
```

12.2.5 EXAMPLES OF CULTURE AND SUSCEPTIBILITY RESULTS

Using the template above, this example shows a report of three pathogens identified from a sputum specimen with their respective antimicrobial susceptibility tests. Examples are provided for the FRU and FRN component profile combinations. Fields bolded and highlighted in **green** are used for linking parent and child results as identified in the template above. For these examples, message details have been omitted to emphasize the salient fields.

12.2.5.1 EXAMPLE FRU-GU PROFILE COMBINATION

In the FRU profile combinations (FRU-GU and FRU-GN) the order number alone is sufficient to uniquely identify the parent OBR. This means the child ORC(s) need only include the parent order number in OBR-29 to uniquely identify the parent OBR.

Example

```
MSH|...
PID|...
ORC|RE|RP723234^...|250401^...|RGP12356^...
OBR|1|RP723234^...|250401^...|624-7^Bacteria Spt Resp
   Cul^LN^...
TQ1|1|...
OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^1^1|MNY^Many^L^...|...||RSLT|MSS
OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^1^2|WBCS^WBCS^L^...|...||RSLT|MSS
OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^2^1|MOD^Moderate^L^...|...||RSLT|MSS
OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^2^2|GPR^Gram Positive Rods^L^...|...||RSLT|MSS
OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^3^1|MOD^Moderate^L^...|...||RSLT|MSS
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^3^2|GPCCH^Gram Positive Cocci in
   chains^L^...|...||RSLT|MSS
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^4^1|MNY^Many^L^...|...||RSLT|MSS
```

```
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^4^2|GNR^Gram Negative Rods^L^...|...||RSLT|MSS
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^5^1|MNY^Many^L^...|...||RSLT|MSS
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^5^2|GPCCL^Gram Positive Cocci in
   clusters^L^...|...||RSLT|MSS
OBX|11|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^6^1|263812008^Moderate
   growth^SCT^...|...||RSLT|MIG
OBX|12|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^6^2|23506009^Normal flora^SCT^...|...||RSLT|MCS
OBX|13|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^7^1^1|655938018^Heavy
   growth^SCT^...|...||RSLT|MIG
OBX|14|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^7^2^1|56415008^Klebsiella
   pneumonia^SCT^...|...||RSLT|MIN
OBX|15|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^8^1^2|655938018^Heavy
   growth^SCT^...|...||RSLT|MIG
OBX|16|CWE|624-7^Bacteria Spt Resp
   Cul^LN^...|^8^2^2|3092008^Staphylococcus
   aureus^SCT^...|...||RSLT|MIN
SPM|1|^C448&...||45710003^Sputum specimen^SCT^...|...
ORC|RE||S-2010733^...|RGP12356^...|...
OBR|2||S-2010733^...|50545-3^Bacterial susceptibility panel:-
   :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
   Resp Cul&LN&...^ &7&2&1^Klebsiella
   pneumonia|||RP723234&...|...
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
   MIC^LN^...|^1^1^1|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|2|SN|185-9^Ciprofloxacin Islt
   MIC^LN^...|^1^2^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|3|SN|267-5^Gentamicin Islt
   MIC^LN^...|^1^3^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
SPM|1|^C448-1&...||119303007^Microbial isolate
   specimen^SCT^...|...
ORC|RE||S-2010734^...|RGP12356^...|...
OBR|3||S-2010734^...|50545-3^Bacterial susceptibility panel:-
   :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
   Resp Cul&LN&...^ &8&2&2^Staphylococcus
```

```
   aureus|||RP723234&...|...
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
   MIC^LN^...|^1^1^2|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|2|SN|185-9^Ciprofloxacin Islt
   MIC^LN^...|^1^2^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|3|SN|267-5^Gentamicin Islt
   MIC^LN^...|^1^3^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
SPM|1|^C448-2&...||119303007^Microbial isolate
   specimen^SCT^...|...
```

12.2.5.2 EXAMPLE FRN PROFILE COMBINATIONS

In the FRN profile combinations (FRN-GU and FRN-GN) the order number in conjunction with the universal service identifier are necessary to uniquely identify the parent OBR. This means the child ORC(s) must include ORC-31 and OBR(s) must include OBR-50 (Parent Universal Service Identifier) along with the parent order number in OBR-29 to uniquely identify the parent OBR. OBR-26 identifies the result that the follow up order is based upon, if needed. For this example, message details have been omitted to emphasize the salient fields.

Example

```
MSH|...
PID|...
ORC|RE|RP723234^...|250401^...|RGP12356^...
OBR|1|RP723234^...|250401^...|624-7^Bacteria Spt Resp Cul^LN^...
TQ1|1|...
OBX|1|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^1^1|MNY^Many^L^...|...||RSLT|MSS
OBX|2|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^1^2|WBCS^WBCS^L^...|...||RSLT|MSS
OBX|3|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^2^1|MOD^Moderate^L^...|...||RSLT|MSS
OBX|4|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^2^2|GPR^Gram Positive Rods^L^...|...||RSLT|MSS
OBX|5|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^3^1|MOD^Moderate^L^...|...||RSLT|MSS
OBX|6|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^3^2|GPCCH^Gram Positive Cocci in
   chains^L^...|...||RSLT|MSS
OBX|7|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^4^1|MNY^Many^L^...|...||RSLT|MSS
OBX|8|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
   STAIN|^4^2|GNR^Gram Negative Rods^L^...|...||RSLT|MSS
```

```
OBX|9|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
  STAIN|^5^1|MNY^Many^L^...|...||RSLT|MSS
OBX|10|CWE|664-3^GRAM STN XXX^LN^GMS^GRAM STAIN^LAB^^^GRAM
  STAIN|^5^2|GPCCL^Gram Positive Cocci in
  clusters^L^...|...||RSLT|MSS
OBX|11|CWE|624-7^Bacteria Spt Resp
  Cul^LN^...|^6^1|263812008^Moderate
  growth^SCT^...|...||RSLT|MIG
OBX|12|CWE|624-7^Bacteria Spt Resp
  Cul^LN^...|^6^2|23506009^Normal flora^SCT^...|...||RSLT|MCS
OBX|13|CWE|624-7^Bacteria Spt Resp
  Cul^LN^...|^7^1^1|655938018^Heavy growth^SCT^...|...||RSLT|MIG
OBX|14|CWE|624-7^Bacteria Spt Resp
  Cul^LN^...|^7^2^1|56415008^Klebsiella
  pneumonia^SCT^...|...||RSLT|MIN
OBX|15|CWE|624-7^Bacteria Spt Resp
  Cul^LN^...|^8^1^2|655938018^Heavy growth^SCT^...|...||RSLT|MIG
OBX|16|CWE|624-7^Bacteria Spt Resp
  Cul^LN^...|^8^2^2|3092008^Staphylococcus
  aureus^SCT^...|...||RSLT|MIN
SPM|1|^C448&...||45710003^Sputum specimen^SCT^...|...
ORC|RE||S-2010733^...|RGP12356^...|...|624-7^Bacteria Spt Resp
  Cul^LN^...
OBR|2||S-2010733^...|50545-3^Bacterial susceptibility panel:-
  :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
  Resp Cul&LN&...^ &7&2&1^Klebsiella
  pneumonia|||RP723234&...|...|624-74^Bacteria Spt Resp
  Cul^LN^...
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
  MIC^LN^...|^1^1^1|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|2|SN|185-9^Ciprofloxacin Islt
  MIC^LN^...|^1^2^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|3|SN|267-5^Gentamicin Islt
  MIC^LN^...|^1^3^1|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
SPM|1|^C448-1&...||119303007^Microbial isolate
  specimen^SCT^...|...
ORC|RE||S-2010734^...|RGP12356^...|...|624-7^Bacteria Spt Resp
  Cul^LN^...
OBR|3||S-2010734^...|50545-3^Bacterial susceptibility panel:-
  :MIC:Isolate:OrdQn:MIC^LN^...|...|G|...|F|624-7&Bacteria Spt
  Resp Cul&LN&...^ &8&2&2^Staphylococcus
  aureus|||RP723234&...|...|624-74^Bacteria Spt Resp Cul^LN^...
```

```
TQ1|1|...
OBX|1|SN|28-1^Ampicillin Islt
   MIC^LN^...|^1^1^2|<^0.06|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|2|SN|185-9^Ciprofloxacin Islt
   MIC^LN^...|^1^2^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
OBX|3|SN|267-5^Gentamicin Islt
   MIC^LN^...|^1^3^2|<^0.05|ug/mL^^UCUM^...||S|||F|...||RSLT|SUR
SPM|1|^C448-1&...||119303007^Microbial isolate
   specimen^SCT^...|...
```

12.3 Confirmatory and Reflex Testing

Definition: Additional laboratory testing included in the original test request by reference to specific follow-up testing, e.g. “Urinalysis w/Culture Reflex” as opposed to “Urinalysis” ordered as a standalone test. The decision to perform the reflex or confirmatory test is based upon the results of the initial test and application of a predetermined local or national practice guideline, approved protocol or legal requirement.

- **Example:** A Urinalysis with elevated WBCs signals the potential for bacterial infection and a confirmatory Urine Culture is ordered on the same specimen as a reflex test. Depending on the laboratory standard operating procedure, LIS and nature of the reflexed or confirmatory test one or more of the following may be generated: a new accession number, new test codes and additional charges.
- **CLIA Compliance:** The initial test request received in the laboratory is adequate to demonstrate an order for both the initial and the additional testing for CLIA compliance and CMS auditing purposes.
    - **LIS Process:** The LIS shall report the reflexed test as one of the following:
        1. one or more additional OBXs as part of an existing OBR or
        2. one or more additional OBR/OBX(s) or
        3. a new accession.

In the event method two or three is used (one or more additional OBR/OBX(s), or a new accession), then the new OBR(s) shall be referenced to the original OBR using the parent-child relationship via the unique identifier in OBR-2 or using OBR-2/OBR-4 if OBR-2 is not unique. In addition, the date specimen was collected or obtained, OBR-7, in the new OBR shall be the same as OBR-7 in the original OBR.

- **EHR Process:** The EHR should support all three methods of reporting a reflexed test (see above) and associate it with the original test request for the specimen.

12.4 Add-On Testing

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

- **Example:** A physician orders a Complete Blood Count and Basic Metabolic Panel on an outpatient who presented in the office with symptoms of fatigue and a low-grade fever

following a camping trip to Wisconsin. After consultation with an infectious disease physician later in the day, he calls the laboratory and requests the addition of a Lyme's Disease Antibody test to the specimens already in the laboratory.

- **CLIA Compliance:** CLIA requires the laboratory to obtain a written or electronic test request for the add-on testing from the authorized provider for its records. If the test request is verbal the laboratory must document its efforts to receive a written or electronic test request within 30 days. [42CFR493.1241(b)]
- **LIS Process:** The LIS shall report the add-on test as one of the following:
    - one or more additional OBR/OBX(s) or
    - a new order.
- **EHR Process:** The EHR should support both methods of reporting an add-on test (see above).

13 ADDITIONAL IMPLEMENTATION GUIDANCE – OTHER

13.1 Clinical Laboratory Improvement Amendments Considerations

In the United States, clinical laboratory testing of human specimens is regulated by the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Several sections of the regulations implementing CLIA impact how electronic laboratory data is formatted for the US Realm and these are outlined in this section. Impacted areas include mandatory reporting requirements, report retention and display, and those authorized to receive a report. Specifics on the CLIA Regulation are found at http://www.cdc.gov/clia/. Interpretative Guidelines on the elements required in a report may be found at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html.

13.1.1 MANDATORY REPORTING REQUIREMENTS

The CLIA Regulations at 42 CFR 493.1291 - Test Report define the items that must appear on a clinical laboratory report. Note that the value(s) of some items that are supplied on the order and flow through to the Test Report are defined in 42 CFR 493.1241 - Test Request, 42 CFR 493.1273 – Histopathology, 42 CFR 493.1274 – Cytology, 42 CFR 493.1276 – Clinical Cytogenetics, and 42 CFR 493.1278 - Histocompatibility.

Specific report fields impacted include the following:

TABLE 13-1. MANDATORY REPORTING REQUIREMENTS

CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(a) §493.1241(c)(3) §493.1241(c)(6) §493.1241(c)(7)	"... patient-specific data are accurately and reliability send [*sic*] from point of data entry (whether interfaced or entered manually) to final report destination..." 493.1241 (c) (3) "The sex and age or date of birth of the patient" 42 CFR 493.1241 (c) (6) "The date and, if appropriate, time of specimen collection" 42 CFR 493.1241 (c) (7) "Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable" **Note:** For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment or biopsy.	PID-7 – Date/Time of Birth PID-8 – Administrative Sex (OBX or using OBX-2 = 46098-0^^L) OBR-7 – Observation Date/Time NTE-3 – Comment OBR-13 – Relevant Clinical Information OBX-5 – Observation Value (AOE, Prior Results) OBX-3 – Observation Identifier OBR-4 – Universal Service Identifier
§493.1273 (d) §493.1273 (e)	(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results.	OBR-32 – Principal Result Interpreter OBX-3 – Observation Identifier OBX-5 – Observation Value OBX-23 – Performing Organization Name OBX-24 – Performing Organization Address OBX-25 – Performing Organization Medical Director Note that the actual electronic signature is not included.

TABLE 13-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1274 (2) §493.1274 (3) §493.1274 (4) §493.1274 (6)	(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. (3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. (4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. (5) The report contains narrative descriptive nomenclature for all results. (6) Corrected reports issued by the laboratory indicate the basis for correction.	OBR-32 – Principal Result Interpreter OBX-3 – Observation Identifier OBX-5 – Observation Value OBX-23 – Performing Organization Name OBX-24 – Performing Organization Address OBX-25 – Performing Organization Medical Director SPM-21 – Specimen Reject Reason SPM-24 – Specimen Condition NTE Segment after corrected OBX segment Note that the actual electronic signature is not included.
§493.1276 (a) §493.1276 (b) §493.1276 (c)	(a) The laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, photographic printing, and reporting and storage of results, karyotypes, and photographs. (b) The laboratory must have records that document the following: (1) The media used, reactions observed, number of cells counted, number of cells karyotyped, number of chromosomes counted for each metaphase spread, and the quality of the banding. (c) Determination of sex must be performed by full chromosome analysis.	ORC-3 – Filler Order Number OBR-3 – Filler Order Number SPM-2 – Specimen ID OBX Segment OBX-5 using OBX-2 = 46098-0^^L to report on sex determined.
§493.1278 (4)	(4) Use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O.) Committee on Nomenclature. Potential new antigens not yet approved by this committee must have a designation that cannot be confused with W.H.O. terminology.	OBX-3 – Observation Identifier OBX-5 – Observation Value

TABLE 13-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(c)(1)	"For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number." Clarification: Patient name includes, when available, the patient's legal name consisting of a first name, middle name or initial, and last name [PID-5] The unique patient Identification number assigned by the facility (may be used when the patient name is not available) and the unique identification number for the order [PID-3] which may contain either numbers or letters or both numbers and letters.	PID-3 – Patient Identifier List PID-5 – Patient Name
§493.1291(c)(2)	"The name and address of the laboratory location where the test was performed." Clarification: The name of the laboratory as indicated on the CLIA certificate [OBX-23] and The actual physical location of the laboratory facility or location within the facility (including room, suite, floor as applicable) where testing is performed, as indicated on the CLIA certificate [OBX-24]. **Note:** Populating with the CLIA ID Number in OBX-23 meets the requirement **if** the receiving EHR-S has the ability to populate the Organization Name and Address in the Laboratory Test Report based on the CLIA ID Number.	OBX-23 – Performing Organization Name OBX-24 – Performing Organization Address
§493.1291(c)(3)	"The test report date." Clarification: The date (e.g. mm/dd/yyyy hh/mm) the test report/status change was finalized by the laboratory.	OBR-22 – Results Rpt/Status Chng Date/Time
§493.1291(c)(4)	"The test performed." Clarification: The specific name of the test/analyte that is assigned by the laboratory. Use of LOINC codes for additional tests is strongly encouraged. Addition of a local laboratory code is allowed. For certain tests CLIA requires additional information: Laboratories using manufacturer's instruments, kits or test systems labeled for "investigational use only" or "research use only" must clearly state that the test results are not to be used for treatment or diagnostic purposes. If results of such tests are being reported without a disclaimer statement, or are being used by the provider for patient care, they are in the same category as in-house developed tests and the laboratory must establish performance specifications in accordance with §493.1253. The disclaimer for Analyte Specific Reagents (ASR) should state, "This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration." The ASR disclaimer on the test report is required by the FDA under *21 CFR, Part 809.30, "Restrictions on the sale, distribution and use of analyte-specific reagents."*	OBR-4 – Universal Service Identifier OBX-3 – Observation Identifier

TABLE 13-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(c)(5)	"Specimen source, when appropriate." Clarification: The type of specimen submitted for testing and/or the collection site/method of collection as applicable. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display. CLIA reporting requirements call for the specimen source, which equates at minimum to the Specimen Type in the SPM segment. Additional Information may be provided by Ask at Order Questions (AOE).	SPM-4 – Specimen Type OBX-5 – Specimen Source (AOE)
§493.1291(c)(6)	"The test result and, if applicable, the units of measurement or interpretation, or both." Clarification: The corresponding test result value, and interpretation (where available) of that value for the requested analyte/test in numeric or text format [OBX-5]. Where available, the corresponding units of measure for the requested analyte/test identified and used by the performing laboratory [OBX-6] Where available, the laboratory's interpretation communicated by defined text/symbols indicating test results that do not fall within the established reference/normal range [OBX-8]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display. The laboratory's additional, miscellaneous notes, comments, interpretations regarding the test/analyte/report [NTE-3].	OBX-5 – Observation Value OBX-6 – Units OBX-8 – Abnormal Flags NTE-3 – Comment
§493.1291(c)(7)	"Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability." Clarification: When available, the laboratory's defined comment(s) denoting specimen suitability or not for testing [any of OBX-5/NTE-3/SPM-21]. The coded values received from the laboratory may be translated in the EHR to an equivalent description prior to display. When available, the laboratory's comment(s) denoting the condition of the specimen (hemolysis, lipemia, icterus, clotted, etc.) [any of OBX-5/NTE-3/SPM-24]. The coded values received from the laboratory may be translated in the EHR to an equivalent concept prior to display. Additional Notes: SPM-21: Use this field in connection with OBX-11 if a test is cancelled for specimen related reason. SPM-24: Use this field in combination with SPM-21 to further specify the reason for specimen rejection.	OBX-5 – Observation Value NTE-3 – Comment SPM-21 – Specimen Reject Reason SPM-24 – Specimen Condition

TABLE 13-1. MANDATORY REPORTING REQUIREMENTS		
CLIA Reference	CLIA Requirement, Additional Guidance	Segment/Field Description
§493.1291(d)	"Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the test, must be available to the authorized person who ordered the test and, if applicable, the individual responsible for using the test results" Clarification: The "reference intervals" or "normal" values that are determined by the performing laboratory and correspond to the particular test/analyte result [OBX-7]	OBX-7 – Reference Range
§493.1291(k)	"When errors in the reported patient test results are detected, the laboratory must do the following... (2) Issue corrected reports..." Clarification: The laboratory's status of the test result/report (preliminary, partial, final, corrected, etc.) [OBX-11/OBR-25]. The coded values received from the laboratory may be translated in the EHR to an equivalent concept prior to display.	OBX-11 – Observation Result Status OBR-25 – Result Status

13.1.2 LABORATORY TEST REPORT

The Laboratory Test Report is comprised of all of the CLIA required data elements. Such data are intended to be concurrently displayed in their entirety by the EHR technology and the content must be presented in a human readable format.

When all of the required data elements cannot be concurrently displayed in their entirety on a single display (for example, due to complexity or technology limitations), additional electronic display screens are permitted. When multi-page electronic display screens are utilized, they shall follow these characteristics:

- Identify individual electronic display screens unambiguously as part of the same report and as belonging to the specific patient.
- Indicate on each electronic display screen the continuation of the report on additional display screens.
- Provide each additional display of information with no more than two user actions for electronic displays, e.g., hover, click, scroll, pan, zoom.

See the *HL7 EHR-S Implementation Guide: S&I Framework EHR-S Functional Requirements For Laboratory Results Interface (LRI), Release 1– Us Realm* for additional guidance on handling CLIA elements in an EHR system, e.g. rules for display, translate, etc

13.1.3 REGULATORY COMPLIANCE

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

13.1.4 AUTHORIZED PARTIES

Local laws, generally at the State level, govern who is authorized to receive laboratory reports. CLIA restricts the availability of those authorized to receive laboratory reports to just those approved at the

local level and sets no national standards. Testing laboratories may not report results to unauthorized parties under CLIA.

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

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

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

13.2.1 QUANTITATIVE

A characterization applied to laboratory tests that give results expressing a numerical amount or level (concentration) of an analyte in a specimen;

NOTE 1: It is usually compared to an accredited recognized standard;

NOTE 2: This is in contrast to qualitative tests.

When used to describe a test, means a test that produces a result that is numerical. For example, a point-of-care blood glucose test might generate a result of 120 mg/dL (1.20 g/L). In contrast, a qualitative test generates a non-numerical result such as ‘positive’ or ‘detected.’

13.2.2 SEMI-QUANTITATIVE

A subset of quantitative tests called semi-quantitative provides results either over a range of values, such as a urine dipstick that results in glucose ranges of 0–40, 40–100, and >100 mg/dL (0–0.4, 0.4–1, and >1 g/L), or as a series of relative values, such as the same multiple test urine dipstick that results in hemoglobin as 0, +, ++, +++, and ++++.

A test that has a dose-response gradient that may be included in the reported result, but for which no authoritative calibration scale exists to determine inaccuracy and imprecision; tests that yield results in an approximate range of values (e.g., trace, moderate);

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

13.2.3 QUALITATIVE

When used to describe a test, means a test that produces a result that is descriptive rather than numerical. For example, a urine pregnancy test might generate a result of ‘positive’ or ‘negative’ for urinary hCG. In contrast, a quantitative test generates a numerical result. The quality control and reporting procedures differ significantly for quantitative and qualitative tests.

Characterization applied to laboratory tests that detect and/or identify a particular analyte, constituent, or condition;

NOTE 1: This term is applied to tests that detect whether a particular analyte, constituent, or condition is present or absent;

NOTE 2: It may also be called semi-quantitative tests;

NOTE 3: For Microbiology tests, identification of organisms may be performed.

13.3 LRI_PH_Component

13.3.1 EXAMPLES OF PARTIAL, FINAL AND CORRECTED MESSAGES

Refer to Section 1.4.10 Snapshot Mode for a discussion of snapshot mode.

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

Partial Message

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

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

Final Message

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

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

Corrected Message

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

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

13.3.2 HOW TO FURTHER CONSTRAIN THIS CONSTRAINABLE PROFILE

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

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

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

  R → R

  RE→ R, RE

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

  O → R, RE, C(a/b), X

  X→X

- Cardinality: Usage Rules above outlines the cardinalities allowed for various usage constraints. Refer to the cardinality table from the V2.7.1 Section 2.B.7.4 base standard. Additionally, for the purposes of creating an implementable profile from this guide, consider the cardinalities as the minimum allowed. If the receiver is expecting fewer repetitions of an

element that the bound set by the implementable profile, the burden is on the receiver to determine which repetitions it is interested in receiving.

- Length: For the purposes of creating an implementable profile from this guide, the upper limit of allowed length published above will be considered the conformance length. Truncation characters (#, =) can be assigned a to all lengths not already defined.

- Data types: the data types cannot be changed, except IS can be extended to CWE (example is OBX-8) and ID can be extended to CNE.

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

- Repurposing or redefining existing elements: The elements as defined in the standard and this IG should not be repurposed or redefined in a local implementation.

13.3.3 EPIDEMIOLOGICAL IMPORTANT INFORMATION FROM ASK AT ORDER ENTRY RESPONSES

There are several common data elements that have been identified as important data elements for Public Health laboratory reporting that do not have a supported field in the HL7 v2.5.1 message. This data may be available in the result sender system as Ask at Order Entry (AOE) responses for a particular test order. See the Section 1.4.10 of the *HL7 Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1 STU Release 2 – US Realm* for further discussion of AOE observations and how they relate to ordering.

For this profile, appropriate AOE answers should be sent along to the local public health jurisdiction as an observation in an OBX segment under the respective Order_ Observation group (ORC/OBR segment pair). In addition, OBX-29 (Observation Type) should be valued “QST” to flag this as an AOE answer rather than an actual result. OBX-30 (Observation Subtype) will be valued “AOE” (Ask at Order Entry), or”ASC” (Asked at Specimen Collection). The OBX-11 (Observation Result Status) field SHALL be valued “O” (Order Detail Only).

A table of example AOE questions is provided in Appendix A in the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS), Release 2, STU R3 - US Realm.*

The following Testing scenario gives context for the example LRI_PH_Component message below (The ellipses represent omitted details)

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

```
MSH...
...
```

```
OBX|1|CWE|5195-3^Hepatitis B virus surface Ag [Presence] in
   Serum^LN...|1|11214006^Reactive^SCT...|F|…|RSLT
OBX|2|CWE|11449-6^Pregnancy  status^LN...||77386006^Patient
   currently pregnant^SCT...|O|…|QST|AOE
...
```

13.3.4 REFERENCE TEST RESULTS

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

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

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

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

```
MSH...
...
OBR|1...
OBX|1|CWE|625-4^Bacteria identified in Stool by Culture^LN...||
   27268008^Salmonella^SCT...|...|Filler Lab Name^...|123 Filler
   Lab Street^...|Director^Filler^L^^Dr....
OBX|2|CWE|20951-0^Salmonella sp serotype [Identifier] in Isolate by
   Agglutination...||50136005^Salmonella
   Typhimurium^SCT...|...|State Lab Name^...|123 State Lab
   Street^...|Director^State^L^^Dr.....
...
```

Usage note

Specimen sent for further testing

The Sender may want to report to the jurisdiction the fact that they are sending a sample for further testing to a reference lab. The following SNOMED result code may be used as a coded observation: "`415564008^Specimen sent to reference laboratory for testing`".

14 CLINICAL GENOMICS CODE SYSTEMS

Information on code systems with name, HL70396 Code, OID, Source Information Links, and description.

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
Cytogenetic (chromosome) location	**Chrom-Loc**	**2.16.840.1.113883.6.335**
	Source Organization: National Center for Biotechnology Information (NCBI) Source Table Information: https://www.ncbi.nlm.nih.gov/genome/tools/gdp Source Table Download: ftp://ftp.ncbi.nlm.nih.gov/pub/gdp Place to explore table: https://clin-table-search.lhc.nlm.nih.gov/apidoc/cytogenetic_locs/v3/doc.html	
	Chromosome location (AKA chromosome locus or cytogenetic location), is the standardized syntax for recording the position of genes and large variants. It consists of three parts: the Chromosome number (e.g. 1-22, X, Y), an indicator of which arm – either "p" for the short or "q" for the long, and then generally a series of numbers separated by dots that indicate the region and any applicable band, sub-band, and sub-sub-band of the locus (e.g. 2p16.3). There are other conventions for reporting ranges and locations at the ends of the chromosomes. The table of these chromosome locations was loaded with all of the locations found in NCBI's ClinVar variation tables. It will expand as additional sources become available. This does not include all finely grained chromosome locations that exist. Users can add to it as needed.	
ClinVar Variant ID	**CLINVAR-V**	**2.16.840.1.113883.6.319**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: http://www.ncbi.nlm.nih.gov/clinvar/ Source table download: ftp://ftp.ncbi.nlm.nih.gov/pub/clinvar/tab_delimited/ Place to explore table: https://clin-table-search.lhc.nlm.nih.gov/apidoc/variants/v3/doc.html	
	ClinVar processes submissions reporting variants found in patient samples, assertions made regarding their clinical significance, information about the submitter, and other supporting data. The alleles described in submissions are mapped to reference sequences, and reported according to the HGVS standard. ClinVar includes simple and complex variants composed of multiple small variants. However, it now also includes large structural variants, which have a known clinical implication. So now simple, complex and many structural variants can all be found in ClinVar. The ClinVar records have a field for Allele ID and for Variant ID. All simple variants have an Allele ID. At present, all complex and most simple variants also have a Variant ID, and by the end of 2016, all simple variants will also have a variant ID. We focus mostly on the variant ID in this guide. This coding system uses the variant ID as the code and the variant name from NCBI's "variant_summary.txt.gz" file as the code's print string. The "variant_summary.txt.gz" file caries more than 20 useful fields, including the separate components of the variant name, the cytogenetic location, the genomic reference, etc. So based on the Variant ID, you can use ClinVar to find most you would ever want to know about the variant. In the LHC Clinical Table Search Service and LHC-Forms, we have indexed many of these attributes to assist users and applications that need to find the ID for a particular variant.	
COSMIC –Simple variants	**COSMIC-Smpl**	**2.16.840.1.113883.6.320**
	Source organization: Wellcome Trust Sanger Institute Source table information: https://cancer.sanger.ac.uk/cosmic/about Source table download: https://cancer.sanger.ac.uk/cell_lines/download Place to Explore Table: : https://clinicaltables.nlm.nih.gov/apidoc/cosmic/v3/doc.html Copyright: Wellcome Trust Sanger Institute, http://cancer.sanger.ac.uk/cosmic/license	
	This table includes only simple somatic (cancer) mutations, one per unique mutation ID. The code is the COSMIC mutation ID, and the name is constructed from Ensembl transcript reference sequences and p.HGVS that use the	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
	single letter codes for amino acids. It carries fields analogous to most of the key fields in ClinVar, but its reference sequences are Ensembl transcript reference sequences with prefixes of ENST; it specifies amino acid changes with the older HGVS single letter codes and it carries examples of primary cancers and primary tissues - fields that are not in ClinVar. COSMIC's source table includes multiple records per mutation - one per submission. The COSMIC- Simple Variants table that we have extracted from the original file includes only one record per unique mutation – a total of more than 3 million records. These contents are copyright COSMIC (http://cancer.sanger.ac.uk/cosmic/license). LHC has produced a look up table for these records, and for users to look up particular mutation IDs, both with permission from COSMIC. However, interested parties must contact COSMIC directly for permission to download these records.	
COSMIC-Structural variants	**COSMIC-Strc**	**2.16.840.1.113883.6.321**
	Source organization: Wellcome Trust Sanger Institute Source table information: https://cancer.sanger.ac.uk/cosmic/about Source table download: https://cancer.sanger.ac.uk/cell_lines/download Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/cosmic_struct/v3/doc.html Copyright: Wellcome Trust Sanger Institute, http://cancer.sanger.ac.uk/cosmic/license	
	COSMIC also has files containing structural variants. These are divided into two tables, one containing structural variants and one containing copy number variants. In contrast, NCBI does not separate structural variants this way. The table for this coding system derives from COSMIC's structural variation tables. The identifiers for these are pure numbers with no prefix, and each record includes information about the mutation type, the histological classification of the sample, and the primary tissue/cancer from which the sample originated. Like COSMIC simple variants, these also use Ensembl reference sequences, but uses the genomic reference sequences instead of the transcript ones (those whose codes begin with ENSG). These contents are copyright COSMIC (http://cancer.sanger.ac.uk/cosmic/license). LHC has produced a look up table for these records, also sub-setted to include only unique mutations, for users to look up particular mutation IDs with permission from COSMIC. However, interested parties must contact COSMIC directly for permission to download these records.	
dbSNP	**dbSNP**	**2.16.840.1.113883.6.284**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: http://www.ncbi.nlm.nih.gov/books/NBK21088/ Source table download: : ftp://ftp.ncbi.nih.gov/snp/ Place to Explore Table: https://clin-table-search.lhc.nlm.nih.gov/apidoc/snps/v31/doc.html	
	The Short Genetic Variations database (dbSNP) is a public-domain archive maintained by NCBI for a broad collection of short genetic polymorphisms. The SNP ID is unique for each position and length of DNA change. For example, a change of 3 nucleotides will have a different SNP ID than a change of 4 nucleotides at the same locus, but the code will be the same for all changes at the same locus and with the same length. So to specify a variation, the alt allele and the SNP code must be included.	
dbVar- Germline	**dbVar-GL**	**2.16.840.1.113883.6.322**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: https://www.ncbi.nlm.nih.gov/dbvar/content/overview Source: ftp://ftp.ncbi.nlm.nih.gov/pub/dbVar/data/Homo_sapiens/ Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/dbvar/v3/doc.html	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
	dbVar is NCBI's database of genomic structural variations (including copy number variants) that are larger than 50 contiguous base pairs. It is the complement of dbSNP, which identifies variants occurring in 50 or fewer contiguous base pairs. dbVar contains insertions, deletions, duplications, inversions, multi-nucleotide substitutions, mobile element insertions, translocations, and complex chromosomal rearrangements. dbVar carries structured Germline and Somatic variants in separate files. Accordingly, we have divided the coding system for dbVar the same way. This coding system represents the Germline dbVar variants. Its record ID may begin with one of four prefixes: nsv, nssv, esv and essv. These are accession prefixes for variant regions (nsv) and variant calls (or instances, nssv), respectively. Typically, one or more variant instances (nssv – variant calls based directly on experimental evidence) are merged into one variant region (nsv – a pair of start-stop coordinates reflecting the submitters' assertion of the region of the genome that is affected by the variant instances). The "n" preceding sv or indicates that the variants were submitted to NCBI (dbVar). The prefix, "e" for esv and essv represent variant entities (corresponding to NCBI's nsv and nssv) that were submitted to EBI (DGVa). The relation between variant call, and variant region, instances is many to one. The LHC lookup table for dbVar germline variations includes both variant instances (essv or nssv) and the variant region records (nsv, esv). Users can sub-select by searching on the appropriate prefix.	
dbVar- Somatic	**dbVar-Som**	**2.16.840.1.113883.6.323**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: http://www.ncbi.nlm.nih.gov/dbvar/content/overview/ Source table download: ftp://ftp.ncbi.nlm.nih.gov/pub/dbVar/data/ Place to Explore Table: Pending	
	dbVar is NCBI's database of genomic structural variations (including copy number variants) that are larger than 50 contiguous base pairs. It is the complement of dbSNP, which only contains variants occurring in 50 or fewer contiguous base pairs. It contains insertions, deletions, duplications, inversions, multi-nucleotide substitutions, mobile element insertions, translocations, and complex chromosomal rearrangements. Germline and Somatic variants are presented in separate files. Accordingly, we have divided the coding system within dbVar the same way. This coding system represents the Somatic (mostly cancer) variants in dbVar. As is true for the Germline portion of dbVar, the record IDs for the somatic dbVar's have prefixes of nsv, nssv, esv or essv with the leading "e" and "n" having the corresponding meaning as described above for germline or structural variant. We also include both the variant calls and variant region records in the LHC dbVar somatic variant file.	
Ensembl genomic reference sequence	**Ensembl-G**	**2.16.840.1.113883.6.324**
	Source organization: European Bioinformatics Institute (EBI) Source table information: http://useast.ensembl.org/info/genome/genebuild/genome_annotation.html Source table download: http://useast.ensembl.org/info/data/ftp/index.html Place to Explore Table: Pending	
	Set of Ensembl gene reference sequences whose identifiers have a prefix of "ENSG." It only includes genomic sequences associated with genes and uses the whole build plus the chromosome number to identify chromosome reference sequences, rather than a separate set of reference sequence identifier as NCBI does. LHC has not yet produced a convenient look up table for these files, but they are available from the URL cited above.	
Ensembl protein reference sequence	**Ensembl-P**	**2.16.840.1.113883.6.325**
	Source organization: European Bioinformatics Institute (EBI) Source table information: http://useast.ensembl.org/info/genome/genebuild/genome_annotation.html Source table download: http://useast.ensembl.org/info/data/ftp/index.html Place to Explore Table: Pending	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
	Set of Ensembl protein reference sequences. Their identifiers are distinguished by the prefix of "ENSP," and correspond to NCBI's "NP_" reference sequence identifiers. LHC has not yet produced a convenient look up table for these files, but they are available from the URL cited above.	
Ensembl transcript reference sequence	**Ensembl-T**	**2.16.840.1.113883.6.326**
	Source organization: European Bioinformatics Institute (EBI) Source table information: http://useast.ensembl.org/info/genome/genebuild/genome_annotation.html Source table download: http://useast.ensembl.org/info/data/ftp/index.html Place to Explore Table: Pending	
	Set of reference sequences for transcripts of coding regions. Their identifiers all have a prefix of "ENST." There are parallels for most (if not all) of what is in Ensembl within NCBI and most of the content is shared. "ENST" parallels NCBI's "NM_" identifiers. In general, Ensembl takes its reference sequences directly from the genomic build. NCBI may adjust its reference sequences by replacing known "variants" with sequences that better reflect the population "normal". LHC has not yet produced a convenient look up table for these files, but they are available from the URL cited above.	
HGNC-Symbol	**HGNC-Symb**	**2.16.840.1.113883.6.336**
	Source organization: HUGO Gene Nomenclature Committee (HGNC) Source table information: http://www.genenames.org/ Source table download: ftp://ftp.ebi.ac.uk/pub/databases/genenames/new/tsv/hgnc_complete_set.txt Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/genes/v3/doc.html	
	The HGNC gene table carries the gene ID, gene symbol and full gene name. The GENE ID is specific to the species. The gene symbol and name is shared by all species with the same gene. The HGNC-Symb table carries only human genes. The code for this coding system is the HGNC gene code, the "name" or print string is the HGNC gene symbol. More than 28,000 human gene symbols and names have been assigned so far, including almost all of the protein coding genes. But close to 10,000 non-protein coding “genes” do not yet have HGNC names. NCBI creates what might be thought of as interim codes but includes many more genes. The codes from NCBI and from HGNC are pure numbers and can’t be distinguished by their format. The gene codes we propose in this guide and use in our examples and in the LHC form that inputs gene information are all HGNC codes. If the study includes more than one gene, they can all be entered in one OBX, separated by the repeat delimiter. Alternatively they can be entered into separate OBX’s but the content of OBX-4 will have to be unique for each such repeat. We recommend n.1, n.2, n.3 etc. for such repeated variables in the report section which reports gene symbols (See Table 2).	
HGVS-Genomic syntax	**HGVS.g**	**2.16.840.1.113883.6.327**
	Source organization: Human Genome Variation Society (HGVS) Source table information: : http://varnomen.hgvs.org/bg-material/refseq/#DNAg HGVS validator: https://mutalyzer.nl/	
	HGVS syntax that describes the variations (mutations) at the genome level (the DNA before it is spliced to remove introns). The genomic syntax statements which can describe simple or structural variants are distinguished by a leading "g."	
HGVS-Transcript syntax	**HGVS.c**	**2.16.840.1.113883.6.328**
	Source organization: Human Genome Variation Society (HGVS) Source table information: http://varnomen.hgvs.org/bg-material/refseq/#DNAc HGVS validator: https://mutalyzer.nl/	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
	HGVS syntax that describes variations (mutations) at the transcript (messenger RNA) level. The transcript syntax statements, which can describe simple and complex variants, are distinguished by a leading "c."	
HGVS-Protein syntax	**HGVS.p**	**2.16.840.1.113883.6.329**
	Source organization: Human Genome Variation Society (HGVS) Source table information: http://varnomen.hgvs.org/bg-material/refseq/#proteinp HGVS validator: https://mutalyzer.nl/	
	HGVS syntax that specifies the variations (mutations) at the amino acid level, which are induced by underlying DNA variants. The protein change statements are distinguished by a leading "p." HGVS.p representations will not exist for variants that occur outside of coding regions.	
HLA Nomenclature	**HLA-Allele**	**2.16.840.1.113883.6.341**
	Source Organization: Immuno Polymorphism Database (IPD) Source Table Information: https://www.ebi.ac.uk/ipd/imgt/hla/ Source Table Download: ftp://ftp.ebi.ac.uk/pub/databases/imgt/mhc/hla/	
	Human leukocyte antigen (HLA) complex contains more than 220 genes that encode for the proteins of the immune system. HLA alleles are most commonly used for histocompatibility testing for stem cell and solid organ transplantation. The WHO Nomenclature Committee for Factors of the HLA System is responsible for a common nomenclature of HLA alleles, allele sequences, and quality control, to communicate histocompatibility typing information to match donors and recipients. An HLA allele is defined as any set of variations found on a sequence of DNA comprising a HLA gene. So, if there are five variations found in this one gene sequence, this set is defined as one allele (vs. the definition of an allele being the variation found between the test specimen and the reference along a contiguous stretch of DNA). In the case of HLA, the contiguous stretch of DNA represents the entire gene, and the variations do not need to be contiguous within the gene sequence. Each HLA allele name has a unique name consisting of the gene name followed by up to four fields, each containing at least two digits, separated by colons. There are also optional suffixes added to indicate expression status. For the full specification, please go to this website: http://hla.alleles.org/nomenclature/naming.html. HLA nomenclature can also be used to represent sets of alleles that share sequence identity in the Antigen Recognition Site (ARS). G-groups are alleles that have identical DNA sequences in the ARS, while P-groups are alleles that have identical protein sequences in the ARS. These are described, respectively, in http://hla.alleles.org/alleles/g_groups.html and http://hla.alleles.org/alleles/p_groups.html .	
HPO	**HPO**	**2. .16.840.1.113883.6.339**
	Source organization: Human Phenotype Ontology Consortium Source table information: http://human-phenotype-ontology.github.io/about.html Source table download: http://human-phenotype-ontology.github.io/downloads.html Place to Explore Table: Pending License: Sebastian Köhler, Sandra C Doelken, Christopher J. Mungall, Sebastian Bauer, Helen V. Firth, et al. The Human Phenotype Ontology project: linking molecular biology and disease through phenotype data Nucl. Acids Res. (1 January 2014) 42 (D1): D966-D974 doi:10.1093/nar/gkt1026	
	The Human Phenotype Ontology (HPO) aims to provide a standardized vocabulary of phenotypic abnormalities encountered in human disease. Each term in the HPO describes a phenotypic abnormality, such as atrial septal defect.	
ICD-10-CM	**I10C**	**2.16.840.1.113883.6.90**
	Source organization: National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) Source table information: https://www.cdc.gov/nchs/icd/icd10cm.htm	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
	Source table download: https://www.cdc.gov/nchs/icd/icd10cm.htm# FY 2017 release of ICD-10-CM Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/icd10cm/v3/doc.html Copyright: World Health Organization, http://www.who.int/classifications/icd/en/	
	The International Classification of Diseases (ICD) is the classification used to code and classify mortality data from death certificates. The International Classification of Diseases, Clinical Modification (ICD-10-CM) is used to code and classify morbidity data from the inpatient and outpatient records, physician offices, and most National Center for Health Statistics (NCHS) surveys. The ICD-10-CM is used to code and classify mortality data from death certificates, having replaced ICD-9 for this purpose as of January 1, 1999. ICD-10-CM is the replacement for ICD-9-CM, volumes 1 and 2, effective October 1, 2015, but of course, decades of ICD-9 data recorded before 2015 will be in medical record systems for a long time. The codes are an alphanumeric string. The name is a diagnosis, symptom or other clinical concepts. Some of these codes can be related in a shallow hierarchy. ICD-10-CM codes are 7 digits: digit 1 is alpha; digit 2 is numeric; digits 3–7 are alpha or numeric; and a decimal/dot is placed after the third character. ICD-10-CM includes extensive Combination Codes to better capture complexity. NCHS, which is part of the U.S. Centers for Disease Control and Prevention (CDC), serves as the World Health Organization (WHO) Collaborating Center for the Family of International Classifications for North America and in this capacity is responsible for coordination of all official disease classification activities in the United States relating to the ICD and its use, interpretation, and periodic revision.	
ICD-9-CM	**I9CDX**	**2.16.840.1.113883.6.103**
	Source organization: National Center for Health Statistics (NCHS) Source table information: https://www.cdc.gov/nchs/icd/icd9.htm Source table download: http://www.cdc.gov/nchs/icd/icd9cm.htm; https://www.cms.gov/medicare/coding/ICD9providerdiagnosticcodes/codes.html Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/icd9cm_dx/v3/doc.html Copyright: World Health Organization, http://www.who.int/classifications/icd/en/	
	The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9- CM) is a subset of ICD-9. ICD-9-CM is the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States. The ICD-9 was used to code and classify mortality data from death certificates until 1999, when use of ICD-10 for mortality coding started. Most ICD-9-CM codes are purely numeric consisting of 3 digits followed by a dot and one or more digits. A select subset start with the letter E or V followed by a number. ICD-9-CM codes are 3-5 digits. This subset of ICD-9 carries only diagnostic codes (the surgical and other procedure codes are excluded).	
International System for Human Cytogenetic Nomenclature (ISCN)	**ISCN**	**2.16.840.1.113883.6.299**
	Source organization: The International System for Human Cytogenetic Nomenclature (ISCN) Source table information: https://www.karger.com/Article/FullText/353118 ISCN (2016): An International System for Human Cytogenetic Nomenclature, J McGowan-Jordan, Simons A, M. Schmid (eds). S. Karger, Basel 2016	
	Like HGVS, The International System for Human Cytogenetic Nomenclature (ISCN) is a syntax. It came out of cytopathology and deals with reporting karyotypes down to the chromosome fusions and many types of small copy number variants. However, cytogenetics is out of the scope in this guide. We use ISCN syntax to report large deletion-duplications in structural variants, as well we include other variants that have been observed.	
Logical Observation Identifier Names and Codes	**LN**	**2.16.840.1.113883.6.1**
	Source organization: Regenstrief Institute	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
	Source table information: http://loinc.org/background Source table download: http://loinc.org/downloads Place to Explore Table: https://clin-table-search.lhc.nlm.nih.gov/apidoc/loinc/v1/doc.html Copyright: Regenstrief Institute, http://loinc.org/terms-of-use	
	Logical Observation Identifiers Names and Codes (LOINC®) provides a set of universal codes and names for identifying laboratory and other clinical observations. One of the main goals of LOINC is to facilitate the exchange and pooling of results for clinical care, outcomes management, and research. LOINC was initiated by Regenstrief Institute research scientists who continue to develop it with the collaboration of the LOINC Committee.	
Locus Reference Genomic (LRG)	**LRG-RefSeq**	**2.16.840.1.113883.6.337**
	Source organization: Locus Reference Genomic (LRG) Source table information: http://www.lrg-sequence.org/about Source table download: http://www.lrg-sequence.org/downloads Place to Explore Table: Pending	
	LRG is a manually curated record that contains stable, and thus un-versioned, reference sequences designed specifically for reporting sequence variants with clinical implications. It provides a genomic DNA sequence representation of a single gene that is idealized, has a permanent ID (with no versioning), and core content that never changes. Their database includes maps to NCBI, Ensembl and UCSC reference sequences. It contained sequences for a total of 1073 genes as of April 2016, with identifiers of the form: "LRG_####", where #### can be from 1 to N, and N is the last gene processed. See PMIDs: 24285302, 20398331, and 20428090 for more information.	
NCBI MedGen disease subset	**MedGen-Dis**	**2.16.840.1.113883.6.333**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: https://www.ncbi.nlm.nih.gov/medgen/ Source table download: ftp://ftp.ncbi.nlm.nih.gov/pub/medgen/ Place to Explore Table: https://clin-table-search.lhc.nlm.nih.gov/apidoc/disease_names/v3/doc.html	
	MedGen-disease is a subset of disease concepts (about 20,000 as of January 2016) taken from the NCBI's MedGen table. It includes most known genetic and clinical diseases. It drew its content from the NIH Genetic Testing Registry (GTR®), UMLS, HPO, OMIM, Orphanet, ClinVar and other sources, and is probably the most complete compendium of genetic diseases, though it also includes most common clinical diseases. It uses UMLS IDs when they exist and its own ID when not, and links to SNOMED CT and other disease identifiers. The MedGen database includes the inheritance and clinical features of each disease, as well as the map location of underlying genetic basis.	
NCBI- gene code	**NCBI-gene code**	**2.16.840.1.113883.6.340**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: https://www.ncbi.nlm.nih.gov/gene Source table download: ftp://ftp.ncbi.nih.gov/gene/ Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/ncbi_genes/v3/doc.html	
	When applicable, this variable identifies the gene on which the variant is located. The gene identifier is also carried in the transcript reference sequence database, and is part of a full HGVS expression. Not all genes have HGNC names and codes so NCBI has created gene IDs that cover the genes that are not registered by HGNC.	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
NCBI -genomic and chromosome reference sequences	**RefSeq-G**	**2.16.840.1.113883.6.330**
	Source organization: National Center for Biotechnology Information (NCBI), U.S. National Library of Medicine (NLM) Source table information: https://www.ncbi.nlm.nih.gov/refseq/ Source table download: ftp://ftp.ncbi.nlm.nih.gov/genomes/Homo_sapiens/ARCHIVE/BUILD.37.3/GFF/ Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/refseqs/v3/doc.html	
	Subset of NCBI Human RefSeqs with prefix of NC_ or NG_. Those prefixed with "NC_" represent the whole genomic RefSeq for individual chromosomes. Those prefixed with "NG_" represent genes with all of their introns and flanking regions and other larger or smaller genomic sequences. These are available separately in the NCBI source data file, which includes all human RefSeqs (including those with prefix of NR_ or XM_): ftp://ftp.ncbi.nlm.nih.gov/genomes/Homo_sapiens	
NCBI -protein reference sequence	**RefSeq-P**	**2.16.840.1.113883.6.331**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: https://www.ncbi.nlm.nih.gov/refseq/ Source table download: ftp://ftp.ncbi.nlm.nih.gov/genomes/Homo_sapiens/ARCHIVE/BUILD.37.3/GFF/ Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/refseqs/v3/doc.html	
	Subset of NCBI RefSeqs that represent reference sequences for proteins. Not routinely included in reports because Amino acid changes can be computed directly from DNA changes based on transcript reference sequence. However some fields are interested only in the protein sequence change, and proteins can be sequenced independently of DNA sequencing. We will explore the creation of coding systems for other protein reference identifiers such as UniProtKB accession numbers (http://www.uniprot.org/help/uniprotkb).	
NCBI-transcript reference sequences (RefSeq)	**RefSeq-T**	**2.16.840.1.113883.6.332**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: http://www.ncbi.nlm.nih.gov/refseq/ Source table download: ftp://ftp.ncbi.nlm.nih.gov/genomes/Homo_sapiens/ARCHIVE/BUILD.37.3/GFF/ Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/refseqs/v3/doc.html	
	Subset of NLM RefSeq records with prefix of "NM_" are reference sequences that represent messenger RNA.	
RxTerms- Ingredients Subset	**RxT-Ingrd**	**2.16.840.1.113883.6.334**
	Source organization: National Center for Biotechnology Information (NCBI) Source table information: https://wwwcf.nlm.nih.gov/umlslicense/rxtermApp/rxTerm.cfm Source table download: https://wwwcf.nlm.nih.gov/umlslicense/rxtermApp/rxTermCondition.cfm Place to Explore Table: https://clinicaltables.nlm.nih.gov/apidoc/drug_ingredients/v3/doc.html	
	RxT-Ingrd is a specialization of the RxNorm database that includes the ingredients in RxTerms (derived from RxNorm) except allergens (used for allergy testing), combination ingredients, and inactive ingredients. The subset is designed for identifying drugs that might be the focus of pharmacogenetic testing.	
SNOMED-CT	**SCT**	**2.16.840.1.113883.6.96**
	Source organization: International Health Terminology Standards Development Organisation Source table information: http://www.ihtsdo.org/snomed-ct Source table download: https://www.nlm.nih.gov/healthit/snomedct/us_edition.html (requires free UMLS License)	

TABLE 14-1. CLINICAL GENOMICS CODING SYSTEMS		
Coding System name	HL70396 Code	HL7 OID
	Place to Explore Table: Not implemented in the LHC public site, but registered users (with free UMLS license) can browse SNOMED CT via: https://www.nlm.nih.gov/research/umls/Snomed/snomed_browsers.html Copyright: International Health Terminology Standards Development Organisation, https://www.snomed.org/snomed-ct/get-snomed-ct	
	SNOMED CT is a concept-based, scientifically validated terminology that provides a unique and permanent concept identifier that can be included in multiple HL7 data types, including CD and CE. If the concept is found to be ambiguous or the meaning changes, the concept is inactivated but still retained and the identifier is never reused. It is required by Meaningful Use for many purposes. SNOMED CT's concepts are interrelated hierarchically and use description logic. SNOMED CT code development is in process for some of the Clinical Genomics specific answer lists in this guide, and in the meantime only LOINC answer codes may be the only available code system for some answers.	
Star Alleles (Pharmacogenomic)	**Star-Allele**	**2.16.840.1.113883.6.342**
	Source Organization: The Human Cytochrome P450 (CYP) Allele Nomenclature Database Source Table Information: https://www.pharmvar.org	
	The star allele nomenclature is commonly used in pharmacogenomics as shorthand to specify one or more specific variants in a gene that is known to impact drug metabolism or response. A star allele can identify either a single variant or a group of variants found in cis, and therefore it usually represents a haplotype. A star allele name is composed of the gene symbol and an allele number, separated by an asterisk, e.g. TPMT*2. By convention, the *1 allele represents the allele that contains the "reference" sequence, although that is not true in all cases. Closely related alleles may be assigned a common number and be differentiated by a unique letter that specifies the suballele (e.g., TPMT*3A, TPMT*3B). Pharmacogenomics tests commonly report patient phenotypes as diplotypes, i.e. *1/*3A. The star nomenclature system is inadequately defined and inconsistently adopted. Therefore, although the system we are proposing supports the inclusion of pharmacogenomics star alleles as a legacy syntax, we strongly encourage messages that include star alleles to rigorously define those alleles in Report Section 5, Glossary for Haplotype Definition, which allows the reporting lab to specify the variants with their local definitions.	
Unified Code for Units of Measure (UCUM)	**UCUM**	**2.16.840.1.113883.6.8**
	Source organization: Regenstrief Institute HL7 Long Name: Unified Code for Units of Measure Source table information: http://unitsofmeasure.org/trac Source table download (common UCUM units in clinical care): https://loinc.org/usage/units UCUM validator and converter: https://ucum.nlm.nih.gov/ucum-lhc/	
	Unified Code for Units of Measure (UCUM) is a syntax for defining units of measure including both metric and conventional units. It comes with tables and software for validating and converting values expressed in one unit of measure to a different but commensurate unit of measure. Its purpose is to facilitate unambiguous electronic communication of quantities together with their units. UCUM codes are intended for computer use. In HL7 V2, traditional unit strings can be included along with UCUM as needed. UCUM defines a syntax; so, like HGVS, there is no numeric code attached and no table with a complete enumeration. However, NLM and Regenstrief Institute developed a table of common UCUM units used in clinical care, available at: https://loinc.org/usage/units. Lister Hill Center at NLM has also developed a JavaScript program to convert and validate UCUM units, available at: https://github.com/lhncbc/ucum-lhc.	

15 NDBS LOINC REQUIREMENTS

Basic structure of the NDBS LOINC panel – not all diseases are tested in every state:

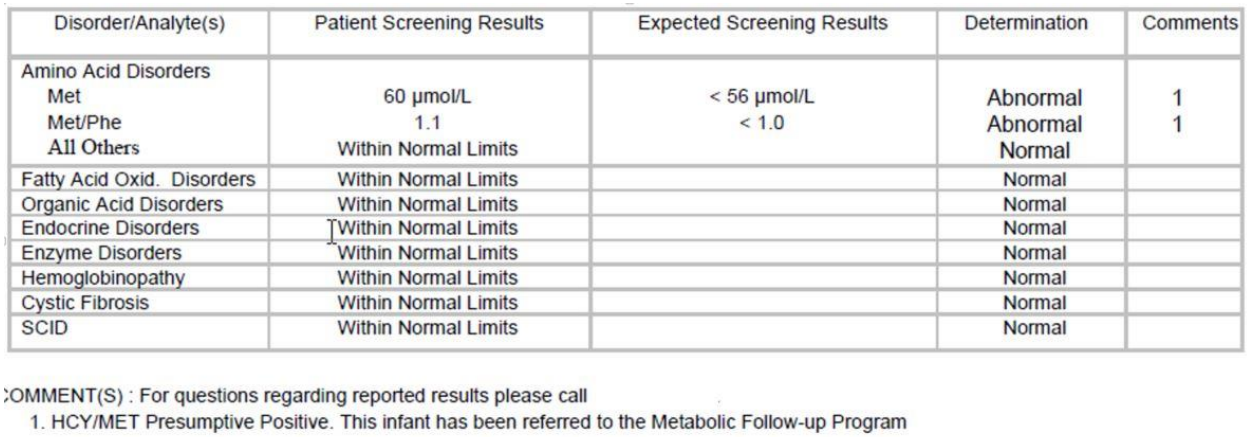
- High level panel order code
  - Group 1 = summary of all results for dried blood spot screening with several observations
  - Group 2 = Blood Spot Card Data (collected at time of order, aka Ask at Order Entry questions) with several observations
  - Group 3 = Dried Blood Spot test results with the following sub-groups
    - Group 3a = Amino acid newborn screen panel with several observations
    - Group 3 b1 = Acylcarnitine newborn screen panel with several observations
    - Or alternatively/additionally:
      - Group 3 b2 = Fatty acid oxidation newborn screen panel with several observations
      - And
      - Group 3b3 = Organic acid newborn screen panel with several observations
    - Group 3c = Cystic fibrosis newborn screening panel with several observations
    - Group 3d = Endocrine newborn screening panel with the following sub-groups
      - Group 3d1 = Congenital adrenal hyperplasia newborn screening panel with several observations
      - Group 3d2 = Thyroid newborn screening panel with several observations
    - Group 3e = Galactosemia newborn screening panel with several observations
    - Group 3f = Hemoglobinopathies newborn screening panel with several observations and a subgroup
      - Group 3f1 = Hemoglobin observations newborn screening panel with several observations
    - Group 3g = Infectious diseases newborn screening panel with several observations
    - Group 3h = Biotinidase newborn screening panel with several observations
    - Group 3i = Glucose-6-Phosphate dehydrogenase newborn screen panel with several observations
    - Group 3j = Lysosomal storage disorders newborn screening panel with several observations

Or alternatively/additionally

- Group 3j1 = Fabry disease newborn screening panel with several observations
- Group 3j2 = Krabbe disease newborn screening panel with several observations
- Group 3j3 = Gaucher disease newborn screening panel with several observations
- Group 3j4 = Niemann Pick disease A/B newborn screening panel with several observations
- Group 3j5 = Pompe disease newborn screening panel with several observations
- Group 3k = Severe combined immunodeficiency (SCID) newborn screening panel with several observations

- The following are point-of-care screening, and do not use dried blood spot, so they are technically out of scope for this Use Case; however, we list them because they are part of the LOINC newborn screening panel (and some states include this information in their NDBS report):
    - Group 4 = Newborn screening test results panel - Point of Care with several sub-groups
        - Group 4a = Newborn hearing screening panel with several observations and subgroups
            - Group 4a1 = Newborn hearing screen panel of Ear – right with several observations
            - Group 4a2 = Newborn hearing screen panel of Ear – left with several observations
        - Group 4b = CCHD newborn screening panel with several observations

Reports often summarize at the grouping level - see Figure 15-1.



Disorder/Analyte(s)	Patient Screening Results	Expected Screening Results	Determination	Comments
Amino Acid Disorders				
Met	60 µmol/L	< 56 µmol/L	Abnormal	1
Met/Phe	1.1	< 1.0	Abnormal	1
All Others	Within Normal Limits		Normal	
Fatty Acid Oxid. Disorders	Within Normal Limits		Normal	
Organic Acid Disorders	Within Normal Limits		Normal	
Endocrine Disorders	Within Normal Limits		Normal	
Enzyme Disorders	Within Normal Limits		Normal	
Hemoglobinopathy	Within Normal Limits		Normal	
Cystic Fibrosis	Within Normal Limits		Normal	
SCID	Within Normal Limits		Normal	

:OMMENT(S) : For questions regarding reported results please call
1. HCY/MET Presumptive Positive. This infant has been referred to the Metabolic Follow-up Program

Figure 15-1. Report Summarization by Group

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

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

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS

Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
54089-8	Newborn screening panel American Health Information Community (AHIC)	Order Only	N/A	R	[1..1]	This is the high-level order panel, it will be in OBR-4 (Universal Service Identifier) in the order message. It will NOT be in the result message in OBR-4 (Universal Service Identifier), but it may be identified in OBR-50 (Parent Universal Identifier) for all related Order_Observation groups.
57128-1	Newborn Screening Report summary panel	Order Only	54089-8	R	[1..1]	Must be present in one OBR-4 (Universal Service Identifier) in the result message.
57721-3	Reason for lab test in Dried blood spot	Coded	57128-1	O	[0..1]	**Normative Answer List** (LL831-9) Initial screen LA12421-6 Subsequent screen - required by law LA12425-7 Subsequent screen - required by protocol LA12426-5 Subsequent screen - for clarification of initial results (not by law or protocol LA12427-3 Subsequent screen - reason LA16473-3 No sample collected due to parental refusal LA14132-7 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57721-3.html?sections=Simple

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57718-9	Sample quality of Dried blood spot	Coded	57128-1	C	[0..*]	Condition: At minimum one of either SPM-24 (Specimen Condition) or an OBX with this LOINC MUST be present. **Preferred Answer List** (LL832-7) Acceptable LA12432-3 No sample received LA12433-1 Specimen damaged during transport LA20623-7 Specimen received in sealed plastic container LA20624-5 Specimen quantity insufficient due to incomplete saturation (blood did not soak through paper) LA20625-2 Specimen quantity insufficient because blood did not completely fill specimen circles LA20626-0 Specimen has uneven saturation LA20627-8 Specimen appears scratched or abraded LA12682-3 Specimen not dry before mailing LA12683-1 Specimen appears supersaturated LA12684-9 Specimen appears diluted, discolored or contaminated LA12685-6 Specimen exhibits serum rings LA12686-4 Specimen appears clotted or layered LA12435-6 Specimen not eluting LA20628-6 No blood LA12687-2 Sample too old LA12441-4 Testing of this specimen indicates more than one source of blood is present on the filter paper card LA20630-2 Unsuitable for other reasons LA20629-4 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57718-9.html?sections=Simple

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57130-7	Newborn screening report - overall interpretation	Coded	57128-1	R	[1..*]	**Example Answer List** (LL771-7) All screening is in range for the conditions tested LA12428-1 Screen is borderline for at least one condition LA12429-9 Screen is indeterminate for at least one condition LA18943-3 Screen is out of range for at least one condition LA18944-1 Out of range requiring further dried blood spot testing for at least one condition LA12430-7 Out of range requiring immediate referral LA25817-0 Out of range requiring immediate second-tier testing for at least one condition LA12431-5 Out of range requiring deferred follow-up for at least one condition LA18594-4 Screening not done due to parental refusal LA14133-5 One or more tests pending LA16204-2 Specimen unsatisfactory for at least one condition LA16205-9 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57130-7.html?sections=Simple
57131-5	Newborn conditions with positive markers [Identifier] in Dried blood spot	Coded	57128-1	O	[0..*]	Preferred answers are listed at http://s.details.loinc.org/LOINC/57131-5.html?sections=Simple including condition name abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
57720-5	Newborn conditions with equivocal markers [Identifier] in Dried blood spot	Coded	57128-1	O	[0..*]	Preferred answers are listed at http://s.details.loinc.org/LOINC/57720-5.html?sections=Simple including answer text (condition name abbreviation), SNOMED CT codes where available, and LOINC answer (LA) codes.
57724-7	Newborn screening short narrative summary	Text	57128-1	O	[0..1]	
57129-9	Full newborn screening summary report for display or printing	Text	57128-1	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57719-7	Conditions tested for in this newborn screening study [Identifier] in Dried blood spot	Coded	57128-1	C	[0..*]	Condition: This information MUST be reported, either using this LOINC code in repeating OBX segments, or in a NTE segment following the first OBR indicating ALL conditions tested for in this panel. Preferred Answer List (LL841-8) plus answer text (condition name abbreviation), SNOMED CT codes where available, and LOINC answer (LA) codes available at http://s.details.loinc.org/LOINC/57719-7.html?sections=Simple.
69969-4	Newborn screening report overall laboratory comment	Text	57128-1	O	[0..*]	
57717-1	Newborn screen card data panel	Order Only	54089-8	R	[1..1]	This code will be in a new Order_ObservationGroup. Any information that is used for NDBS result interpretation MUST be sent back in the LRI message, even to the ordering provider to document the data used for decision making.
57716-3	State printed on filter paper card [Identifier] in NBS card	Text	57717-1	C	[0..1]	Condition: This LOINC does not appear in the message: this data element is conveyed in SPM-2.1 (Specimen ID.Placer Assigned Identifier) in the message.
79566-6	Collection method – Dried blood spot	Coded	57717-1	C	[0..1]	Condition: This LOINC does not appear in the message; this data element is conveyed in SPM-7 Specimen Collection Method with LRI_NDBS_Component Usage: Data Type: CWE_03; Usage: 'RE', Cardinality: [0..1], Value Set: SNOMED CT and/or LOINC Preferred Answer List (LL3860-5).
8339-4	Birth weight Measured	Numeric	57717-1	C	[0..1]	This information is expected to be provided with the order and will be sent back, if received; If not received with the order, the interpretation will be done on null.
58229-6	Body weight Measured -- when specimen taken	Numeric	57717-1	O	[0..1]	
57715-5	Birth time	TM	57717-1	X	[0..0]	MUST report Birth time, as part of PID-7 (Date/Time of Birth).

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
73806-2	Newborn age in hours	TM	57717-1	O	[0..1]	**Note:** This term can be used to report the number of hours post-birth, aka Newborn Age when the newborn dried blood spot specimen is collected. For sake of simplicity and accuracy, we recommend computing this value based on the difference between birth time (PID-7 or OBX with LOINC 57715-5) and specimen collection time (SPM-17). Therefore, although this information is critical for interpretation of newborn screening results, this term is optional. If this term is used, sender should report and receiver should store and display the time using hours as units of measure.
57722-1	Birth plurality of Pregnancy	Coded	57717-1	O	[0..1]	This information differs from what can be recorded in PID-24 (Multiple Birth Indicator) with a "yes/no" response, and PID-25 (Birth Order) listing the number identifying for multiple births, whether this baby was born first, second, third, etc.. Sending this LOINC in an OBX indicates how many total babies were delivered. In cases of multiple birth, we encourage reporting all three of these attributes. Normative answers represent the number of fetuses (1 - 12), or 'unknown number' using **Normative Answer List** (LL829-3) available at http://s.details.loinc.org/LOINC/57722-1.html?sections=Simple
57714-8	Obstetric estimation of gestational age	Numeric	57717-1	O	[0..1]	Estimate of the infant's gestation in completed weeks; include 'wk' drawn from UCUM in OBX-6 (Units).
57713-0	Infant factors that affect newborn screening interpretation	Coded	57717-1	O	[0..*]	This information is expected to be provided with the order and will be sent back, if received. **Preferred Answer List** (LL830-1): None LA137-2 Infant in NICU at time of specimen collection LA12419-0 Infant in special care setting (other than ICU) at time of specimen collection LA25801-4 Preterm/Low birth weight (LBW) LA25802-2 Any blood product transfusion (including ECLS/ECMO) LA12417-4 Dopamine LA16923-7 Topical iodine LA16924-5 Acute illness LA25803-0 Hypothyroxinemia of preterm birth LA25804-8 Significant hypoxia LA25812-1

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
						Immature hypothalamic/pituitary axis LA25805-5 Immature liver enzymes LA25806-3 Immature renal system LA25807-1 Iodine deficiency LA25809-7 Liver disease LA25810-5 Other conditions, such as biliary atresia, intestinal perforation, abdominal wall defects, septicemia, CMV, renal failure, T21, T18, T13 LA25811-3 Parenteral steroid treatment LA16925-2 Systemic antibiotics before newborn screening LA12420-8 Meconium ileus or other bowel obstruction LA16927-8 Thoracic surgery involving thymectomy LA25815-4 Immunosuppressive therapy of baby or mother LA25808-9 Total parenteral nutrition (TPN) or similar feeding LA25816-2 Special lactose-free diet LA25813-9 Special low protein diet LA25814-7 Other LA46-8 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57713-0.html?sections=Simple
67703-9	Other infant factors that affect newborn screening interpretation Narrative	Text	57717-1	C	[0..*]	Condition: If 'other' is reported under 57713-0^Infant factors that affect newborn screening interpretation^LN, this element is required.
67706-2	Maternal factors that affect newborn screening interpretation	Coded	57717-1	O	[0..*]	**Preferred Answer List** (LL1736-9) None LA137-2 HELLP syndrome LA16928-6 Fatty liver of pregnancy LA16929-4 Packed red blood cell (PRBC) transfusion LA16930-2 Steroid treatment LA16931-0 Thyroid treatment (including propylthiouracil (PTU), methimazole (Tapazole), or past treatment with radioactive iodine (I-131)) LA16932-8 TPN LA12418-2 Other LA46-8 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/67706-2.html?sections=Simple

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
67707-0	Other maternal factors that affect newborn screening interpretation Narrative	Text	57717-1	C	[0..*]	Condition: If 'Other' is reported under 67706-2^Maternal factors that affect newborn screening interpretation^LN, this element is required.
77739-1	Mother's Hepatitis B virus surface Ag status	Coded	57717-1	O	[0..1]	**Preferred Answer List** (LL3639-3) Positive LA6576-8 Negative LA6577-6 Not tested LA13538-6 Unknown LA4489-6 **Note:** Some may prefer to report this using 67706-2 Maternal factors that affect newborn screening interpretation and 67707-0 Other maternal factors that affect newborn screening interpretation Narrative. **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/77739-1.html?sections=Simple
57712-2	Mother's education	Coded	57717-1	O	[0..1]	Please refer to existing HL7 implementation guide for Early Hearing Detection and Intervention (EHDI at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=344 **Normative Answer List** (LL836-8) 8th grade/less LA36-9 9th - 12th grade, no diploma LA12456-2 High school graduate or GED completed LA12457-0 Some college credit but no degree LA12458-8 Associate degree (e.g., AA, AS) LA12459-6 Bachelor's degree (e.g., BA, AB, BS) LA12460-4 Master's degree (e.g., MA, MS, MEng, MEd, MSW, MBA) LA12461-2 Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD) LA12462-0 Unknown LA4489-6 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/57712-2.html?sections=Simple

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
67704-7	Feeding types	Coded	57717-1	O	[0..*]	This information is expected to be provided with the order and will be sent back, if received. **Normative Answer List** (LL1735-1): Breast milk LA16914-6 Lactose formula LA16915-3 Lactose free formula (including soy or hydrolyzed)* LA14041-0 NPO LA16917-9 TPN LA12418-2 Carnitine LA16918-7 MCT (medium-chain triglyceride) oil LA16919-5 IV dextrose LA16920-3 Other LA46-8 None** LA137-2 Unknown LA4489-6 * Infant is on a soy or hydrolyzed formula. Only these two types of formulas do not contain lactose, which can affect galactosemia screening results because the infant does not have a sufficient lactose load. This answer is important for result interpretation. Absence of lactose can give a false negative result. ** Indicates that the infant has had no feeds of any kind (by mouth, by IV, etc.) **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/67704-7.html?sections=Simple
67705-4	Other feeding types Narrative	Text	57717-1	C	[0..*]	Condition: If 'other' is reported under 67704-7^Feeding types^LN, this element is required.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
79569-0	Blood product given	Coded	57717-1	O	[0..*]	**Preferred Answer List** (LL3859-7) Blood product transfusion that includes Red Blood Cells (RBC) LA25396-5 Blood product transfusion that does NOT include Red Blood Cells (RBC) LA25397-3 Extracorporeal life support (ECLS)/Extracorporeal membrane oxygenation (ECMO) LA25398-1 Intrauterine Fetal Blood Transfusion that includes Red Blood Cells (RBC) LA25399-9 Intrauterine Fetal Blood Transfusion that does not includes Red Blood Cells (RBC) LA25400-5 Other blood product transfusion LA25401-3 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/79569-0.html?sections=Simple
62317-3	Date of last blood product transfusion	DTM	57717-1	O	[0..1]	This is the date of the last transfusion prior to dried blood spot specimen collection.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
58232-0	Hearing loss risk indicators [Identifier]	Coded	57717-1	O	[0..*]	Please refer to existing HL7 implementation guide for Early Hearing Detection and Intervention (EHDI at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=344). **Preferred Answer List** (LL862-4): None LA137-2 Caregiver concern about hearing LA12667-4 Family Hx of hearing loss LA12668-2 ICU stay > 5 days LA12669-0 ECMO LA12670-8 Assisted ventilation LA12671-6 Ototoxic medication use LA12672-4 Exchange transfusion for Hyperbilirubinemia LA12673-2 In utero infection(s) LA12674-0 Craniofacial anomalies LA12675-7 Physical findings of syndromes that include hearing loss LA12681-5 Syndromes associated with hearing loss LA12676-5 Neurodegenerative disorders LA12677-3 Postnatal infections LA12678-1 Head trauma LA12679-9 Chemotherapy LA6172-6 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/58232-0.html?sections=Simple

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
74482-1	Reason for unsatisfactory specimen not related to sample quality of dried blood spot	Coded	57717-1	O	[0..*]	Note that this LOINC code will still need to be officially added to the published AHIC panel by RegenstriefCoded **Preferred Answer List** (LL2768-1): Demographic information is incomplete or invalid LA20631-0 Demographic information on filter paper does not match electronically submitted information LA20632-8 Serial number on filter paper does not match serial number on patient information form LA20633-6 Specimen submitted on expired filter paper LA20634-4 Sample collected too early LA20635-1 Specimen unsatisfactory due to delay in transit LA20636-9 Specimen results inconsistent LA20637-7 Assay interference LA20638-5 Unable to analyze specimen due to laboratory accident LA20639-3 Unsuitable for other reasons LA20629-4
54106-0	Newborn hearing screen method	Coded	54089-8	O	[0..1]	**Note:** This code is out of scope for this Newborn Dried Blood Spot Screening (NDBS) use case, but listed here because some state newborn screening programs do report this information with their NDBS results. Additional details available in the existing HL7 implementation guide for Early Hearing Detection and Intervention (EHDI at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=344). For additional LOINC code details including definitions/descriptions and answer lists, please refer to http://s.details.loinc.org/LOINC/73738-7.html?sections=Comprehensive
54108-6	Newborn hearing screen of Ear - left	Coded	54089-8	O	[0..1]	See Note above.
54109-4	Newborn hearing screen of Ear - right	Coded	54089-8	O	[0..1]	See Note above.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
73700-7	CCHD newborn screening interpretation	Coded	54089-8	O	[0..1]	**Note:** This code is out of scope for this Newborn Dried Blood Spot Screening (NDBS) use case, but listed here because some state newborn screening programs do report this information with their NDBS results. Additional details available in the existing HL7 implementation guide for Critical Congenital Heart Defects and pulse oximetry screening (CCHD at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=366). For additional LOINC code details including definitions/descriptions and answer lists, please refer to http://s.details.loinc.org/LOINC/73805-4.html?sections=Comprehensive
73698-3	Reason CCHD oxygen saturation screening not performed	Coded	54089-8	O	[0..1]	[see Note above]
57723-9	Unique bar code number of Current sample	Text	57717-1	R	[1..1]	
57711-4	Unique bar code number of Initial sample	Text	57717-1	O	[0..1]	
62323-1	Post-discharge provider ID [Identifier]	Text	57717-1	O	[0..1]	
62324-9	Post-discharge provider name in Provider	Text	57717-1	O	[0..1]	
62325-6	Post-discharge provider practice ID	Text	57717-1	O	[0..1]	
62326-4	Post-discharge provider practice name	Text	57717-1	O	[0..1]	
62327-2	Post-discharge provider practice address	XAD	57717-1	O	[0..1]	
62328-0	Post-discharge provider practice telephone number	XTN	57717-1	O	[0..1]	
62329-8	Birth hospital facility ID [Identifier] in Facility	Text	57717-1	O	[0..1]	
62330-6	Birth hospital facility name	Text	57717-1	O	[0..1]	
62331-4	Birth hospital facility address	XAD	57717-1	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
62332-2	Birth hospital facility phone number in Facility	XTN	57717-1	O	[0..1]	
57794-0	Newborn screening test results panel - Dried blood spot	Order Only	54089-8	X	[0..0]	Not included in the message, does not have individual OBX segments, rather is the overall grouper in the LOINC panel.
53261-4	Amino acid newborn screen panel	Order Only	54089-8	C	[0..1]	Condition: MUST be included in the message, if state tests for condition.
46733-2	Amino acidemias newborn screen interpretation	Coded	53261-4	C	[0..*]	Condition: Either this is required or the individual results are required, when preceding OBR-4 is 53261-4^Amino acid newborn screen panel^LN. Both are permitted. **Preferred Answer List** (LL840-0): In range LA18592-8 Borderline LA4259-3 Indeterminate LA11884-6 Out of range LA18593-6 Out of range requiring further dried blood spot testing for at least one condition LA12430-7 Out of range requiring immediate referral LA25817-0 Out of range requiring immediate second-tier testing for at least one condition LA12431-5 Out of range requiring deferred follow-up for at least one condition LA18594-4 One or more tests pending LA16204-2 Specimen unsatisfactory for at least one condition LA16205-9 **Note:** Definitions and additional details available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
57710-6	Amino acidemias newborn screening comment-discussion	Text	53261-4	C	[0..*]	Condition: If 46733-2^Amino acidemias newborn screen interpretation^LN is included and the result necessitates comments.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57793-2	Amino acidemia disorder suspected [Identifier] in Dried blood spot	Coded	53261-4	C	[0..*]	Condition: If 46733-2^Amino acidemias newborn screen interpretation^LN is included. Preferred answers are listed at http://s.details.loinc.org/LOINC/57793-2.html?sections=Simple including condition name abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
46746-4	Phenylketonuria and variants/Biopterin defects newborn screen interpretation	Coded	53261-4	C	[0..*]	Condition: MSUD and PKU are special cases, Either A. the disorder group interpretation is required or B. the disorder list suspected within the group (e.g. 57793-2 amino acid disorders suspected) along with the individual results (values) are required. All are permitted. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
58231-2	Phenylketonuria and variants/Biopterin defects newborn screening comment-discussion	Text	53261-4	C	[0..*]	Condition: If 46746-4^Phenylketonuria and variants/Biopterin defects newborn screen interpretation^LN is included and the result necessitates comments.
46743-1	Maple syrup urine disease newborn screen interpretation	Coded	53261-4	C	[0..*]	Condition: MSUD and PKU are special cases, Either A. the disorder group interpretation is required or B. the disorder list suspected within the group (e.g. 57793-2 amino acid disorders suspected) along with the individual results (values) are required. All are permitted. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
58230-4	Maple syrup urine disease newborn screening comment-discussion	Text	53261-4	C	[0..*]	Condition: If 46743-1^Maple syrup urine disease newborn screen interpretation^LN is included and the result necessitates comments.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
47539-2	3-Methylhistidine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	**Note:** Definitions/descriptions, related names and example units of measure in computable UCUM format for all numeric NDBS measures are available at http://r.details.loinc.org/LOINC/54089-8.html?sections=Comprehensive. **Note:** Relationships between the conditions that are targeted by newborn screening and the tests/analytes/measurements that are used as markers for newborn screening conditions, as well as synonyms, and mappings to other code systems including International Classification of Diseases (ICD-9-CM and ICD-10-CM), Enzyme Commission (EC) codes and classifications, Online Mendelian Inheritance in Man® (OMIM®), and Universal Protein Resource (UniProt) are available at: https://newbornscreeningcodes.nlm.nih.gov/
53232-5	5-Oxoproline+Pipecolate [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53394-3	5-Oxoproline+Pipecolate/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53150-9	Alanine+Beta Alanine+Sarcosine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53393-5	Alloisoleucine+Isoleucine+Leucine+Hydroxyproline+Valine/Phenylalanine+Tyrosine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53152-5	Alloisoleucine+Isoleucine+Leucine+Hydroxyproline [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53153-3	Alloisoleucine+Isoleucine+Leucine+Hydroxyproline/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53154-1	Alloisoleucine+Isoleucine+Leucine+Hydroxyproline/Alanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47562-4	Arginine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
75214-7	Arginine/Ornithine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53398-4	Arginine/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53062-6	Argininosuccinate [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53200-2	Argininosuccinate/Arginine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53155-8	Asparagine+Ornithine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53395-0	Asparagine+Ornithine/Serine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53396-8	Asparagine+Ornithine/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47573-1	Aspartate [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
42892-0	Citrulline [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
54092-2	Citrulline/Arginine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53157-4	Citrulline/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53399-2	Citrulline/Tyrosine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47623-4	Glutamate [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47633-3	Glycine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47643-2	Histidine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53158-2	Homocitrulline [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47689-5	Lysine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47700-0	Methionine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53397-6	Methionine/Alloisoleucine+ Isoleucine+Leucine+ Hydroxyproline [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53156-6	Methionine/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
75215-4	Ornithine/Citrulline [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
29573-3	Phenylalanine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
35572-7	Phenylalanine/Tyrosine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47732-3	Proline [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53392-7	Proline/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47742-2	Serine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53231-7	Succinylacetone [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47784-4	Threonine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53159-0	Tryptophan [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
35571-9	Tyrosine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
47799-2	Valine [Moles/volume] in Dried blood spot	Numeric	53261-4	O	[0..1]	
53151-7	Valine/Phenylalanine [Molar ratio] in Dried blood spot	Numeric	53261-4	O	[0..1]	
58092-8	Acylcarnitine newborn screen panel	Order Only	54089-8	C	[0..1]	Condition: MUST be included in the message, if state tests for any of these conditions. HOWEVER, if tested, but 57084-6^Fatty acid oxidation newborn screen panel^LN and 57085-3^Organic acid newborn screen panel^LN are reported, this might NOT be reported.
58088-6	Acylcarnitine newborn screen interpretation	Coded	58092-8	C	[0..*]	Condition: Required if state tests for these conditions, and preceding OBR-4 is 58092-8^Acylcarnitine newborn screen panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
58093-6	Acylcarnitine newborn screening comment-discussion	Text	58092-8	C	[0..*]	Condition: If 58088-6^Acylcarnitine newborn screen interpretation^LN is included and the result necessitates comments.
57084-6	Fatty acid oxidation newborn screen panel	Order Only	54089-8	C	[0..1]	Condition: MUST be included in the message, if state tests for any of these conditions. HOWEVER, if tested but 58088-6^Acylcarnitine newborn screen interpretation^LN is reported, this might NOT be reported.
46736-5	Fatty acid oxidation defects newborn screen interpretation	Coded	57084-6	C	[0..*]	Condition: Required if state tests for these conditions, and preceding OBR-4 is 57084-6^Fatty acid oxidation newborn screen panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
57792-4	Fatty acid oxidation conditions suspected [Identifier] in Dried blood spot	Coded	57084-6	C	[0..*]	Condition: If 46736-5^Fatty acid oxidation defects newborn screen interpretation^LN is included. Preferred answers are listed at http://s.details.loinc.org/LOINC/57792-4.html?sections=Simple including condition name abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
57709-8	Fatty acid oxidation defects newborn screening comment-discussion	Text	57084-6	C	[0..*]	Condition: If 46736-5^Fatty acid oxidation defects newborn screen interpretation^LN is included and the result necessitates comments.
38481-8	Carnitine free (C0) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53233-3	Carnitine free (C0)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53234-1	Carnitine free (C0)/Stearoylcarnitine (C18) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53235-8	Carnitine free (C0)/Palmitoylcarnitine (C16)+Stearoylcarnitine (C18) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53236-6	Carnitine.free (C0)+Acetylcarnitine (C2)+Propionylcarnitine (C3)+Palmitoylcarnitine (C16)+Oleoylcarnitine (C18:1)+Stearoylcarnitine (C18)/Citrulline [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
75211-3	Propionylcarnitine (C3)+Palmitoylcarnitine (C16) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
75212-1	Malonylcarnitine (C3-DC)/Decanoylcarnitine (C10) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
54462-7	Malonylcarnitine (C3-DC) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
75213-9	Malonylcarnitine (C3-DC)+3-Hydroxybutyrylcarnitine (C4-OH)/Decanoylcarnitine (C10) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
50157-7	Acetylcarnitine (C2) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53166-5	Butyrylcarnitine+Isobutyryl carnitine (C4) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53167-3	Butyrylcarnitine+Isobutyryl carnitine (C4)/Acetylcarnitine (C2) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53168-1	Butyrylcarnitine+Isobutyryl carnitine (C4)/Propionylcarnitine (C3) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53169-9	Butyrylcarnitine+Isobutyryl carnitine (C4)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
50102-3	3-Hydroxybutyrylcarnitine (C4-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
45211-0	Hexanoylcarnitine (C6) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53173-1	3-Hydroxyhexanoylcarnitine (C6-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
45207-8	Glutarylcarnitine (C5-DC) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
75216-2	Glutarylcarnitine (C5-DC)/Malonylcarnitine (C3-DC) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53174-9	Octenoylcarnitine (C8:1) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53175-6	Octanoylcarnitine (C8) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53176-4	Octanoylcarnitine (C8)/Acetylcarnitine (C2) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53177-2	Octanoylcarnitine (C8)/Decanoylcarnitine (C10) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53178-0	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53178-0	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53402-4	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC)/Butyrylcarnitine+Isobutyrylcarnitine (C4) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53402-4	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC)/Butyrylcarnitine+Isobutyrylcarnitine (C4) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53179-8	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC)/Decanoylcarnitine (C10) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53179-8	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC)/Decanoylcarnitine (C10) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53180-6	Decadienoylcarnitine (C10:2) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
45198-9	Decenoylcarnitine (C10:1) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
45197-1	Decanoylcarnitine (C10) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53182-2	3-Hydroxydecenoylcarnitine (C10:1-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53183-0	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53183-0	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53403-2	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Butyrylcarnitine+Isobutyrylcarnitine (C4) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53403-2	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Butyrylcarnitine+Isobutyrylcarnitine (C4) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53184-8	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/3-Hydroxyisovalerylcarnitine (C5-OH) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53184-8	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/3-Hydroxyisovalerylcarnitine (C5-OH) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53185-5	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53185-5	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53186-3	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53186-3	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
45200-3	Dodecenoylcarnitine (C12:1) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
45199-7	Dodecanoylcarnitine (C12) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53188-9	3-Hydroxydodecenoylcarnitine (C12:1-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53189-7	3-Hydroxydodecanoylcarnitine (C12-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53190-5	Tetradecadienoylcarnitine (C14:2) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53191-3	Tetradecenoylcarnitine (C14:1) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53192-1	Tetradecanoylcarnitine (C14) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53193-9	Tetradecenoylcarnitine (C14:1)/Acetylcarnitine (C2) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53194-7	Tetradecenoylcarnitine (C14:1)/Dodecenoylcarnitine (C12:1) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53195-4	Tetradecenoylcarnitine (C14:1)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
70159-9	Tetradecenoylcarnitine (C14:1)/Tetradecanoylcarnitine (C14) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53196-2	3-Hydroxytetradecadienoylcarnitine (C14:2-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53197-0	3-Hydroxytetradecenoylcarnitine (C14:1-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
50281-5	3-Hydroxytetradecanoylcarnitine (C14-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53198-8	Palmitoleylcarnitine (C16:1) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53199-6	Palmitoylcarnitine (C16) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
50121-3	3-Hydroxypalmitoleylcarnitine (C16:1-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
50125-4	3-Hydroxypalmitoylcarnitine (C16-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53201-0	3-Hydroxypalmitoylcarnitine (C16-OH)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	
45217-7	Linoleoylcarnitine (C18:2) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53202-8	Oleoylcarnitine (C18:1) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53241-6	Stearoylcarnitine (C18) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
53400-8	Stearoylcarnitine (C18)/Propionylcarnitine (C3) [Molar ratio] in Dried blood spot	Numeric	57084-6	O	[0..1]	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
50109-8	3-Hydroxylinoleoylcarnitine (C18:2-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
50113-0	3-Hydroxyoleoylcarnitine (C18:1-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
50132-0	3-Hydroxystearoylcarnitine (C18-OH) [Moles/volume] in Dried blood spot	Numeric	57084-6	O	[0..1]	
57085-3	Organic acid newborn screen panel	Order Only	54089-8	C	[0..1]	Condition: Must be included in the message, if state tests for any of these conditions. However, if tested but 58088-6^Acylcarnitine newborn screen interpretation^LN is reported, this might NOT be reported.
46744-9	Organic acidemias newborn screen interpretation	Coded	57085-3	C	0..*	Condition: Required if state tests for any of these conditions, and preceding OBR-4 is 57085-3^Organic acid newborn screen panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
57791-6	Organic acidemia conditions suspected [Identifier] in Dried blood spot	Coded	57085-3	C	0..*	Condition: If 46744-9^Organic acidemias newborn screen interpretation^LN is included. **Preferred Answer List** at http://s.details.loinc.org/LOINC/57791-6.html?sections=Simple including condition name abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
57708-0	Organic acidemias defects newborn screening comment-discussion	Text	57085-3	C	0..*	Condition: If 46744-9^Organic acidemias newborn screen interpretation^LN is included and the result necessitates comments.
50157-7	Acetylcarnitine (C2) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53237-4	Acrylylcarnitine (C3:1) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53160-8	Propionylcarnitine (C3) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53161-6	Propionylcarnitine (C3)/Methionine [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53162-4	Propionylcarnitine (C3)/Carnitine.free (C0) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53163-2	Propionylcarnitine (C3)/Acetylcarnitine (C2) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
54462-7	Malonylcarnitine (C3-DC) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
67708-8	Malonylcarnitine (C3-DC)+3-Hydroxybutyrylcarnitine (C4-OH) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
75213-9	Malonylcarnitine (C3-DC)+3-Hydroxybutyrylcarnitine (C4-OH)/Decanoylcarnitine (C10) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53164-0	Propionylcarnitine (C3)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53166-5	Butyrylcarnitine+Isobutyryl carnitine (C4) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53167-3	Butyrylcarnitine+Isobutyryl carnitine (C4)/Acetylcarnitine (C2) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53168-1	Butyrylcarnitine+Isobutyryl carnitine (C4)/Propionylcarnitine (C3) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53169-9	Butyrylcarnitine+Isobutyryl carnitine (C4)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53170-7	Tiglylcarnitine (C5:1) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
45207-8	Glutarylcarnitine (C5-DC) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
75216-2	Glutarylcarnitine (C5-DC)/ Malonylcarnitine (C3-DC) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
67701-3	Glutarylcarnitine (C5-DC)+3-Hydroxyhexanoylcarnitine (C6-OH)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
67710-4	Glutarylcarnitine (C5-DC)+3-Hydroxyhexanoylcarnitine (C6-OH) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
67711-2	Glutarylcarnitine (C5-DC)+3-Hydroxyhexanoylcarnitine (C6-OH)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
45216-9	Isovalerylcarnitine+Methylbutyrylcarnitine (C5) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53238-2	Isovalerylcarnitine+Methylbutyrylcarnitine (C5)/Carnitine.free (C0) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53239-0	Isovalerylcarnitine+Methylbutyrylcarnitine (C5)/Acetylcarnitine (C2) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53240-8	Isovalerylcarnitine+Methylbutyrylcarnitine (C5)/Propionylcarnitine (C3) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53401-6	Isovalerylcarnitine+Methylbutyrylcarnitine (C5)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
50106-4	3-Hydroxyisovalerylcarnitine (C5-OH) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53171-5	3-Hydroxyisovalerylcarnitine (C5-OH)/Carnitine.free (C0) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53172-3	3-Hydroxyisovalerylcarnitine (C5-OH)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53178-0	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53402-4	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC)/Butyrylcarnitine+Isobutyrylcarnitine (C4) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53179-8	3-Hydroxyoctanoylcarnitine (C8-OH)+Malonylcarnitine (C3-DC)/Decanoylcarnitine (C10) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
45222-7	Methylmalonylcarnitine (C4-DC) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
67709-6	Methylmalonylcarnitine (C4-DC)+3-Hydroxyisovalerylcarnitine (C5-OH) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53181-4	Methylmalonylcarnitine (C4-DC)/3-Hydroxyisovalerylcarnitine (C5-OH) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53183-0	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53403-2	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Butyrylcarnitine+Isobutyrylcarnitine (C4) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
53184-8	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/3-Hydroxyisovalerylcarnitine (C5-OH) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53185-5	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Octanoylcarnitine (C8) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53186-3	Glutarylcarnitine (C5-DC)+3-Hydroxydecanoylcarnitine (C10-OH)/Palmitoylcarnitine (C16) [Molar ratio] in Dried blood spot	Numeric	57085-3	O	0..1	
53187-1	Methylglutarylcarnitine (C6-DC) [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
53165-7	Formiminoglutamate [Moles/volume] in Dried blood spot	Numeric	57085-3	O	0..1	
54078-1	Cystic fibrosis newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
46769-6	Cystic fibrosis newborn screen interpretation	Coded	54078-1	C	0..*	Condition: Required if state tests for this condition, and preceding OBR-4 should be 54078-1^Cystic fibrosis newborn screening panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57707-2	Cystic fibrosis newborn screening comment-discussion	Text	54078-1	C	0..*	Condition: If 46769-6^Cystic fibrosis newborn screen interpretation^LN is included and the result necessitates comments.
54083-1	CFTR gene mutations found [Identifier] in Dried blood spot Nominal	Text/Coded	54078-1	O	0..*	
2077-6	Chloride [Moles/volume] in Sweat	Numeric	54078-1	O	0..1	
48633-2	Trypsinogen I Free [Mass/volume] in Dried blood spot	Numeric	54078-1	O	0..1	
54076-5	Endocrine newborn screening panel	Order Only	54089-8	X		Not included in the message, does not have individual OBX segments, rather is the overall grouper in the LOINC panel.
57086-1	Congenital adrenal hyperplasia newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
46758-9	Congenital adrenal hyperplasia newborn screen interpretation	Coded	57086-1	C	0..*	Condition: Required if state tests for this condition, and preceding OBR-4 should be 57086-1^Congenital adrenal hyperplasia newborn screening panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
57706-4	Congenital adrenal hyperplasia newborn screening comment-discussion	Text	57086-1	C	0..*	Condition: If 46758-9^Congenital adrenal hyperplasia newborn screen interpretation^LN is included and the result necessitates comments.
53347-1	11-Deoxycorticosterone [Mass/volume] in Dried blood spot	Numeric	57086-1	O	0..1	
53338-0	11-Deoxycortisol [Mass/volume] in Dried blood spot	Numeric	57086-1	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
38473-5	17-Hydroxyprogesterone [Mass/volume] in Dried blood spot	Numeric	57086-1	O	0..1	
53336-4	17-Hydroxyprogesterone+Androstenedione/Cortisol [Mass Ratio] in Dried blood spot	Numeric	57086-1	O	0..1	
53341-4	21-Deoxycortisol [Mass/volume] in Dried blood spot	Numeric	57086-1	O	0..1	
53343-0	Androstenedione [Mass/volume] in Dried blood spot	Numeric	57086-1	O	0..1	
53345-5	Cortisol [Mass/volume] in Dried blood spot	Numeric	57086-1	O	0..1	
54090-6	Thyroid newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
46762-1	Congenital hypothyroidism newborn screen interpretation	Coded	54090-6	C	0..*	Condition: Required if the state tests for this condition, and preceding OBR-4 should be 54090-6^Thyroid newborn screening panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
57705-6	Congenital hypothyroidism newborn screening comment-discussion	Text	54090-6	C	0..*	Condition: If 46762-1^Congenital hypothyroidism newborn screen interpretation^LN is included and the result necessitates comments.
31144-9	Thyroxine (T4) [Mass/volume] in Dried blood spot	Numeric	54090-6	O	0..1	
29575-8	Thyrotropin [Units/volume] in Dried blood spot	Numeric	54090-6	O	0..1	
54079-9	Galactosemia newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
46737-3	Galactosemias newborn screen interpretation	Coded	54079-9	C	0..*	Condition: Required if the state tests for these conditions, and preceding OBR-4 should be 54079-9^Galactosemia newborn screening panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
57704-9	Galactosemias newborn screening comment-discussion	Text	54079-9	C	0..*	Condition: If 46737-3^Galactosemias newborn screen interpretation^LN is included and the result necessitates comments.
54084-9	Galactose [Mass/volume] in Dried blood spot	Numeric	54079-9	O	0..1	
33288-2	Galactose 1 phosphate uridyl transferase [Presence] in Dried blood spot	Ordinal	54079-9	O	0..1	
42906-8	Galactose 1 phosphate uridyl transferase [Enzymatic activity/volume] in Dried blood spot	Numeric	54079-9	O	0..1	
40842-7	Galactose 1 phosphate [Mass/volume] in Dried blood spot	Numeric	54079-9	O	0..1	
54081-5	Hemoglobinopathies newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
46740-7	Hemoglobin disorders newborn screen interpretation	Coded	54081-5	C	0..*	Condition: Required if the state tests for these conditions, and the preceding OBR-4 should be 54081-5^Hemoglobinopathies newborn screening panel^LN. **Preferred Answer List** (LL840-0) is available at: http://s.details.loinc.org/LOINC/46733-2.html?sections=Simple
57703-1	Hemoglobin disorders newborn screening comment-discussion	Text	54081-5	C	0..*	Condition: If 46740-7^Hemoglobin disorders newborn screen interpretation^LN is included and the result necessitates comments.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
71592-0	Hemoglobinopathies conditions suspected [Identifier] in Dried blood spot	Coded	54081-5	C	0..*	Condition: If 46740-7^Hemoglobin disorders newborn screen interpretation^LN is included. **Preferred Answer List** at http://s.details.loinc.org/LOINC/71592-0.html?sections=Simple including condition name abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
64116-7	Hemoglobin observations newborn screening panel	Order Only	54081-5	O	0..1	
64122-5	Hemoglobins that can be presumptively identified based on available controls in Dried blood spot	Coded	64116-7	O	0..*	If hemoglobin observations (patterns of Hb types identified and listed in order of predominance) are reported, this information must be reported, either using this LOINC code in repeating OBX segments, or in a NTE segment, following the OBR 64116-7, indicating ALL Hemoglobins that can be presumptively identified based on available controls in Dried blood spot. **Answer List** (LL1511-6) is available at http://r.details.loinc.org/AnswerList/LL1511-6.html including hemoglobin type abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
64117-5	Most predominant hemoglobin in Dried blood spot	Coded	64116-7	O	0..1	If reported, must also report 64122-5 (Hemoglobins that can be presumptively identified based on available controls in Dried blood spot), or equivalent information in an NTE segment. **Answer List** (LL1511-6) is available at http://r.details.loinc.org/AnswerList/LL1511-6.html including hemoglobin type abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
64118-3	Second most predominant hemoglobin in Dried blood spot	Coded	64116-7	O	0..1	See note above.
64119-1	Third most predominant hemoglobin in Dried blood spot	Coded	64116-7	O	0..1	See note above.
64120-9	Fourth most predominant hemoglobin in Dried blood spot	Coded	64116-7	O	0..1	See note above.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
64121-7	Fifth most predominant hemoglobin in Dried blood spot	Coded	64116-7	O	0..1	See note above
54072-4	Hemoglobin A/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
54069-0	Hemoglobin Barts/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
54073-2	Hemoglobin C/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
54070-8	Hemoglobin D/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
54071-6	Hemoglobin E/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
54074-0	Hemoglobin F/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
54068-2	Hemoglobin O-Arab/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
56476-5	Hemoglobin S/ Hemoglobin.total in Dried blood spot	Numeric	54081-5	O	0..1	
54082-3	Infectious diseases newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
57702-3	Infectious diseases newborn screen interpretation	Coded	54082-3	C	0..*	Condition: Required if state test for condition, preceding OBR-4 should be 54082-3^Infectious diseases newborn screening panel^LN. **Preferred Answer List** (LL833-5): Normal LA6626-1 Borderline LA4259-3 Suspect HIV LA12446-3 Suspect TOXO LA12447-1 **Note:** Additional details available at http://s.details.loinc.org/LOINC/57702-3.html?sections=Simple
57701-5	Infectious diseases newborn screening comment-discussion	Text	54082-3	C	0..*	Condition: If 57702-3^Infectious diseases newborn screen interpretation^LN is included and the result necessitates comments.
54086-4	HIV 1+2 IgG Ab [Presence] in Dried blood spot	Ordinal	54082-3	O	0..1	
54087-2	Toxoplasma gondii IgG Ab [Presence] in Dried blood spot	Ordinal	54082-3	O	0..1	
54088-0	Toxoplasma gondii IgM Ab [Presence] in Dried blood spot	Ordinal	54082-3	O	0..1	
57087-9	Biotinidase newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
46761-3	Biotinidase deficiency newborn screen interpretation	Coded	57087-9	C	0..*	Condition: Required if state tests for condition, preceding OBR-4 should be 57087-9^Biotinidase newborn screening panel^LN. **Preferred Answer List** (LL840-0) at http://r.details.loinc.org/AnswerList/LL840-0.html
57699-1	Biotinidase deficiency newborn screening comment-discussion	Text	57087-9	C	0..*	Condition: If 46761-3^Biotinidase deficiency newborn screen interpretation^LN is included and the result necessitates comments.
38478-4	Biotinidase [Presence] in Dried blood spot	Ordinal	57087-9	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
75217-0	Biotinidase [Enzymatic activity/volume] in Dried blood spot	Numeric	57087-9	O	0..1	
58091-0	Glucose-6-Phosphate dehydrogenase newborn screen panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
58089-4	Glucose-6-Phosphate dehydrogenase newborn screen interpretation	Coded	58091-0	C	0..*	Condition: Required when preceding OBR-4 is 58091-0^Glucose-6-Phosphate dehydrogenase newborn screen panel^LN. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
58090-2	Glucose-6-Phosphate dehydrogenase newborn screening comment-discussion	Text	58091-0	C	0..*	Condition: If 58089-4 Glucose-6-Phosphate dehydrogenase newborn screen interpretation^LN is included and the result necessitates comments.
33287-4	Glucose-6-Phosphate dehydrogenase [Presence] in Dried blood spot	Ordinal	58091-0	O	0..1	
62300-9	Lysosomal storage disorders newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
62301-7	Lysosomal storage disorders newborn screen interpretation	Coded	62300-9	C	0..*	Condition: If state tests for any of these conditions, either this is required or the individual LSD panels are required, and preceding OBR-4 is 62300-9^Lysosomal storage disorders newborn screening panel^LN. Both are permitted. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
62303-3	Lysosomal storage disorders newborn screening comment-discussion	Text	62300-9	C	0..*	Condition: If 62301-7^Lysosomal storage disorders newborn screen interpretation^LN is included and the result necessitates comments.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
62302-5	Lysosomal storage disorders suspected [Identifier] in Dried blood spot	Coded	62300-9	C	0..*	Condition: If 62300-9^Lysosomal storage disorders newborn screen panel^LN is included. **Preferred Answer List** at http://s.details.loinc.org/LOINC/62302-5.html?sections=Simple including hemoglobin type abbreviation, SNOMED CT codes where available, and LOINC answer (LA) codes.
62304-1	Fabry disease newborn screening panel	Order Only	62300-9	C	0..1	Condition: If state tests for this condition, either this panel is required or 62300-9^Lysosomal storage disorders newborn screening panel^LN. Both are permitted.
62305-8	Fabry disease newborn screen interpretation	Coded	62300-9	C	0..*	Condition: If state tests for this condition, either this is required or 62301-7^Lysosomal storage disorders newborn screen interpretation^LN. Both are permitted. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
62306-6	Fabry disease newborn screening comment-discussion	Text	62300-9	C	0..*	Condition: If 62305-8^Fabry disease newborn screen interpretation^LN is included and the result necessitates comments.
55908-8	Alpha galactosidase A [Enzymatic activity/volume] in Dried blood spot	Numeric	62300-9	O	0..1	
62307-4	Krabbe disease newborn screening panel	Order Only	62300-9	C	0..1	Condition: If state tests for this condition, either this panel is required or 62300-9^Lysosomal storage disorders newborn screening panel^LN. Both are permitted.
62308-2	Krabbe disease newborn screen interpretation	Coded	62300-9	C	0..*	Condition: If state tests for this condition, either this is required or 62301-7^Lysosomal storage disorders newborn screen interpretation^LN. Both are permitted. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
62309-0	Krabbe disease newborn screening comment-discussion	Text	62300-9	C	0..*	Condition: If 62308-2^Krabbe disease newborn screen interpretation^LN is included and the result necessitates comments.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
62310-8	Galactocerebrosidase [Enzymatic activity/volume] in Dried blood spot	Numeric	62300-9	O	0..1	
62311-6	Gaucher disease newborn screening panel	Order Only	62300-9	C	0..1	Condition: If state tests for this condition, either this panel is required or 62300-9^Lysosomal storage disorders newborn screening panel^LN. Both are permitted.
62312-4	Gaucher disease newborn screen interpretation	Coded	62300-9	C	0..*	Condition: If state tests for this condition, either this is required or 62301-7^Lysosomal storage disorders newborn screen interpretation^LN. Both are permitted. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
62313-2	Gaucher disease newborn screening comment-discussion	Text	62300-9	C	0..*	Condition: If 62312-4^Gaucher disease newborn screen interpretation^LN is included and the result necessitates comments.
55917-9	Acid beta glucosidase [Enzymatic activity/volume] in Dried blood spot	Numeric	62300-9	O	0..1	
79563-3	Mucopolysaccharidosis type I newborn screening panel	Order Only	62300-9	C	0..1	Condition: If state tests for this condition, either this panel is required or 62300-9^Lysosomal storage disorders newborn screening panel^LN. Both are permitted.
79564-1	Mucopolysaccharidosis type I newborn screen interpretation	Coded	62300-9	C	0..*	Condition: If state tests for this condition, either this is required or 62301-7^Lysosomal storage disorders newborn screen interpretation^LN. Both are permitted. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
79565-8	Mucopolysaccharidosis type I newborn screening comment-discussion	Text	62300-9	C	0..*	Condition: If 79564-1^Mucopolysaccharidosis type I newborn screen interpretation^LN is included and the result necessitates comments.
55909-6	Alpha-L-iduronidase [Enzymatic activity/volume] in Dried blood spot	Numeric	62300-9	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
62315-7	Niemann Pick disease A/B newborn screening panel	Order Only	62300-9	C	0..1	Condition: If state tests for this condition, either this panel is required or 62300-9^Lysosomal storage disorders newborn screening panel^LN. Both are permitted.
62318-1	Niemann Pick disease A/B newborn screen interpretation	Coded	62300-9	C	0..*	Condition: If state tests for this condition, either this is required or 62301-7^Lysosomal storage disorders newborn screen interpretation^LN. Both are permitted. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
62319-9	Niemann Pick disease A/B newborn screening comment-discussion	Text	62300-9	C	0..*	Condition: If 62318-1^Niemann Pick disease A/B newborn screen interpretation^LN is included and the result necessitates comments.
62316-5	Acid sphingomyelinase [Enzymatic activity/volume] in Dried blood spot	Numeric	62300-9	O	0..1	
63414-7	Pompe disease newborn screening panel	Order Only	62300-9	C	0..1	Condition: If state tests for this condition, either this panel is required or 62300-9^Lysosomal storage disorders newborn screening panel^LN. Both are permitted.
63415-4	Pompe disease newborn screen interpretation	Coded	62300-9	C	0..*	Condition: If state tests for this condition, either this is required or 62301-7^Lysosomal storage disorders newborn screen interpretation^LN. Both are permitted. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
63416-2	Pompe disease newborn screening comment-discussion	Text	62300-9	C	0..*	Condition: If 63415-4^Pompe disease newborn screen interpretation^LN is included and the result necessitates comments.
55827-0	Malonylcarnitine (C3-DC) [Moles/volume] in Dried blood spot	Numeric	62300-9	O	0..*	
62333-0	Severe combined immunodeficiency (SCID) newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
62321-5	Severe combined immunodeficiency newborn screen interpretation	Coded	62333-0	C	0..*	Condition: Required if state tests for condition; preceding OBR-4 should be 62333-0^Severe combined immunodeficiency (SCID) newborn screening panel^LN. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
62322-3	Severe combined immunodeficiency newborn screening comment-discussion	Text	62333-0	C	0..*	Condition: If 62321-5^Severe combined immunodeficiency newborn screen interpretation^LN is included and the result necessitates comments.
62320-7	T-cell receptor excision circle [#/volume] in Dried blood spot by Probe and target amplification method	Numeric	62333-0	O	0..1	
85267-3	X-linked Adrenoleukodystrophy (X-ALD) newborn screening panel	Order Only	54089-8	C	0..1	Condition: MUST be included in the message, if state tests for condition.
85269-9	X-linked Adrenoleukodystrophy (X-ALD) newborn screen interpretation	Coded	85267-3	C	0..*	Condition: Required if state tests for condition; preceding OBR-4 should be 85267-3^X-linked Adrenoleukodystrophy (X-ALD) newborn screening panel^LN. **Preferred Answer List** (LL840-0) at: http://r.details.loinc.org/AnswerList/LL840-0.html
85268-1	X-linked Adrenoleukodystrophy (X-ALD) newborn screening comment-discussion	Text	85267-3	C	0..*	Condition: If 85269-9^X-linked Adrenoleukodystrophy (X-ALD) newborn screen interpretation^LN is included and the result necessitates comments.
79321-6	Fatty acids.very long chain.C26:0-lysophosphatidylcholine (C26:0-LPC)	Numeric	85267-3	O	0..1	

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
73738-7	Newborn screening test results panel - Point of Care	Order Only	54089-8	--		**Note:** This code and the rest of the rows in this table are out of scope for this Newborn Dried Blood Spot Screening (NDBS) use case, but listed here because they are part of the LOINC Newborn Screening Panel and some state newborn screening programs report this information with their NDBS results. For HL7 message guidance, please refer to existing HL7 implementation guides for Early Hearing Detection and Intervention (EHDI at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=344) and for Critical Congenital Heart Defects and pulse oximetry screening (CCHD at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=366.) For additional LOINC code details including definitions/descriptions and answer lists, please refer to http://s.details.loinc.org/LOINC/73738-7.html?sections=Comprehensive
54111-0	Newborn hearing screening panel	Order Only	73738-7	--		Please refer to existing HL7 implementation guide for Early Hearing Detection and Intervention (EHDI at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=344). For additional LOINC code details including definitions/descriptions and answer lists, please refer to http://s.details.loinc.org/LOINC/73738-7.html?sections=Comprehensive
57700-7	Hearing loss newborn screening comment/discussion	Text	54111-0			
58232-0	Hearing loss risk indicators [Identifier]	Coded	54111-0			
54106-0	Newborn hearing screen method	Coded	54111-0			
73741-1	Newborn hearing screen panel of Ear - left	Order Only	54111-0			
54108-6	Newborn hearing screen of Ear - left	Coded	73741-1			
73740-3	Duration of screening of Ear - left	Numeric	73741-1			

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
73739-5	Newborn hearing screen reason not performed of Ear - left	Coded	73741-1			
73744-5	Newborn hearing screen panel of Ear - right	Order Only	54111-0			
54109-4	Newborn hearing screen of Ear - right	Coded	73744-5			
73743-7	Duration of screening of Ear - right	Numeric	73744-5			
73742-9	Newborn hearing screen reason not performed of Ear - right	Coded	73744-5			
73805-4	CCHD newborn screening panel	Order Only	73738-7	--		Please refer to existing HL7 implementation guide for Critical Congenital Heart Defects and pulse oximetry screening (CCHD at http://www.hl7.org/implement/standards/product_brief.cfm?product_id=366). For additional LOINC code details including definitions/descriptions and answer lists, please refer to http://s.details.loinc.org/LOINC/73738-7.html?sections=Comprehensive
73700-7	CCHD newborn screening interpretation	Coded	73805-4			
73696-7	Oxygen saturation.preductal-oxygen saturation.postductal [Mass fraction difference] in Bld.preductal and Bld.postductal	Numeric	73805-4			
73806-2	Newborn age in hours	Numeric	73805-4			
73699-1	Number of prior CCHD screens [#] Qualitative	Coded	73805-4			
73804-7	Oxygen saturation sensor name	Text	73805-4			

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
73803-9	Oxygen saturation sensor type	Coded	73805-4			
73802-1	Oxygen saturation sensor wrap name	Text	73805-4			
73801-3	Oxygen saturation sensor wrap type	Coded	73805-4			
73800-5	Oxygen saturation sensor wrap size	Text	73805-4			
73697-5	CCHD newborn screening protocol used [Type]	Text	73805-4			
73698-3	Reason CCHD oxygen saturation screening not performed	Coded	73805-4			
59407-7	Oxygen saturation in Blood Preductal by Pulse oximetry	Numeric	73805-4			
73799-9	Heart rate Blood Preductal Pulse oximetry	Numeric	73805-4			
73798-1	Perfusion index Blood Preductal Pulse oximetry	Numeric	73805-4			
73797-3	Signal quality Blood Preductal Pulse oximetry	Coded	73805-4			
73796-5	Infant activity during preductal oxygen saturation measurement	Coded	73805-4			
59418-4	Oxygen saturation in Blood Postductal by Pulse oximetry	Numeric	73805-4			
73795-7	Heart rate Blood Postductal Pulse oximetry	Numeric	73805-4			
73794-0	Perfusion index Blood Postductal Pulse oximetry	Numeric	73805-4			
73793-2	Signal quality Blood Postductal Pulse oximetry	Coded	73805-4			

TABLE 15-1. NDBS LOINC PANEL REQUIREMENTS						
Newborn Dried Blood Spot Screening (NDBS) LOINC Requirements						
LOINC	LOINC Name	Result Type/Order Only	Belongs to Order Code	R/O/C	Cardinality	Comment
73792-4	Infant activity during postductal oxygen saturation measurement	Coded	73805-4			

16 GLOSSARY

TABLE 16-1. GLOSSARY

Term	Definition
Analyte	Component represented in the name of a measurable quantity. It is the most granular level at which measurements are made and always represented using a single OBX.
Cancellation	Act of cancelling the order.
Electronic Health Record (EHR)	Clinical information for a specific patient that is stored electronically within an EHR-S.
Electronic Health Record System (EHR-S)	A software application that is capable of managing clinical patient information.
Future Order	A future order is an order with a start date/time where that start date/time indicates the earliest time the specimen can be collected.
Laboratory	A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health[12].
Laboratory Information System (LIS)	An information system that receives, processes, and stores information related to laboratory processes. LIS may interface with HIS and EHR applications. To meet the requirements of the LOI/LRI Use Case the LIS, at minimum, must have the following characteristics: • Data model that includes discrete representations of patients, clinician end-users, laboratory test requisitions, laboratory tests (including panels), and laboratory test results (at the level of an individual analyte); • Capability to receive electronic messages that communicate a laboratory order from a physician; • Capability to send electronic messages that report the status and results of laboratory tests that have been ordered; This definition is very minimal and omits many features and capabilities that are typically associated with laboratory information systems. This minimal characterization is intentional, as to include the broadest possible set of LIS systems in the use case. The minimal nature of the definition by no means excludes LIS with significantly greater capabilities.
Laboratory Message	An electronic communication between a Laboratory Order System and a Laboratory Information System related to laboratory testing. Laboratory messages may be used to request that one or more tests be performed, to change previous requests for testing, to report the cancellation of requested tests, or to report the results of requested tests.
Laboratory Order	Synonymous with a Requisition when referring to a single ORC/OBR pair.
Laboratory Order System	Software, either stand-alone or as part of an EHR system, used by a Provider *(Order Placer)* to manage a laboratory order, including generating the laboratory requisition, sending it to a laboratory, and monitoring/tracking of the status of the laboratory order. Typically a laboratory order system is an integral part of an order management system that enables users to manage orders for many different types of services, procedures, supplies, etc. Since we only focus on data exchange relative to laboratory orders we are purposely using a very limited definition.

TABLE 16-1. GLOSSARY	
Term	Definition
Laboratory Requisition	A set of information that constitutes an official request for one or more laboratory tests to be performed on an individual patient. A laboratory requisition is specified in a clinical setting and communicated to a laboratory as a discrete paper or electronic artifact. Laboratory requisitions always include at least one test order. In terms of an HL7 order transaction it represents one or more orders (ORC/OBR pairs) transmitted as part of the same OML^O21^OML_O21 new or append order message.
Newborn	A human infant from the time of birth through the 28th day of life per Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier, and the World Health Organization standardization for perinatal definitions.
Orderable Test or Test	A request to perform an individual test or panel. It always refers to an single ORC/OBR pair and may have one or more associated analytes (OBXs).
Panel	While there are differences in the meanings of the terms “panel” among various laboratories, for the purposes of this guide, it is defined as a grouping of procedures that measure multiple analytes from a single specimen and can be requested through one laboratory order. This is also referred to as battery. For example, a CBC or a urinalysis may be referred to as a panel.
Request for Cancellation (RFC)	Request by the Provider *(Order Placer)* not to perform the order.
Test	A medical procedure or named set of related procedures that involves analyzing one analyte using a single sample of blood, urine, or other specimen from a patient for the purpose of diagnosing a disease or medical condition, planning or evaluating treatment, or monitoring the course of a disease.