Integrating the Healthcare Enterprise

IHE Pathology and Laboratory Medicine (PaLM) Technical Framework

Volume 2b
(PaLM TF-2b)
Transactions (cont.)

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CONTENTS

1 Introduction

This document, Volume 2b of the IHE Pathology and Laboratory Medicine (PaLM) Technical Framework, defines transactions used in one profile of the IHE Pathology and Laboratory Medicine domain: the Laboratory Analytical Workflow (LAW) Profile.

1.1 Introduction to IHE

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE Profiles. IHE publishes each profile through a well-defined process of public review and trial implementation and gathers profiles that have reached final text status into an IHE Technical Framework, of which this volume is a part.

For general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, the reader familiarizes themselves with the concepts defined in the IHE Technical Frameworks General Introduction.

1.2 Intended Audience

The intended audience of IHE Technical Frameworks Volume 2 is:

- IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative
- Experts involved in standards development

1.3 Overview of Technical Framework Volume 2

Volume 2 is comprised of several distinct sections:

- Section 1 provides background and reference material.
- Section 2 presents the conventions used in this volume to define the transactions.
- Section 3 defines Pathology and Laboratory Medicine transactions in detail, specifying the roles for each actor, the standards employed, the information exchanged, and in some cases, implementation options for the transaction.

The appendices in Volume 2 provide clarification of technical details of the IHE data model and transactions. A glossary of terms and acronyms used in the IHE Technical Framework, including those from relevant standards, is provided in the *IHE Technical Framework General Introduction*, which is published on this page. Due to the length of the document, some domains may divide Volume 2 into smaller volumes labeled 2a, 2b, etc. In this case, the Volume 2

appendices are gathered in Volume 2x. Code and message samples may also be stored on the IHE ftp server. In this case, explicit links to the ftp server will be provided in the transaction text.

1.4 Comment Process

IHE International welcomes comments on this document and the IHE initiative. Comments on the IHE initiative can be submitted by sending an email to the co-chairs and secretary of the Pathology and Laboratory Medicine domain committees at palm@ihe.net. Comments on this document can be submitted at http://ihe.net/PaLM_Public_Comments.

1.5 Copyright Licenses

IHE technical documents refer to, and make use of, a number of standards developed and published by several standards development organizations. Please refer to the IHE Technical Frameworks General Introduction, Section 9 - Copyright Licenses for copyright license information for frequently referenced base standards. Information pertaining to the use of IHE International copyrighted materials is also available there.

1.6 Trademark

IHE® and the IHE logo are trademarks of the Healthcare Information Management Systems Society in the United States and trademarks of IHE Europe in the European Community. Please refer to the IHE Technical Frameworks General Introduction, Section 10 - Trademark for information on their use.

1.7 Disclaimer Regarding Patent Rights

Attention is called to the possibility that implementation of the specifications in this document may require use of subject matter covered by patent rights. By publication of this document, no position is taken with respect to the existence or validity of any patent rights in connection therewith. IHE International is not responsible for identifying Necessary Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of the specifications in this document are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information about the IHE International patent disclosure process including links to forms for making disclosures is available at http://www.ihe.net/Patent_Disclosure_Process. Please address questions about the patent disclosure process to the secretary of the IHE International Board: secretary@ihe.net.

1.8 History of Document Changes

This section provides a brief summary of changes and additions to this document.

Date	Document Revision	Change Summary
July 2016	7.0	Adoption of IHE_TF_Template_Vol2_Rev1.0_2014-07-01, Incorporation of the LAW Profile "Final Text", Update of the LDA Profile by removal of the transactions transferred to LAW. Incorporation of option "labels & containers delivered" for the LBL Profile. Reorganization of Vol 2 content in 4 volumes: • 2a contains LTW and LDA transactions, • 2b contains LAW transactions and specific appendices, • 2c contains LBL, LPOCT and LCSD transactions • 2x contains common appendices
June 2017	8.0	Clarifications on Analyzer Manager behavior in conveying dilution instructions (CP 252) Additional guidance on usage of optional elements and of demographics (CP 253)
August 2018	9.0	Allow [LAB-29] messages with no results (no OBX) when ORC-5 = "IP" (integration of CP 260)
August 2019	10.0	Republished without change in PaLM TF 10.0
April 2024	11.0	Updated some sections to coincide with latest template Clarification of HL7 version and table used for OBX-2 (integration of CP-263) Allow supplemental results in transaction LAB-32 (integration of CP-267) Support sending Sample ID and Carrier/Position as informational information (integration of CP-270) Changing conformance Lengths several identifiers (SAC-3,-4, -10, -13 and SPM-2, -3) and adapt the Query Parameters (QPD-3,-4, -6 and -9) accordingly (integration of CP-271) Correct location of End of PATIENT Group in LAB-29 (integration of CP-274)

2 Conventions

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based SHALL be applied.

2.1 Transaction Modeling and Profiling Conventions

In order to maintain consistent documentation, modeling methods for IHE transactions and profiling conventions for frequently used standards are maintained in the IHE Technical Frameworks General Introduction, Appendix E - Standards Profiling and Documentation Conventions. Methods described include the Unified Modeling Language (UML) and standards conventions include DICOM, HL7 v2.x, HL7 Clinical Document Architecture (CDA) Documents, etc. These conventions are critical to understanding this volume and should be reviewed prior to reading this text.

The transactions specified in this Volume 2b apply these general profiling conventions, and extend them with the additional conventions defined in Section 2.2 below.

2.2 Additional Standards Profiling Conventions for LAW Transactions

This section defines additional conventions for profiling the HL7 v2.x standard, which have been adopted to specify the transactions of the Laboratory Analytical Workflow (LAW) Profile described in this Volume 2b.

2.2.1 Message and Segment Usage Conventions

The following conventions are used to establish the usage of segment groups, segments, and fields in the message description tables. The usage for data type components and sub-components follows the HL7 v2.5.1 standard.

> **M**: Mandatory. This new usage code is a more restrictive version of the **R** (Required) code. The segments and fields having this usage represent the basic information (introduced in PaLM TF-1:5.2) for AWOS and result transfer. This code identifies a mandatory segment or field that must be provided by the sender. A receiver will raise an error if a mandatory segment or field is absent. Although a value must always be provided for a mandatory field, in some cases it is acceptable to send a NULL ("") value in a mandatory field to indicate no value to report. See Section E.3.2.6 in appendix E "Profiling" (of the *IHE Technical Frameworks General Introduction* published on this page) for a discussion of empty and nullified fields. The segment definitions will indicate when NULL ("") must be sent when a value for the field does not exist. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete information from data records maintained by the Analyzer Manager. An application will report an application error (MSA-1 = "AE") in the message acknowledgment if a value for a mandatory field is not provided.

R: Required: The coded value for required usage is slightly modified from the HL7 definition. Required is used for those segments and fields that are part of the enhanced information (introduced in PaLM TF-1:5.2) and have a required usage in the HL7 standard. For example, the usage of the segment group PATIENT of OML^O33 ([LAB-28]) is RE when the Patient Demographics Option is supported. However, if the group is provided, then the PID segment is required. A compliant sending application SHALL populate all **R** elements with a non-empty value. A compliant receiving application SHALL process (save/print/archive/etc.) or ignore the information conveyed by required elements. A compliant receiving application SHALL not raise an error due to the presence of a required element, but may raise an error due to the absence of a required element.

RE: Required if Available. This code characterizes enhanced information provided only when the data is available or applicable. For example, when the Patient Demographics Option is supported the PATIENT segment group is provided only if there is patient demographic information associated with the AWOS request. The Analyzer will ignore segments or fields of the enhanced information it does not support. The Analyzer Manager is required to send these segments or fields if the information is available. The availability of these data elements may ultimately depend on the use of the information within the laboratory environment.

RE.AN: Required if available from Analyzer. This new usage code is defined for enhanced information that depends on the Analyzer capabilities, and the usage is not standardized by a profile option. This usage only applies to message sent by the Analyzer. This code characterizes segments or fields that are part of the enhanced information, and Analyzers may support none, some, or all of the elements. An Analyzer may produce an Implementation Profile by assigning supported segments and fields to **R (Required)** or **RE (Required if Available)** and unsupported segments and fields to **X (Not supported)**. Analyzer Managers will not raise an error if an **RE.AN** segment or field is transmitted by an Analyzer. It is assumed the field has a usage of **X** when Analyzer capabilities are not declared or known.

C (a/ b): Conditional. The definition for conditional usage requires defining the usage for the true and false outcomes of the condition predicate. This definition is pre-adopted from HL7 v2.7.1 for conditional usage. An element with a conditional usage code has an associated condition predicate that determines the usage of the element.

If the condition predicate associated with the element is true, follow the rules for "**a**" which SHALL be one of **M**, **R**, **RE**, or **X**.

If the condition predicate associated with the element is false, follow the rules for "**b**" which SHALL be one of **M**, **R**, **RE**, or **X**.

"**a**" and "**b**" SHALL be different and defined by the message profile.

X: Not supported. The usage code for elements not supported. Conformant sending applications will not send the element. Conformant receiving applications will ignore the

element if it is sent. For readability, segments not supported do not appear in the message tables. Similarly, fields that are not supported by the Analyzer or Analyzer Manager do not appear in the segment tables.

For segment definitions, a usage is provided for the Analyzer Manager (AM) and the Analyzer. The usage identifies how the Analyzer Manager or Analyzer populates the field when the segment is sent in a message. The receiver is expected to process any populated field according to the same usage as the sender's.

2.2.2 Data Types

The usage conventions defined in HL7 v2.5.1 Section 2.12.6.2 are followed when describing data types. Tables are used to provide the static definition, and consist of four columns:

- **Component/Sub-component**: The elements of a data type
- **Usage:** Usage code for the element
- **LEN:** Length of the element. See the discussion in Section 2.2.3 for more information on data type lengths.
- **Comment:** Any applicable comments about the element

For readability of the data type table, in most cases the usage "X" is not shown. If a component of a data type is not supported by the LAW Profile, it simply doesn't appear in the table representing the data type structure. See the table below for an example.

Table 2.2.2-1: Example using Element MSH-21 Message Profile Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	<domain>-<transaction number>
Namespace ID (IS)	R	20	IHE

2.2.3 Field Element Lengths

The primitive data elements of the LAW Profile have one of the following characteristics:

- Use a well-defined value domain and cannot be truncated
- Are used as keys/primary identifiers and cannot be truncated
- Provide general information (e.g., CE.2 Text (TX)) and cannot be truncated
- Have no clearly established domain value boundaries and can be truncated

HL7 v2.7 Section 2.5.5 Length describes concepts related to the length of primitive message elements that are adopted by transactions of this Volume 2b. These concepts were used to guide the definition of lengths for the LAW Profile.

A Normative or Conformance Length is defined for fields that cannot be truncated. No annotation is provided to differentiate the lengths. When applicable, the length overrides any lengths associated with the underlying data types. If a value is received that exceeds the length, the receiving system SHALL generate an error. For some elements (e.g., OBR-4 Observation ID) the Analyzer establishes the set of keys/primary identifiers. Thus, the maximum length used by the Analyzer may actually be less than the conformance length.

The following table establishes the non-truncatable conformance lengths for specific segment field elements used as keys/primary identifiers. For some elements the conformance length has been increased to 50 in order to support machine-generated GUIDs. The sections describing the segments fields identify when the element length has been increased to 50.

HL7 v2.7 and later limits EI based Entity Identifiers (EI.1) conformance length to 199 and these Entity Identifiers MAY never be truncated. This Technical Framework strongly recommends keeping this in mind as receiving systems do not truncate received identifiers at all. IHE LAW is based on HL7 v2.5.1 where this rule is not part of the base standard, so for practical reasons the conformance length of several identifiers (SPM-2, SPM-3, SAC-3, SAC-4, SAC-10 and SAC-13) is set to 50.

Table 2.2.3-1: Conformance Lengths for Keys/Primary Identifiers

Field	Field Element	Conformance Length (cannot be truncated)
INV-1 Identifier of Substance	CE.1 (ST) Identifier	50
INV-16 Manufacturer Lot Number	ST	50[1]
MSA-2 Message Control ID	ST	50
MSH-10 Message Control ID	ST	50
OBR-2 AWOS-ID	EI.1 (ST) Entity Identifier	50
OBR-3 Filler Order Number	EI.1 (ST) Entity Identifier	50
OBR-4 Universal Service Identifier	CE.1 (ST) Identifier	20[1]
OBR-16 Ordering Provider	XCN.1 (ST) ID Number	15
OBX-3 Observation Identifier	CE.1 (ST) Identifier	20[1]
OBX-3 Observation Identifier	CE.4 (ST) Alternate Identifier	7[2]
OBX-5 Observation Value	CE.1 (ST) Identifier	20[1]
OBX-6 Units	CE.1 (ST) Identifier	20[1]
OBX-16 Responsible Observer	XCN.1 (ST) ID Number	15
OBX-21 Observation Instance Identifier	EI.1 (ST) Entity Identifier	50[1]
ORC.2 Placer Order Number (AWOS ID)	EI.1 (ST) Entity Identifier	50

Field	Field Element	Conformance Length (cannot be truncated)
ORC-4 Placer Group Number	EIP.EI.1 (ST) Entity Identifier	50
ORC-8 Parent (AWOS ID)	EIP.EI.1 (ST) Entity Identifier	50
PID-3 Patient Identifier List	CX.ID.1 (ST) ID Number	20
SAC-3 Container Identifier	EI.1 (ST) Entity Identifier	50
SAC-4 Parent Container Identifier	EI.1 (ST) Entity Identifier	50
SAC-10 Carrier Identifier	EI.1 (ST) Entity Identifier	50[1]
SAC-13 Tray Identifier	EI.1 (ST) Entity Identifier	50[1]
SPM-2 Specimen ID	EIP.EI.1 (ST) Entity Identifier	50
SPM-3 Specimen Parent IDs	EIP.EI.1 (ST) Entity Identifier	50
TCD-1 Universal Service Identifier	CE.1 (ST) Identifier	20[1]

Note 1: Actual length is established by the Analyzer, but will not be greater than the conformance length.

Note 2: This is a normative length established by Table 2.3.1-5 LAW Codes for Supplemental Results

For fields that can be truncated, a Conformance Length will be defined and the profile will use the "#" character to identify lengths that can be truncated. If a value is received that exceeds the Conformance Length and the system cannot support values greater than the Conformance Length, the receiving system will truncate the value and use the "#" character as the very last character of the value to annotate that the string was truncated. If the system can support more than the Conformance Length, then it may save the value without truncation. This concept is pre-adopted from HL7 v2.7.1, Section 2.5.5.3 Conformance Length (see this section for more information). The following table identifies the field elements that can be truncated.

Table 2.2.3-2: Conformance Lengths for Field Elements that Can Be Truncated

Field	Field Element	Conformance Length (can be truncated)
ERR-8 User Message	TX	250#
NTE-3 Comment	FT	120#
OBR-16 Ordering Provider	XCN.2.1 Surname (ST)	20#
OBR-16 Ordering Provider	XCN.3 Given Name (ST)	20#

Field	Field Element	Conformance Length (can be truncated)
OBR-16 Ordering Provider	XCN.4 Second and Further Given Names (ST)	20#
OBR-16 Ordering Provider	XCN.5 Suffix (ST)	10#
ORC-21 Ordering Facility Name	XON.1 Organization Name (ST)	50#
PID-5 Patient name	XPN.1.1Surname (ST)	20#
PID-5 Patient name	XPN.2 Given Name (ST)	20#
PID-5 Patient name	XPN.3 Second and Further Given Names (ST)	20#
PID-5 Patient name	XPN.4 Suffix (ST)	10#
PV1-3 Assigned Patient Location	PL.2 Room (IS)	16#

2.2.4 Profile Types

Three major profile types are defined in Section 2.12.5 Profile Types of HL7 v2.5.1:

- HL7 Standard Profile – represents an HL7 specific published standard, creation and publication limited to HL7 use.
- Constrainable Profile – with **O (Optional)** elements that must be further constrained in order to create implementation profiles.
- Implementation Profile – no **O (Optional)** parts, fully implementable.

The objective of the LAW Profile is to allow Analyzer vendors to establish in a standardized manner the information the Analyzer receives and sends when performing testing. The basic interface elements of the LAW Profile, which are identified through the use of the **M** usage type for segments and fields, define an Implementation Profile for exchanging test orders and results with minimal configuration. Vendor coordination may be necessary for the Analyzer Manager to establish test and result mappings if LOINC® or JLAC10 (see Section 2.3.1) is not used by the Analyzer. At a minimum, an Analyzer Manager will be able to successfully exchange orders and results with an Analyzer through the basic interface elements.

The enhanced interface elements of the LAW Profile support the various functionalities provided by Analyzers. Profile options have been defined in order to standardize the use of most of the additional information (see Table 5.2-1 Laboratory Analytical Workflow - Actors and Options in PaLM TF-1: 5.2), and the usage for the elements covered by each option is summarized in the sections below. Vendors must publish which options are supported by their interface implementation. The Analyzer Manager should send the enhanced information associated with an Analyzer profile option only when the Analyzer supports that option. This convention prevents the Analyzer Manager from sending unnecessary AWOS data for options that are not supported by the Analyzer.

Some enhanced interface elements are not covered by a profile option (see Section 2.2.4.18 Optional Message Elements). Analyzer vendors must publish which elements are supported by their interface implementation. Analyzer Managers are required to support these enhanced interface elements so that no interface changes are necessary when connecting to Analyzers using one or more of these enhanced interface elements, but should only transmit them when used by the Analyzer.

To provide the most flexibility, some elements have an Analyzer usage code of RE.AN (see Section 2.2.1 Message and Segment Usage Conventions) that indicates "Required if available from Analyzer." This usage convention allows a vendor to selectively specify the enhanced interface elements applicable for the Analyzer. Because the use of these elements results in a Constrainable Profile, the Analyzer vendor must create an Implementation Profile that defines their usage.

The enhanced interface elements sent by the Analyzer provide additional information about the generation, interpretation, or identification of the test result value produced by the Analyzer. For example, consider LAW_AWOS_PRIORITY (see Section 2.2.4.10). The Analyzer is required to support a segment group (TIMING_QTY), segment (TQ1), and segment field (TQ1-9 Priority). The Analyzer Manager sends the elements in AWOS Broadcast [LAB-28] to control the testing performed, and the Analyzer sends the elements in AWOS Status Change [LAB-29] to identify that value that applies to the test result computed.

In addition, the LAW Profile identifies enhanced interface elements that the Analyzer Manager and Analyzer should not send by specifying a usage code of "X", which indicates "Not supported". For example, consider LAW_SPECIMEN (see Section 2.2.4.11). The Analyzer Manager transmits the enhanced interface elements defined by these options in AWOS Broadcast [LAB-28], allowing the Analyzer to provide additional functionality based on the information. These elements are not associated with the generation of the test result value, and thus are unnecessary in the AWOS Status Change [LAB-29] transaction because they are not needed by the Analyzer Manager. Therefore, the Analyzer usage for the unnecessary enhanced interface elements is "X" (see Section C.12).

The following sections describe the conventions for the LAW Profile options.

2.2.4.1 Basic Interface

The Implementation Profile established by the basic interface is identified through the use of the common LAW message transaction identifiers [LAB-27], [LAB-28], and [LAB-29]. One of these Message Profile Identifiers is **required** to be the first identifier listed in MSH-21. This mandatory component establishes the use of the basic interface elements as defined by this profile. The Message Profile Identifiers establish the usage code for all enhanced interface message elements as **X** or **Not Supported**, unless the vendor has published an Implementation Profile documenting the usage codes based on the conventions defined by this profile for the pre-defined profile options and enhanced interface elements.

2.2.4.2 Query

The profile supports multiple query types (see Sections 5.2.1 to 5.2.5 in PaLM TF-1). These query types are easily differentiated by the value of field QPD-1 (see Section 3.27.4.1.2.3) in transaction [LAB-27].

The following table defines how the SAC container identification fields (see Section B.1 Specimen Identification in Appendix B) of the [LAB-28] response transaction are populated depending on the query executed.

Table 2.2.4.2-1: Analyzer Query Message Elements

Element	Transaction	Usage	Comment
SAC-3 Container Identifier	LAB-28: OML^O33	M	LAW_QUERY_WOS LAW_QUERY_ALL LAW_QUERY_ISOLATE
SAC-4 Primary (parent) Container Identifier	LAB-28: OML^O33	RE	LAW_QUERY_WOS LAW_QUERY_ALL
SAC-4 Primary (parent) Container Identifier	LAB-28: OML^O33	M	LAW_QUERY_RACK LAW_QUERY_TRAY LAW_QUERY_ISOLATE
SAC-10 Carrier Identifier	LAB-28: OML^O33	M	LAW_QUERY_RACK
SAC-11 Position in Carrier	LAB-28: OML^O33	M	LAW_QUERY_RACK
SAC-13 Tray Identifier	LAB-28: OML^O33	M	LAW_QUERY_TRAY
SAC-14 Position in Tray	LAB-28: OML^O33	M	LAW_QUERY_TRAY
SAC-15 Location	LAB-28: OML^O33	RE	LAW_QUERY_RACK LAW_QUERY_TRAY

The following table defines the impact to the [LAB-28] response transaction for a negative query response to all query types.

Table 2.2.4.2-2: Negative Query Message Elements

Element	Transaction	Usage	Comment
PATIENT Segment Group	LAB-28: OML^O33	X	
SPM-4 Specimen Type	LAB-28: OML^O33	M	ALWAYS NULL ("")
SPM-11 Specimen Role	LAB-28: OML^O33	M	ALWAYS populated with “U”
Fields of SAC Segment	LAB-28: OML^O33	Varies	See Table 2.2.4-1
ORC-1 Order Control	LAB-28: OML^O33	M	ALWAYS “DC”
ORC-9 Date/Time of Transaction	LAB-28: OML^O33	M	

Element	Transaction	Usage	Comment
OBSERVATION REQUEST Segment Group	LAB-28: OML^O33	X	

2.2.4.3 Contributing Substances

This profile option is used by Analyzers that identify substances or disposables that contributed to the result (see PaLM TF-1: 5.2.6). The profile qualifier is LAW_CONTRIB_SUB. The following table identifies the impacted message elements.

Table 2.2.4.3-1: Contributing Substances Message Elements

Element	Transaction	Usage	Comment
INV Segment	[LAB-29]	R	CONTAINER Segment Group and RESULT Segment Group
INV-1 Substance Identifier	[LAB-29]	R	
INV-2 Substance Status	[LAB-29]	R	
INV-3 Substance Type	[LAB-29]	R	
INV-4 Inventory Container Identifier	[LAB-29]	RE.AN	May not be applicable for all substances
INV-12 Expiration Date/Time	[LAB-29]	RE.AN	May not be applicable for all substances
INV-16 Manufacturer Lot Number	[LAB-29]	RE.AN	May not be applicable for all substances

2.2.4.4 Dilutions

This profile option is used by Analyzers that support dilutions (see PaLM TF-1: 5.2.7). The profile qualifier is LAW_DILUTIONS. The following table identifies the impacted message elements.

Table 2.2.4.4-1: Dilutions Message Elements

Element	Transaction	Usage	Comment
TCD Segment	LAB-28: OML^O33 LAB-29	R	
TCD-2 Auto-Dilution Factor	LAB-28: OML^O33 LAB-29	RE	Provide either TCD-2, TCD-11, or both.
TCD-3 Rerun Dilution Factor	LAB-28: OML^O33	RE	

Element	Transaction	Usage	Comment
TCD-5 Endogenous Content of Pre-Dilution Diluent	LAB-28: OML^O33	RE	Availability depends on Analyzer and test performed
TCD-11 Auto-Dilution Type	LAB-28: OML^O33 [LAB-29]	RE	Provide either TCD-2, TCD-11, or both.

2.2.4.5 Patient Demographics

This profile option is used when the Analyzer supports patient demographic (see PaLM TF-1: 5.2.8). The Profile Option Identifier is LAW_PAT_DEM. The Analyzer Manager should only send patient demographic data when the Analyzer supports the option.

The Patient Demographic Option is intended to allow an Analyzer to use patient demographic information for additional clinical evaluation of a test result, and to indicate when patient demographic information is applicable for the observations reported. The scope of the PID segment is the AWOS Broadcast [LAB-28] or AWOS Status Change [LAB-29] transactions. The PID segment is not used to manage patient records. For example, when used in the [LAB-29] transaction, it indicates the patient demographic information the Analyzer associates with the AWOS Status Change [LAB-29]. The use of the PID segment to manage patient records is out-of-scope for LAW.

The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.5-1: Patient Demographics Message Elements

Element	Transaction	Usage	Comments
PATIENT Segment Group	LAB-28: OML^O33	RE	
PID Segment	LAB-28: OML^O33	R	
PV1 Segment	LAB-28: OML^O33	RE	
PATIENT Segment Group	LAB-28: ORL^O34	RE	
PID Segment	LAB-28: ORL^O34	R	
PATIENT Segment Group	[LAB-29]	RE	Contains PID Segment
PID Segment	[LAB-29]	R	
VISIT Segment Group	[LAB-29]	RE.AN	Contains PV1 Segment
PV1 Segment	[LAB-29]	R	Usage controlled by VISIT Segment Group
PID-3 Patient Identifier List	[LAB-28] [LAB-29]	R	
PID-5 Patient Name	[LAB-28] [LAB-29]	R	
PID-7 Date/Time of Birth	LAB-28: OML^O33	RE	

Element	Transaction	Usage	Comments
PID-7 Date/Time of Birth	LAB-28: ORL^O34 [LAB-29]	RE.AN	
PID-8 Administrative Sex	LAB-28: OML^O33	RE	
PID-8 Administrative Sex	LAB-28: ORL^O34 [LAB-29]	RE.AN	
PID-10 Race	LAB-28: OML^O33	RE	May not be allowed in some countries
PID-10 Race	LAB-28: ORL^ O34 [LAB-29]	RE.AN	May not be allowed in some countries
PV1-2 Patient Class	LAB-28: OML^O33 [LAB-29]	R	Usage controlled by PV1 Segment
PV1-3 Assigned Patient Location	LAB-28: OML^O33 [LAB-29]	RE	Usage controlled by PV1 Segment

2.2.4.6 Analyzer Reflex

This profile option is used by Analyzers that perform reflex testing (see PaLM TF-1: 5.2.9 and B.4 Reflex Initiated at the Analyzer in Appendix B). The Profile Option Identifier is LAW_REFLEX. The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.6-1: Analyzer Reflex Message Elements

Element	Transaction	Usage	Comment
ORC-8 Parent	[LAB-29]	RE	Carries the AWOS IDs of the parent for the reflex
OBR-2 Placer Order Identifier	[LAB-29]	M	ALWAYS populated with NULL ("")
OBR-11 Specimen Action Code	[LAB-29]	RE	ALWAYS populated with “G”

2.2.4.7 Analyzer Rerun

This profile option is used by Analyzers that perform reruns (see PaLM TF-1: 5.2.10 and B.3 Observation Identification). The Profile Option Identifier is LAW_RERUN. The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.7-1: Analyzer Rerun Message Elements

Element	Transaction	Usage	Comment
OBX-4 Observation Sub-ID	[LAB-29]	M	Analyzer uses this field to identify the runs

2.2.4.8 Analyzer Manager Rerun/Reflex

This profile option is used by Analyzer Managers that perform reflex testing (see PaLM TF-1: 5.2.11). The profile option identifier is LAW_AM_RR. The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.8-1: Analyzer Manager Rerun/Reflex Message Elements

Element	Transaction	Usage	Comment
TCD Segment	LAB-28: OML^O33	R	OBSERVATION REQUEST Segment Group
TCD-8 Analyte Repeat Status	LAB-28: OML^O33	R	Indicate if original, rerun, or reflex test

2.2.4.9 Analyzer Manager Rerun and Reflex Control

This profile option is used by Analyzers that allow the Analyzer Manager to control the Analyzer rerun and reflex testing (see PaLM TF-1: 5.2.12). The profile option identifier is LAW_AM_RR_CONTOL. The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.9-1: Analyzer Manager Rerun/Reflex Message Elements

Element	Transaction	Usage	Comment
TCD Segment	LAB-28: OML^O33	R	OBSERVATION REQUEST Segment Group
TCD-6 Automatic Repeat Allowed	LAB-28: OML^O33	R	OBSERVATION REQUEST Segment Group
TCD-7 Reflex Allowed	LAB-28: OML^O33	R	OBSERVATION REQUEST Segment Group

2.2.4.10 AWOS Priority

This profile option is used by Analyzers that allow the Analyzer Manager to assign a priority to the AWOS request (see PaLM TF-1: 5.2.13). The profile qualifier is LAW_AWOS_PRIORITY. The following table identifies the impacted message elements.

Table 2.2.4.10-1: AWOS Priority Message Elements

Element	Transaction	Usage	Comment
TIMING Segment Group	LAB-28: OML^O33	RE	
TQ1Segment	LAB-28: OML^O33	R	TIMING Segment Group
TQ1-9	LAB-28: OML^O33	R	Requested AWOS priority
TIMING_QTY Segment Group	[LAB-29]	R	

Element	Transaction	Usage	Comment
TQ1Segment	[LAB-29]	R	
TQ1-9	[LAB-29]	R	Actual AWOS priority

2.2.4.11 Specimen Details

This profile option is used by Analyzers that support receiving additional details about a specimen. The profile option identifier is LAW_SPECIMEN (see PaLM TF-1: 5.2.14). The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.11-1: Specimen Details Message Elements

Element	Transaction	Usage
SPM-2 Specimen ID	LAB-28: OML^O33 [LAB-29]	RE RE.AN
SPM-3 Specimen Parent IDs	LAB-28: OML^O33 [LAB-29]	RE RE.AN
SPM-7 Specimen Collection Method	LAB-28: OML^O33	RE
SPM-8 Specimen Source Site	LAB-28: OML^O33	RE
SPM-9 Specimen Source Site Modifier	LAB-28: OML^O33	RE
SPM-16 Specimen Risk Code	LAB-28: OML^O33	RE
SPM-17 Specimen Collection Date/Time	LAB-28: OML^O33	RE
SPM-18 Specimen Received Date/Time	LAB-28: OML^O33	RE
SPM-27 Container Type	LAB-28: OML^O33	RE

2.2.4.12 Container Details

This profile option is used by Analyzers that support receiving additional information about the specimen container. The profile option identifier is LAW_CONTAINER (see PaLM TF-1: 5.2.15). The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.12-1: Container Details Message Elements

Element	Transaction	Usage
SAC-9 Carrier Type	LAB-28: OML^O33	RE
SAC-21 Container Volume	LAB-28: OML^O33	RE
SAC-22 Available Specimen Volume	LAB-28: OML^O33	RE
SAC-24 Volume Units	LAB-28: OML^O33	RE
SAC-29 Dilution Factor	LAB-28: OML^O33	RE

2.2.4.13 Mass Spectrometry

This profile option is used by Analyzers that report mass spectrometry results (see PaLM TF-1: 5.2.16). The profile qualifier is LAW_MASS_SPEC. The following table identifies the impacted message elements.

Table 2.2.4.13-1: Mass Spectrometry Message Elements

Element	Transaction	Usage
OBX-9 Probability	[LAB-29]	RE

2.2.4.14 Related Observations

This profile option is used by Analyzers that support receiving related lab observations (see PaLM TF-1: 5.2.18). The Profile Option Identifier is LAW_REL_OBS. The Analyzer Manager should only send related observations when the Analyzer supports the option. The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.14-1: Related Observations Message Elements

Element	Transaction	Usage
OBSERVATION Segment Group	LAB-28: OML^O33	RE

2.2.4.15 External Result

This profile option is used by Analyzers that support reporting results using a reference pointer (see PaLM TF-1: 5.2.17 and B.3.12 Observation Result Stored Externally). The profile qualifier is LAW_ RESULT_EXT. The following table identifies the impacted message elements.

Table 2.2.4.15-1: Result Reference Message Elements

Element	Transaction	Usage	Comment
OBR-49 Result Handling	[LAB-29]	RE	Identifies if Reference Pointer is External with value 'RE'
OBX-2 Value Type	[LAB-29]	M	Analyzer must support "RP" data type

2.2.4.16 Pooling of Specimens on the Analyzer

This profile option is used when the Analyzer supports pooling of patient specimens on the analyzer (see PaLM TF-1: 5.2.19). The Profile Option Identifier is LAW_POOL_AN. The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.16-1: Analyzer Pooling of Patient Specimens Message Elements

Element	Transaction	Usage	Comment
TCD-10 Pool Size	LAB-28: OML^O33	R	Maximum size of pool
TCD-10 Pool Size	[LAB-29]	R	Actual size of pool

2.2.4.17 Pooling of Specimens Outside of the Analyzer

This profile option is used when the Analyzer requires information about the pooling of patient specimens that happened outside the analyzer (see PaLM TF-1: 5.2.20). The Profile Option Identifier is LAW_POOL_NOAN. The following table identifies the message elements impacted by the use of this option.

Table 2.2.4.17-1: External Pooling Message Elements

Element	Transaction	Usage	Comment
PATIENT Segment Group	LAB-28:OML^O33	X	Not allowed
PATIENT Segment Group	LAB-28:ORL^O34	X	Not allowed
PATIENT Segment Group	[LAB-29]	X	Not allowed
SPM-3 Specimen Parent IDs	LAB-28: OML^O33 LAB-28: ORL^O34	R	Specimens used in the Pool
SPM-11 Specimen Role	LAB-28: OML^O33 LAB-28: ORL^O34	M	Always populated with "L"
SPM-13 Grouped Specimen Count	LAB-28: OML^O33 LAB-28: ORL^O34	R	The number of patient specimens that were pooled

2.2.4.18 Optional Message Elements

The following enhanced interface elements are not covered by a profile option.

Table 2.2.4.18-1: Optional Message Elements

Element	Transaction	Usage	Comment
ERR-5 Application Error Code	[LAB-27] [LAB-28] [LAB-29]	RE.AN RE RE.AN	Enhanced error reporting
ERR-8 User Message	[LAB-27] [LAB-28] [LAB-29]	RE.AN RE RE.AN	Enhanced error reporting
NTE Segment	[LAB-28] [LAB-29]	RE RE.AN	Used in multiple segment groups
NTE-4 Comment Type	[LAB-28] [LAB-29]	RE RE.AN	
OBR-3 Filler Order Number	[LAB-29]	RE.AN	

Element	Transaction	Usage	Comment
OBR-16 Ordering Provider	[LAB-28	RE	
OBX Segment	[LAB-29]	RE.AN	When used in SPECIMEN Group
OBX-4.2 Group	[LAB-29]	RE.AN	Used by Analyzers to group results
OBX-4.3 Sequence	[LAB-29]	RE.AN	Used by Analyzers to sequence results
OBX-7 Reference Range	[LAB-29]	RE.AN	Used by Analyzers that want to report reference ranges
OBX-21 Observation Instance Identifier	[LAB-28] [LAB-29]	RE RE.AN	Sent by Analyzers that uniquely identify results
ORC-4 Placer Group Number	LAB-28] [LAB-29]	RE RE.AN	
ORC-21 Ordering Facility Name	[LAB-28]	RE	May be used by Analyzers for rule evaluation
ORC-27 Filler Expected Availability Date/Time	[LAB-29]	RE.AN	Used by Analyzers that can report estimated completion for an AWOS
TCD-9 Specimen Consumption Quantity	[LAB-28]	RE	Used by Analyzer when needed for observation accuracy.

2.3 Use of Coded Entities and Coding Schemes

Where applicable, coding schemes required by the DICOM®, HL7®, LOINC®, and SNOMED® standards are used in IHE Profiles. In the cases where such resources are not explicitly identified by standards, implementations may utilize any resource (including proprietary or local) provided any licensing/copyright requirements are satisfied.

IHE does produce and maintain certain terminology. OIDs and URNs have been assigned for specific uses. The IHE process for managing OIDs and URNs is described at http://wiki.ihe.net/index.php/OID_Registration.

The LAW Profile places an emphasis on the clear identification of codes used in the messages. The profile identifies codes that should be known between the Analyzer and Analyzer Manager to minimize the need for either actor to interpret the meaning of a code. In addition, the profile also recognizes that local or vendor-defined codes are necessary.

In order to clarify the use of codes, LAW specifies the following conventions to follow when identifying codes and coding systems as part of an LAW transaction:

- If a code is drawn from a standard code system, it should be identified using the coding system identifier from HL7 Table HL70396 Coding System table.
- Values used from appropriate HL7 tables are identified with “HL7nnnn”, where “nnnn” is the HL7 table number.

- When appropriate, LAW defines codes and the coding system name for these values will be "IHELAW". This includes extensions and codes for user-define tables. The "IHELAW" coding scheme is maintained and published by the IHE Laboratory Committee. It is assigned the OID **1.3.6.1.4.1.19376.1.3.5** and is registered as such in the HL7 OID registry.
- The "99zzz…" construct should be used to identify vendor-defined codes rather than "L". The vendor is free to choose any convention they desire for the "zzz…" elements of the coding system name, and it is not limited to just three alphanumeric characters.
- Even though the values for a table can be extended, or a table may be designated as user defined, the "99zzz…" construct will be used to clearly identify the code as vendor-specific. Thus, the receiver is not required to recognize the meaning of the code.
- The receiver will assume all coding systems beginning with "99" are vendor-defined and thus non-standard. However, vendors may exchange configuration information so that the receiver can be configured to interpret the code.
- The scope of all coding systems beginning with "99" is bound to the interface at hand between the Analyzer and the Analyzer Manager. Since this scope is local, there is no need to define a unique name for this coding scheme on a wider scale.

The following tables describe how the CE and CWE data types are used by this profile. Note that the "Alternate" fields in the CWE flavor are only specified for Supplemental Results and Additional Result Identifiers, as described in Section 2.3.1 below.

Table 2.3-1: CE Data Type

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Only ASCII printable characters (excluding the MSH-1 Field Separator, MSH-2 Encoding Characters, and white space) should be used.
Text (ST)	RE	199	Should always be provided if available, may be R for specific usages.
Name of Coding System (ID)	R	12	• A coding system defined in HL7 Table HL70396 • "HL7nnnn" for an HL7 Table • "IHELAW" for codes defined by the LAW Profile • "99zzz…" identifier for a vendor-defined coding system

Table 2.3-2: CWE Data Type

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Only ASCII printable characters (excluding the MSH-1 Field Separator, MSH-2 Encoding Characters, and white space) should be used.
Text (ST)	RE	199	Should always be provided if available, may be R for specific usages.
Name of Coding System (ID)	R	12	• A coding system defined in HL7 Table HL70396 • "HL7nnnn" for an HL7 Table • "IHELAW" for codes defined by the LAW Profile • "99zzz…" identifier for a vendor or local defined coding system
Alternate Identifier (ST)	C(R/X)	20	Only used for Supplemental Results and additional Result Identifiers in OBX-3 Only ASCII printable characters (excluding the MSH-1 Field Separator, MSH-2 Encoding Characters, and white space) should be used.
Alternate Text (ST)	C(RE/X)	199	Only used for Supplemental Results and additional Result Identifiers in OBX-3. Should always be provided if available, maybe R for specific usages.
Name of Alternate Coding System (ID)	C(RE/X)	12	Only used for Supplemental Results and additional Result Identifiers in OBX-3 • A coding system defined in HL7 Table HL70396 • "HL7nnnn" for an HL7 Table • "IHELAW" for codes defined by the LAW Profile • "99zzz…" identifier for a vendor or local defined coding system
Coding System Version ID	X	10	Not used in this profile
Alternate Coding System Version ID	X	10	Not used in this profile
Original Text	X	199	Not used in this profile
Second Alternate Identifier	C(RE/X)	20	Only used for additional Result Identifiers in OBX-3 Only ASCII printable characters (excluding the MSH-1 Field Separator, MSH-2 Encoding Characters, and white space) should be used.
Second Alternate Text	C (R/X)	199	Only used for additional Result Identifiers in OBX-3 Should always be provided if available, may be R for specific usages.

Component/Sub-Component	Usage	LEN	Comment
Name of Second Alternate Coding System	C (R/X)	12	Only used for additional Result Identifiers in OBX-3 • A coding system defined in HL7 Table HL70396 • "HL7nnnn" for an HL7 Table • "99zzz…" identifier for a vendor or local-defined coding system

For LAW, the objective is to clearly identify codes that the receiver should understand semantically. All codes established by a HL7 or other coding system will be designated with the proper coding system name. In addition, when a code set is extended by LAW it will be identified as part of the "IHELAW" coding system. Likewise, if the code set is extended by a vendor, then is will be identified with the "99zzz…" construct. A receiver does not have to recognize a code from a "99zzz…" coding system.

2.3.1 Order and Result Vocabularies

OBX-3 Observation Identifier, OBR-4 Universal Service Identifier, and TCD-1 Universal Service Identifier are used to identify orders and results. This profile recommends LOINC® and JLAC10 as standard vocabularies for the Universal Service and Observation Identifiers. The profile also supports the use of vendor-defined codes.

When using a LOINC® code, the CWE data type is populated as follows:

Table 2.3.1-1: LOINC® Coding

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	LOINC® Code
Text (ST)	R	199	LOINC® Name
Name of Coding System (ID)	R	2	LN

When using a JLAC10 code, the CWE data type is populated as follows:

Table 2.3.1-2: JLAC10 Coding

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	JLAC10 Code
Text (ST)	R	199	JLAC10 Name
Name of Coding System (ID)	R	4	JC10

When using a vendor-defined observation code, the CWE data type is populated as follows:

Table 2.3.1-3: Vendor Coding

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined code
Text (ST)	R	199	Vendor-defined name
Name of Coding System (ID)	R	12	"99zzz…" identifier for a vendor-defined coding system

In addition, this profile defines specific LAW codes used to classify a **Supplemental Result** (see Section B.3.6 Transmitting Supplemental Results) of an **Observation**. For a **Supplemental Result**, a vendor-defined code that uniquely identifies the representation is sent in OBX-3, along with a LAW **Supplemental Result** code in the alternate code components. The field is populated as follows:

Table 2.3.1-4: LAW Supplemental Result Coding for OBX-3

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined code
Text (ST)	R	199	Vendor-defined name
Name of Coding System (ID)	R	12	"99zzz…" identifier for a vendor-defined coding system
Alternate Identifier (ST)	R	7	LAW Code from Table 2.3.1-5 LAW Codes for Supplemental Results
Alternate Text (ST)	R	18	LAW Name from Table 2.3.1-5 LAW Codes for Supplemental Results
Name of Alternate Coding System (ID)	R	6	IHELAW

The following defines the LAW **Supplemental Result** identifiers.

Table 2.3.1-5: LAW Codes for Supplemental Results

Code	Name	Description
S_IMAGE	Supplemental Image	An image representing some aspect of the observation
S_GRAPH	Supplemental Graph	A graph representing some aspect of the observation
S_RAW	Raw Supplemental	One or more raw values associated with the observation
S_OTHER	Other Supplemental	Vendor specific **Supplemental Result** not covered by LAW

To be able to send multiple result identifiers as Alternate Identifier (OBX-3-4 to OBX-3-6) and Second Alternate Identifier (OBX-3-10 to OBX-3-12) it is possible to use the Coding System name in OBX-3-3, OBX-3-6 and OBX-3-12 to distinguish between them (e.g., a vendor defined one, a LOINC one, and a locally defined one).

615 When sending alternate observation identifiers, the CWE data type is populated as follows (please note that Second Alternate Identifier is in OBX-3-10, Second Alternate Text is in OBX-3-11, and Name of Second Alternate Coding System is in OBX-3-12):

Table 2.3.1-6: Additional Observation Identifiers for OBX-3

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Test code from • LOINC, • JLAC10, • A vendor-defined coding system, or • A local-defined coding system Usually the Ordered Test Identifier (OBR-4-1)
Text	R	199	Human-readable test code description (or copy of Identifier) Usually the Ordered Test Text (OBR-4-2)
Coding System	R	12	One of • "LN" for LOINC, • "JC10" for JLAC10 • "99zzzz" for Vendor defined codes • "99zzz" for local defined codes Usually the Ordered Test Coding System (OBR-4-3)
Alternate Identifier	C(R/X)	20	Test code from • LOINC, • JLAC10, • A vendor-defined coding system, or • A local-defined coding system
Alternate Text	C(R/X)	199	Human-readable test code description (or copy of Alternate Identifier)
Alternate Coding System	C(R/X)	12	One of • "LN" for LOINC, • "JC10" for JLAC10 • "99zzzz" for Vendor defined codes • "99zzz" for local defined codes
Coding System Version ID	X	10	Not used in this profile
Alternate Coding System Version ID	X	10	Not used in this profile
Original Text	X	199	Not used in this profile

Component/Sub-Component	Usage	LEN	Comment
Second Alternate Identifier	C(R/X)	20	Test code from • LOINC, • JLAC10, • A vendor-defined coding system, or • A local-defined coding system
Second Alternate Text	C (R/X)	199	Human-readable test code description (or copy of 2nd Alternate Identifier)
Second Alternate Coding System	C (R/X)	12	One of • "LN" for LOINC, • "JC10" for JLAC10 • "99zzzz" for Vendor defined codes • "99zzz" for local-defined codes

2.3.2 Units of Measure

The Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans.

UCUM is not a traditional coding system in that it does not assign unique identifiers (or codes) to each unit of measure, but instead it is a definition of an algebraic grammar and syntax used to express units that can be unambiguously parsed and semantically understood by computer systems.

UCUM will be used to define units of measure for SAC-24 Volume Units and OBX-6 Units. By using UCUM, a common syntax for defining units of measure is enforced. However, the following constraints were identified when establishing conventions for encoding units:

- Human-readable units in addition to the UCUM machine-readable syntax will be required. This ensures display units (human-readable unit) align with the documentation provided to the customer, while the UCUM syntax can be used for automated processing.
- There will be instances where it may not be possible to use or enforce UCUM syntax for a unit. For example, an Analyzer may support user-defined assays and may not be able to enforce or require UCUM units as part of the definition. Likewise, there may be legacy assays with associated customer documentation that do not align with UCUM syntax. These types of units will be considered to be in a human-readable format, with no coding based on a coding system.

The profile supports transmitting a unit with the UCUM syntax as follows:

Table 2.3.2-1: UCUM Unit (CE)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	UCUM coded unit of measure
Text (ST)	199	R	Vendor human-readable unit
Name of Coding System (ID)	4	R	Fixed "UCUM" (value pre-adopted from HL7 v2.6)

The profile supports transmitting a unit available only in a human-readable format as follows:

645 **Table 2.3.2-2: Human-Readable Unit (CE)**

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)		X	Blank
Text (ST)	199	R	Vendor human-readable unit
Name of Coding System (ID)		X	Blank

3 IHE Transactions

This section defines in detail each transaction of the LAW Profile from the IHE Pathology and Laboratory Medicine domain, specifying the standards used and the information transferred.

3.27 Query for AWOS [LAB-27]

This transaction is used between an Analyzer Manager and an Analyzer working in query mode. It enables the Analyzer to query the Analyzer Manager for analytical work order steps (AWOSs) to be performed on specimens. Transaction [LAB-27] conveys the query, and is combined with on AWOS Broadcast [LAB-28], which carries the actual response to the query, as zero or more AWOS.

The Analyzer uses this transaction to query for the AWOS related to one recognized specimen, or to query for all pending AWOSs prior to the arrival of the specimens.

The transaction provides an initial message exchange of a query for one specimen or all AWOS, and the reply that carries the acknowledgement status of the query. For a query for a single specimen, the Analyzer Manager will follow the query exchange with a second message exchange consisting of an AWOS Broadcast [LAB-28] that provides the AWOS to perform or an indication that there is no AWOS (Negative Query Response) for that specimen. For a query for all work, the Analyzer Manager will follow with one or more AWOS Broadcast [LAB-28] interactions containing the AWOSs to perform, or carrying the Negative Query Response.

The Analyzer can send multiple queries prior to receiving the AWOS Broadcast from the Analyzer Manager. This allows the Analyzer to send a batch of queries, or asynchronous queries, without waiting for the AWOS Broadcast of the two-part message exchange.

3.27.1 Scope

This transaction requires that the Analyzer support the “Bi-directional Communication” Option or one of the other query options described in PaLM TF-1:5.2 and listed below in Section 3.27.4.

This transaction supports use cases #2 “Query ALL” (PaLM TF-1: 5.4.2.2), #3 “AWOS Query” (PaLM TF-1: 5.4.2.3) as well as the use cases derived from these two. It is used by the Analyzer Manager and the Analyzer in "Query Mode".

3.27.2 Actor Roles

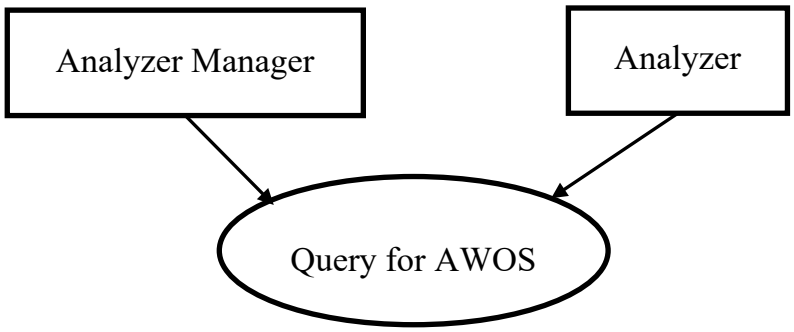

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Figure 3.27.2-1: Use Case Diagram

Table 3.27.2-1: Actor Roles

Actor:	Analyzer Manager
Role:	Manages the Work Orders and AWOS. Responds with AWOS Broadcast [LAB-28] to queries from the Analyzer.
Actor:	Analyzer
Role:	Queries the Analyzer Manager for an AWOS related to the specimen, and receives the query acknowledgement. Waits for the AWOS Broadcast [LAB-28] from the Analyzer Manager. If no AWOS Broadcast [LAB-28] for the queried specimen is received by an Analyzer-specific period of time, the Analyzer may notify the user that no AWOS was received.

3.27.3 Referenced Standards

HL7 v2.5.1:

680 Chapter5: "Query" → QBP and RSP messages.

Chapter5: "Query" → QPD, RCP and QAK segments.

3.27.4 Messages

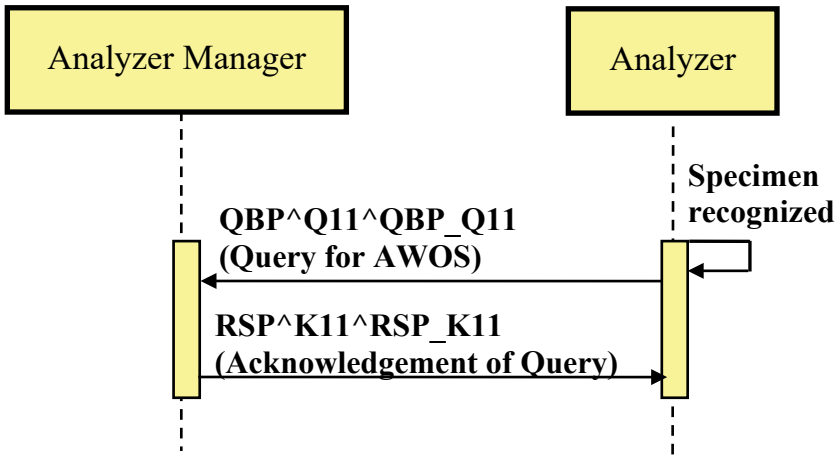

Figure 3.27.4-1: Query for AWOS

3.27.4.1 Message QBP^Q11 and its acknowledgement RSP^K11

3.27.4.1.1 Trigger Events

- An analyzer supporting the "Bi-directional Communication" Option wants to obtain the AWOS related to an identified container.
- An analyzer supporting the "Query All" Option wants to obtain all pending work.
- An analyzer supporting the "Query by Rack" Option wants to obtain the AWOS related to a specimen known by its position in the rack (carrier).
- An analyzer supporting the "Query by Tray" Option wants to obtain the AWOS related to a specimen known by its position on the tray.
- An analyzer supporting the "Query by Isolate" Option wants to obtain the AWOS related to an identified isolate within the primary (parent) specimen.

3.27.4.1.2 Message Semantics

3.27.4.1.2.1 QBP^Q11 Message Static Definition

Table 3.27.4.1.2.1-1: QBP^Q11^QBP_Q11

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
QPD	Query Parameter Definition	M	[1..1]	5
RCP	Response Control Parameter	M	[1..1]	5

MSH-9 – Message Type (MSG) SHALL have its components respectively valued to “QBP”, “Q11”, and “QBP_Q11”.

MSH-21 – Message Profile Identifier SHALL be “LAB-27^IHE”.

3.27.4.1.2.2 RSP^K11 Message Static Definition

Table 3.27.4.1.2.2-1: RSP^K11^RSP_K11

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
MSA	Message Acknowledgement	M	[1..1]	2
[ERR]	Error	C (R/X)[1]	[0..*]	2
QAK	Query Acknowledgement	M	[1..1]	5
QPD	Query Parameter Definition	M	[1..1]	5

Note 1: Predicate: Usage is Required when MSA-2 is not equal to “AA”. There may be multiple repetitions when multiple errors have been discovered. Otherwise usage is Not Supported.

MSH-9 – Message Type (MSG) SHALL have its components respectively valued to “RSP”, “K11”, and “RSP_K11”.

MSH-21 – Message Profile Identifier SHALL be “LAB-27^IHE”.

QPD SHALL be the same as the QPD sent in QBP^Q11^QBP_Q11. If the segments are not the same, the Analyzer may report an error to the user.

3.27.4.1.2.3 QPD Segment Static Definition

HL7 v2.5.1: chapter 5 (5.5.4 QPD – Query Parameter Definition).

This segment provides the specimen information for the query.

Table 3.27.4.1.2.3-1: QPD segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	60	CE	M	[1..1]		01375	Message Query Name
2	32	ST	M	[1..1]		00696	Query Tag
3	80	EI	C (M/X)	[0..1]		01331	SAC-3:Container Identifier
4	80	EI	C (M/X)	[0..1]		01337	SAC-10:Carrier Identifier
5	80	NA	C (M/X)	[0..1]		01338	SAC-11:Position in Carrier
6	80	EI	C (M/X)	[0..1]		01340	SAC-13:Tray Identifier
7	80	NA	C (M/X)	[0..1]		01341	SAC-14: Position in Tray
8	250	CE	C (RE/X)	[0..1]		01342	SAC-15: Location
9	80	EI	C (M/X)	[0..1]		01332	SAC-4: Primary (parent) Container Identifier

“Query” Option (LAW_QUERY_WOS)

An analyzer queries for the AWOS related to an identified container. The only fields populated in the QPD segment SHALL be QPD-1, QPD-2 and QPD-3.

"Query All" Option (LAW_QUERY_ALL)

An analyzer queries for all pending work. The only fields populated in the QPD segment SHALL be QPD-1 and QPD-2.

"Query by Rack" Option (LAW_QUERY_RACK)

An analyzer queries for the AWOS related to a specimen known by its position in the rack (carrier). The only fields populated in the QPD segment SHALL be QPD-1, QPD-2, QPD-4, QPD-5 and QPD-8. The first four are Mandatory, the latter is Required if Available. QPD-4 identifies the rack and QPD-5 is the position in the rack.

"Query by Tray" Option (LAW_QUERY_TRAY)

An analyzer queries for the AWOS related to a specimen known by its position on the tray. The only fields populated in the QPD segment SHALL be QPD-1, QPD-2, QPD-6, QPD-7 and QPD-8. The first four are Mandatory, the latter is Required if Available. QPD-6 identifies the tray and QPD-7 is the position in the tray.

"Query by Isolate" Option (LAW_QUERY_ISOLATE)

An analyzer queries for the AWOS related to an identified isolate within the primary (parent) specimen. The only fields populated in the QPD segment SHALL be QPD-1, QPD-2, QPD-3, and QPD-9. All four are Mandatory. QPD-3 identifies the isolate and QPD-9 identifies the primary specimen from which the microorganism was isolated.

"Query by WOS Informational Rack" Option (LAW_QUERY_WOS_INFORMATIONAL)

An analyzer queries for the AWOS related to a specimen known by an identified container and informs the Automation Manager about its position in the rack (carrier). The only fields populated in the QPD segment SHALL be QPD-1, QPD-2, QPD-3, QPD-4 and QPD-5. All are Mandatory. QPD-4 identifies the rack and QPD-5 is the position in the rack. If this option is used the Carrier Identifier (QPD-4) and Position in Carrier (QPD-5) are informational only.

QPD-1 Message Query Name (CE), mandatory.

This field contains the value of the query for either a single specimen or for all specimens. HL7 User-defined Table 0471 – Query Name defines the identifier and description values to use for each query type. The contents for each query type are described below.

HL7 User-defined Table 0471 – Query Name

Value	Description	Comment
WOS	Work Order Step	Use to query for a single specimen when using option LAW_QUERY_WOS
WOS_ALL	Work Order Step All	Use to query for all analytical work when using option LAW_QUERY_ALL
WOS_BY_RACK	Work Order Step by Rack	Use to query for a single specimen in a specific position in a rack when using option LAW_QUERY_RACK
WOS_BY_TRAY	Work Order Step by Tray	Use to query for a single specimen in a specific position in a tray when using option LAW_QUERY_TRAY
WOS_BY_ISOLATE	Work Order Step by Isolate	Use to query for a single Isolate when using option LAW_QUERY_ISOLATE
WOS_INFORMATIONAL_RACK	Query by WOS and Informational Rack	Use to query for a single specimen when using option LAW_QUERY_WOS_INFORMATIONAL_RACK with Container ID and - as informational data - Rack and Position in Rack.

Query for a Single Specimen

Table 3.27.4.1.2.3-2: Element QPD-1 Message Query Name (CE) for single specimen

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	3	Fixed “WOS”
Text (ST)	R	15	Fixed “Work Order Step”
Name of Coding System (ID)	R	6	Fixed “IHELAW”

Query for All Work

Table 3.27.4.1.2.3-3: Element QPD-1 Message Query Name (CE) for all work

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	7	Fixed "WOS_ALL"
Text (ST)	R	19	Fixed "Work Order Step All"
Name of Coding System (ID)	R	6	Fixed "IHELAW"

Query by rack

Table 3.27.4.1.2.3-4: Element QPD-1 Message Query Name (CE) for single specimen by rack

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	11	Fixed "WOS_BY_RACK"
Text (ST)	R	23	Fixed "Work Order Step by rack"
Name of Coding System (ID)	R	6	Fixed "IHELAW"

Query by tray

Table 3.27.4.1.2.3-5: Element QPD-1 Message Query Name (CE) for single specimen by tray

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	11	Fixed "WOS_BY_TRAY"
Text (ST)	R	23	Fixed "Work Order Step by tray"
Name of Coding System (ID)	R	6	Fixed "IHELAW"

Query by isolate

Table 3.27.4.1.2.3-6: Element QPD-1 Message Query Name (CE) for single specimen by isolate

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	14	Fixed "WOS_BY_ISOLATE"
Text (ST)	R	26	Fixed "Work Order Step by isolate"
Name of Coding System (ID)	R	6	Fixed "IHELAW"

QPD-2 Query Tag (ST), mandatory.

A unique identifier assigned to each query message instance.

QPD-3 Container Identifier (EI), conditional (C(M/X)).

Used when the query is based upon the Container Identifier. It is expected that the Container Identifier is the value encoded on the specimen container.

Predicate: QPD-3 is Mandatory when QPD-1 is equal to WOS, WOS_BY_ISOLATE, or WOS_INFORMATIONAL_RACK. Otherwise usage is Not Supported.

Table 3.27.4.1.2.3-7: Element QPD-3 Container Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	Container ID

QPD-4 Carrier Identifier (EI), conditional (C(M/X)).

Used when the query is based on the location of the specimen container in a carrier. This field contains the identification of the carrier (also known as rack) that contains the specimen container.

Predicate: QPD-4 is Mandatory when QPD-1 is equal to WOS_BY_RACK or WOS_INFORMATIONAL_RACK. Otherwise usage is Not Supported. When using the WOS_INFORMATIONAL_RACK Option QPD-4 is informational only.

Table 3.27.4.1.2.3-8: Element QPD-4 Carrier Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	Rack ID

QPD-5 Position in Carrier (NA), conditional (C(M/X)).

Used when the query is based on the location of the specimen container in a carrier. This field identifies the position of the container in the carrier (e.g., 1…3…). The sub-components allow, if necessary, to transfer multiple axis information, e.g., 2-dimensional carrier (X^Y).

Predicate: QPD-5 is Mandatory when QPD-1 is equal to WOS_BY_RACK or WOS_INFORMATIONAL_RACK. Otherwise usage is Not Supported. When using the WOS_INFORMATIONAL_RACK Option QPD-5 is informational only.

Table 3.27.4.1.2.3-9: Element QPD-5 Position in Carrier (NA)

Component/Sub-Component	Usage	LEN	Comment
Value1 (NM)	RE	16	Position within Rack as an Integer
Value2 (NM)	O	16	
Value2 (NM)	O	16	
…	O	16	

QPD-6 Tray Identifier (EI), conditional (C(M/X)).

Used when the query is based on the location of the specimen in a tray. This field contains the identification of the tray.

Predicate: QPD-6 is Mandatory when QPD-1 is equal to WOS_BY_TRAY. Otherwise usage is Not Supported.

Table 3.27.4.1.2.3-10: Element QPD-6 Tray Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	Tray ID

QPD-7 Position in Tray (NA), conditional (C(M/X)).

Used when the query is based on the location of the specimen in a tray. This field contains the position of the sample on the tray. The sub-components allow, if necessary, to transfer multiple axis information, e.g., 2-dimensional tray (X^Y).

Predicate: QPD-7 is Mandatory when QPD-1 is equal to WOS_BY_TRAY. Otherwise Usage is Not Supported.

Table 3.27.4.1.2.3-11: Element QPD-7 Position in Tray (NA)

Component/Sub-Component	Usage	LEN	Comment
Value1 (NM)	R	16	Position within tray as an Integer
Value2 (NM)	O	16	
Value2 (NM)	O	16	
…	O	16	

QPD-8 Location (CE), conditional (C(RE/X)).

Used when the query is based on a location. This field contains additional information about the physical location of the specimen. This field SHALL be used in combination with the physical

location/position of the specimen on either a carrier or a tray and is used to further clarify the location.

Predicate: QPD-8 is Required if Available when QPD-1 is equal to WOS_BY_TRAY or WOS_BY_RACK. Otherwise usage is Not Supported.

Table 3.27.4.1.2.3-12: Element QPD-8 Location (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Additional location information defined by the vendor
Text (ST)	O	199	Vendor description
Name of Coding System (ID)	R	12	Vendor-defined coding system name “99zzz” (where z is an alphanumeric character)

QPD-9 Primary (parent) Container Identifier (EI), conditional (C(M/X).

Used when the query is based upon the Container Identifier and the Primary Container Identifier. This field contains the primary container from which the specimen came.

Predicate: Usage is Mandatory when QPD-1 is equal to WOS_BY_ISOLATE. Otherwise usage is Not Supported.

Table 3.27.4.1.2.3-13: Element QPD-9 Primary (Parent) Container Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	Parent Container ID

3.27.4.1.2.4 RCP Segment Static Definition

HL7 v2.5.1: chapter 5 (5.5.6 RCP – Response Control Parameter).

This segment provides additional information about the expected query response.

Table 3.27.4.1.2.4-1: RCP segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	1	ID	M	[0..1]	0091	00027	Query Priority
3	60	CE	M	[0..1]	0394	01440	Response Modality

RCP-1 Query Priority (ID), mandatory.

This field is always set to the value of “I” (Immediate).

RCP-3 Response Modality (CE), mandatory.

Table 3.27.4.1.2.4-2: Element RCP-3 Response Modality (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	1	Fixed “R”
Text (ST)	O	9	Fixed “Real Time”
Name of Coding System (ID)	R	7	Fixed “HL70394”

3.27.4.1.2.5 QAK Segment Static Definition

HL7 v2.5.1: chapter 5 (5.5.2 QAK – Query Acknowledgment).

This segment contains information about the query response.

Table 3.27.4.1.2.5-1: QAK segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	32	ST	M	[1..1]		00696	Query Tag
2	2	ID	M	[1..1]	0208	00708	Quantity Response Status
3	60	CE	M	[1..1]	0471	01375	Message Query Name

QAK-1 Query Tag (ST), mandatory.

This field contains “QPD-2 Query Tag” from the query message.

QAK-2 Query Response Status (ID), mandatory.

This field contains one of the following codes from the HL7 Table 0208.

HL7 Table 0208 – Query Response Status

Value	Description	Comment
OK	Query accepted	The query has been accepted for processing
AE	Application Error	An application error occurred when processing the query request
AR	Application Reject	The application has rejected the query request

QAK-3 Message Query Name (CE), mandatory.

This field contains "QPD-1 Message Query Name" from the query message.

Table 3.27.4.1.2.5-2: Element QAK-3 Message Query name (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	3/7	Contains value from QPD-1-1
Text (ST)	R	15/19	Contains value from QPD-1-2

Component/Sub-Component	Usage	LEN	Comment
Name of Coding System (ID)	R	6	Contains value from QPD-1-3

3.27.4.1.3 Expected Actions

The following scenarios describe the expected actions for a query transaction.

Query for a Single Specimen

When a specimen arrives on the Analyzer which supports the "Bi-directional Communication" Option, the Analyzer sends a QBP message to the Analyzer Manager to get the AWOS. The Analyzer identifies the query by using the query name (see description for QPD-1).

The Analyzer can identify the specimen by providing one of the following:

- QPD-3 Container Identifier, and if available QPD-9 Primary Container Identifier, or
- QPD-4 Carrier Identifier, QPD-5 Position in Carrier, and if available QPD-8 Location, or
- QPD-6 Tray Identifier, QPD-7 Position in Tray, and if available QPD-8 Location.
- QPD-9 Parent Specimen Container Identifier (for a query by isolate).

The following example table shows how to correctly populate the QPD fields for proper specimen identification:

Table 3.27.4.1.3-1: Specimen Identification Examples

QPD Fields	Specimen container with barcode	Specimen container in rack[1]	Specimen in tray[2]	Isolate[3]	Specimen Container with Barcode and Rack Position is Known[4]
QPD-1.1 Message Query Name. Identifier	WOS	WOS_BY_RACK	WOS_BY_TRAY	WOS_BY_ISOLATE	WOS_INFORMATIONAL_RACK
QPD-3 Container Identifier	987654	-	-	ISO1	987654
QPD-4 Carrier Identifier	-	12345	-	-	12345
QPD-5 Position in Carrier	-	3	-	-	3
QPD-6 Tray Identifier	-	-	8523	-	-
QPD-7 Position in Tray	-	-	1^8	-	-
QPD-8 Location	-	-	A-8	-	-
QPD-9 Primary (parent) Container Identifier	-	-	-	987654	-

Note 1: Used with option “Query by Rack”

Note 2: Used with option “Query by Tray”

Note 3: Used with option “Query by Isolate”

Note 4: Used with option “Query by WOS and Informational Rack”

The Analyzer Manager receives the QBP message and returns the RSP message with the query acknowledgment status. The Analyzer Manager prepares the AWOS(s) by checking the specimen identification information in the QBP message with a query, and initiates the AWOS Broadcast [LAB-28]. The Analyzer receives the AWOS(s) and performs processing for the specimen.

If the Analyzer Manager has no work for that specimen, it sends a Negative Query Response by setting ORC-1 to “DC” in an AWOS Broadcast [LAB-28] message. See Section 3.28.4.1.2.1 for more details on how to populate the contents of OML^O33 and ORL^O34 for a Negative Query Response.

Query for All Pending Work

A query for all pending work uses the query name “WOS_ALL” (see description of QPD-1). No container information is provided. The Analyzer Manager receives the QBP message and returns the RSP message with the query acknowledgment status. The Analyzer Manager prepares the AWOS(s) for that Analyzer and initiates the AWOS Broadcast [LAB-28]. The Analyzer receives the AWOS(s) and performs processing for the specimen(s).

If the Analyzer Manager has no work for Analyzer, it sends a Negative Query Response by setting ORC-1 to “DC” in a AWOS Broadcast [LAB-28] message. See Section 3.28.4.1.2.1 for more details on how to populate the contents of OML^O33 and ORL^O34 for a Negative Query Response.

3.27.5 Security Considerations

None.

3.28 AWOS Broadcast [LAB-28]

3.28.1 Scope

This transaction is used between an Analyzer Manager and an Analyzer. It enables the Analyzer Manager to send to the Analyzer a new AWOS, unsolicited if the Analyzer operates in “Broadcast Mode” or in response to a query initiated via transaction [LAB-27] by the Analyzer operating in "Query Mode".

It also enables the Analyzer Manager to cancel an existing AWOS previously sent to the Analyzer. Modification of an existing AWOS is achieved by combining cancellation and sending of a new AWOS.

This transaction requires that the Analyzer support the "Bi-directional Communication" Option or one of the query options described in PaLM TF-1:5.2.

This transaction supports use case #1"AWOS Broadcast" (PaLM TF-1:5.4.2.1). The transaction also contributes to use cases #2 "Query ALL" (PaLM TF-1:5.4.2.2), #3 "AWOS Query" (PaLM TF-1:5.4.2.3), and is also necessary to support all use cases derived from these first three.

3.28.2 Actor Roles

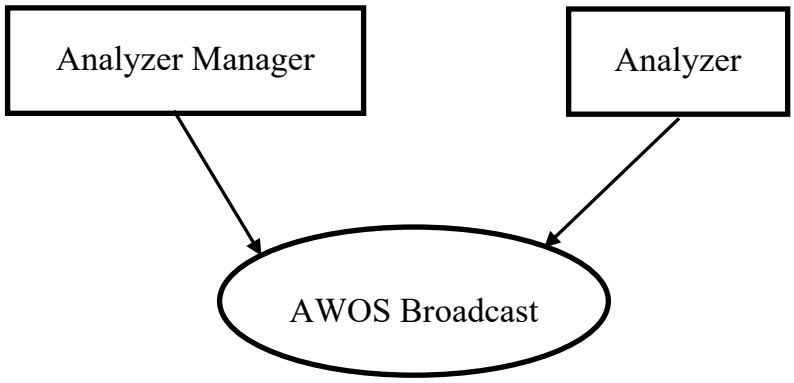

Figure 3.28.2-1: Use Case Diagram

Table 3.28.2-1: Actor Roles

Actor:	Analyzer Manager
Role:	Translates a Work Order into a series of AWOS assigned to the Analyzers. Broadcasts an AWOS related to a specimen to the appropriate Analyzer, either unsolicited (broadcast mode) or in response to a query (query mode).
Actor:	Analyzer
Role:	Receives the AWOS from the Analyzer Manager. Acknowledges it, sending back its intent regarding this AWOS. If the AWOS was accepted, performs it on the related specimen.

3.28.3 Referenced Standards

HL7 v2.5.1:

- chapter 2 "Control": generic segments and data types,
- chapter 3 "ADT": PID & PV1 segments,

- chapter 4 “Order”: OML^O33 and ORL^O34 message structures, OBR, ORC and TQ1 segments
- chapter 7 “Observation”: SPM segment
- chapter 13 “Clinical Laboratory Automation”: SAC & TCD segments

3.28.4 Messages

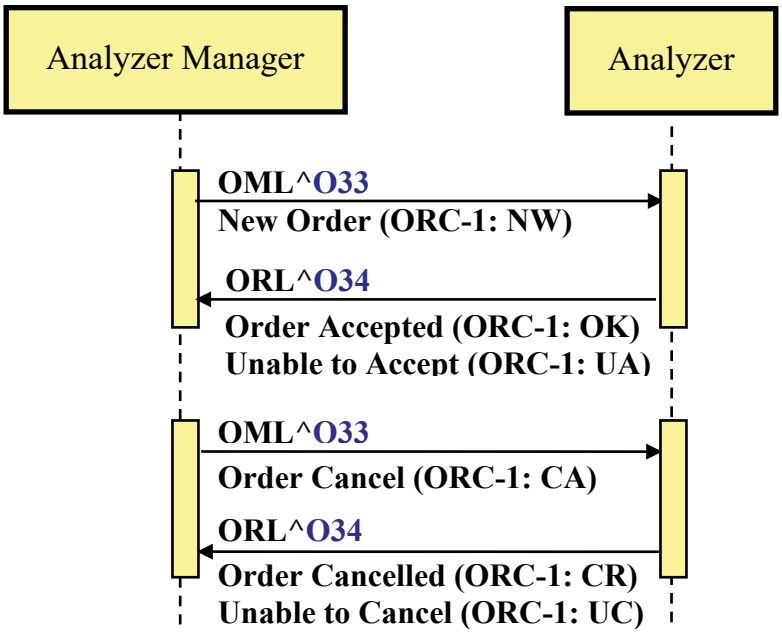

Figure 3.28.4-1: LAB-28 Interactions

3.28.4.1 Message OML^O33 and its acknowledgement ORL^O34

3.28.4.1.1 Trigger Events

- The Analyzer Manager has converted a new Work Order into a series of AWOSs assigned to Analyzers. It wants to send to each Analyzer operating in “broadcast mode” its assigned AWOS.
- The Analyzer Manager wants to cancel an AWOS previously sent to an Analyzer, either because this AWOS is actually to be canceled or because it must be modified, in which case the modified AWOS will be sent as a new AWOS.
- The Analyzer has initiated a query via transaction [LAB-27] and the Analyzer Manager wants to send the actual response consisting of zero or more AWOS.

930 #### 3.28.4.1.2 Message Semantics

The message OML^O33 contains zero or more AWOSs for one or more Specimens. The AWOSs are grouped by specimen.

3.28.4.1.2.1 OML^O33 Message Static Definition

Table 3.28.4.1.2.1-1: OML^O33

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	M	[1..1]	2
[	--- PATIENT begin	LAW_PAT_DEM[2] (RE/X)	[0..1]	
PID	Patient Identification	R	[1..1]	3
[{NTE}]	Notes and comments (for Patient)	RE	[0..*]	2
[	--- PATIENT_VISIT begin	RE	[0..1]	
PV1	Patient Visit	R	[1..1]	3
]	--- PATIENT_VISIT end			
]	--- PATIENT end			
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	M	[1..1]	7
[{NTE}]	Notes and comments (for Specimen)[1]	RE	[0..*]	2
[{	--- SPECIMEN_CONTAINER begin[1]	M	[1..1]	
SAC	Specimen Container	M	[1..1]	13
[{NTE}]	Notes and comments (for Container)[1]	RE	[0..*]	2
}]	--- SPECIMEN_CONTAINER end[1]			
{	--- ORDER begin	M	[1..*]	
ORC	Common Order (for one battery)	M	[1..1]	4
[{NTE}]	Notes and comments (for Common Order)[1]	RE	[0..*]	2
[{	--- TIMING begin	LAW_AWOS_PRIORITY: (RE/X)	[0..1]	
TQ1	Timing Quantity	R	[1..1]	4
}]	--- TIMING end			
[	--- OBSERVATION REQUEST begin	Negative Query Response[3]: (X/RE)	[0..1]	
OBR	Observation Request	M	[1..1]	4
[TCD]	Test Code Details	LAW_DILUTIONS, LAW_REFLEX, LAW_RERUN, LAW_AM_RR, LAW_AM_RR_CONTROL, LAW_POOL_AN: (R/RE)	[0..1]	13

Segment	Meaning	Usage	Card.	HL7 chapter
[{ NTE }]	Notes and comments (for Observation Request)	RE	[0..*]	2
[{	--- OBSERVATION begin	LAW_REL_OBS: (RE/X)	[0..*]	
OBX	Observation/Result	R	[1..1]	7
[TCD]	Test Code Details	RE	[0..1]	13
[{NTE}]	Notes and comments (for Observation Result)	RE	[0..*]	2
}]	--- OBSERVATION end			
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN end			

Note 1: Pre-adopted from HL7 v2.9, as proposed in HL7 OO CR135-755.

Note 2: Option LAW_PAT_DEM cannot be used combination with LAW_POOL_NOAN.

Note 3: Sent in response to [LAB-27] Query.

MSH-9 Message Type (MSG) SHALL have its three components respectively valued to “OML”, “O33” and “OML_O33”.

MSH-21 Message Profile Identifier SHALL be populated with at minimum one occurrence of “LAB-28^IHE”.

SPM-11 Specimen Role (CWE) in SPM segment SHALL be coded “Q” (Control specimen) in the case of a QC AWOS, “P” (Patient) in the case of a patient AWOS, “L” (Pooled patient specimens) in the case of a pooled patient samples AWOS, and “U” (Unknown”) in the case of a Negative Query Response.

The ORDER segment group carries the Analyzer Manager request for execution of new AWOS, request to cancel an AWOS, or Negative Query Response.

To request that the Analyzer perform an AWOS, ORC-1 Order Control is set to “NW”. The TQ1 segment can be used to carry additional information about the request. The OBR segment of the OBSERVATION REQUEST group contains the request details (OBR-2 AWOS ID, OBR-4 Universal Service Identifier, etc.). The TCD segment can be used to provide additional information about the order, such as dilution information. The TCD segment should only be sent if additional order information is populated (in fields between TCD-2 and TCD-11), and should not be sent if the only field populated is TCD-1 Universal Service Identifier.

When ordering replicates (see Section B.8 in Appendix B), each of the replicates is sent in a separate ORDER segment group as a unique AWOS.

When requesting an AWOS, the Analyzer Manager may use the OBSERVATION segment group to provide the Analyzer with results or a variety of clinically relevant information that is

obtained during the ordering or specimen collection process. The OBX segments of the OBSERVATION segment group are used for information specifically observed/measured as part of the ordering process (including specimen collection).

Segment PV1, which is the first segment of the segment group PRIOR RESULT, is mandatory. The presence of this segment at this point in the message structure announces unambiguously a set of prior orders with related prior observations. The segment PV1 represents the patient visit (or encounter) during which these prior observations were produced. The only field mandatory in the segment PV1 is PV1-2 “Patient Class” (as shown in Section C.10 of Appendix C). The sender of this message SHALL set the value the field PV1-2 to “U”, which stands for “patient class unknown”.

OBX-14 of the OBX segment contained in the OBSERVATION segment group can be used to provide the collection date/time associated with the related results. OBX-29 is mandatory and identifies if the OBX segment contains a result, supporting clinical information, answer to a question asked at specimen collection time, or answer to an order entry question.

To request that an Analyzer cancel an AWOS, ORC-1 Order Control is set to “CA”. The OBR segment of the OBSERVATION REQUEST group contains details (OBR-2 AWOS ID and OBR-4 Universal Service Identifier).

To indicate there is no work to perform (Negative Query Response) for a Query for AWOS [LAB-27], only the MSH, SPM, SAC, and ORC segments will be sent. For the SPM segment, the SPM-4 Specimen Type will be set to NULL ("") and SPM-11 Specimen Role will be set to “U” (Unknown). When the message is a Negative Query Response to a *Query for a Single Specimen*, the SAC segment will be populated based on the values of the QPD-3 to QPD-9 values from the query, which were used to identify the specimen. SAC-3 will be set to QPD-3, SAC-4 toQPD-9, SAC-10 to QPD-4, SAC-11 to QPD-5, SAC-13 to QPD-6, SAC-14 to QPD-7, and SAC-15 to QPD-8. When the message is a Negative Query Response to a *Query for All Work*, SAC-3 will be set to NULL (""). For all Negative Query Reponses, ORC-1 Order Control will be set to “DC” (Discontinue Request) and ORC-9 Date/Time of Transaction will be set to the current date/time. The OBSERVATION REQUEST group will not be present.

Repeatable NTE segments after PID, SPM, SAC, ORC, OBR, and OBX can be used to provide human-readable notes and comments to patient, specimens, specimen containers, orders, observation requests, and observation results, respectively. Some of these NTE segments are pre-adopted from HL7 v2.9. For comments generated at the Analyzer Manager, NTE-2 SHALL be populated with “A” (for Analyzer Manager) as specified by C.5 in Appendix C. The contents of NTE-3 SHALL NOT be considered as interpretable by a machine.

3.28.4.1.2.2 ORL^O34 Message Static Definition

Table 3.28.4.1.2.2-1: ORL^O34[1]

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
MSA	Message Acknowledgement	M	[1..1]	2
[{ERR}]	Error	C (R/X)[2]	[0..*]	2
[	--- RESPONSE begin	C (X/RE)[3]	[0..1]	
[	--- PATIENT begin	LAW_PAT_DEM[4]: (RE/X)	[0..1]	
PID	Patient Identification	R	[1..1]	3
]	--- PATIENT end			
{	--- SPECIMEN begin	M	[1..*]	
SPM	Specimen	M	[1..1]	7
[{SAC}]	Specimen Container	M	[1..1]	13
[{	--- ORDER begin	M	[1..*]	
ORC	Common Order	M	[1..1]	4
}]	--- ORDER end			
}	--- SPECIMEN end			
]	--- RESPONSE end			

Note 1: The ORL message structure in use here (ORL_O42) is pre-adopted from HL7 v2.8.1

Note 2: Usage is Required when MSA-2 is not equal to “AA”. There may be multiple repetitions when multiple errors have been discovered. Otherwise usage is Not Supported.

Note 3: Predicate: Usage is Not Supported if the ERR segment is present. Otherwise, Usage is Required if Available. The RESPONSE group should not be present when the acknowledgement is a response to a Negative Query Response. It should be present when the acknowledgement is for an AWOS request or an AWOS cancel.

Note 4: Option LAW_PAT_DEM cannot be used in combination with LAW_POOL_NOAN

MSH-9 Message Type (MSG) SHALL have its Message Code (MSH-9.1) and Trigger Event (MSH-9.2) components respectively valued to "ORL" and "O34". The Message Structure component (MSH-9.3) SHALL be valued to “ORL_O42”.

MSH-21 Message Profile Identifier SHALL be populated with “LAB-28^IHE”.

ORC-2 Placer Order Number SHALL be used to uniquely identify the AWOS to the Analyzer Manager when the RESPONSE segment group is included.

The RESPONSE segment group SHALL be used by the Analyzer to inform the Analyzer Manager about its intent to perform an individual AWOS contained in the OML message:

- For accepted AWOS
  - the ORC-1 Order Control should have value OK and

- the ORC-5 Order Status should have value SC, IP, or CM.

- For rejected AWOS
  - the ORC-1 Order Control should have value UA and
  - the ORC-5 Order Status should have value CA.

The RESPONSE segment group w SHALL be used by the Analyzer to respond to a cancellation request from the Analyzer Manager for each AWOS contained in the OML message:

- In case of successful cancellation
  - the ORC-1 Order Control should have value CR and
  - the ORC-5 Order Status should have value CA.
- In case of not being able to cancel
  - the ORC-1 Order Control should have value UC and
  - the ORC-5 Order Status should have value IP or CM.

3.28.4.1.3 Expected Actions

The Analyzer Manager may send multiple AWOSs for multiple specimens in the same OML^O33, in which cases the response message SHALL convey an acknowledgement for each of these AWOSs, in field ORC-1 of the ORC segment representing this AWOS.

For an individual new AWOS (ORC-1 = “NW”), the Analyzer will register the new AWOS information. This AWOS in the ORL^O34 response will be acknowledged as either “request accepted” (ORC-1 = “OK”) or “unable to accept order/service” (ORC-1 = “UA”).

For an individual AWOS to be cancelled (ORC-1 = “CA”), the Analyzer will evaluate the cancel request. This AWOS in the ORL^O34 response will be acknowledged as either “cancelled as requested” (ORC-1 = “CR”) or “unable to accept order/service” (ORC-1 = “UC”).

If the Analyzer Manager retransmits an AWOS or reuses an AWOS ID, the Analyzer will reject the AWOS request by responding with “Unable to accept order/service”. The rejection is for this specific request only, and has no influence on the original request. For example, if an AWOS is retransmitted, the Analyzer is rejecting the duplicate request but not the original request. See the ORC-1/ORC-5 discussion above for further details.

When the Analyzer Manager sends the OML^O33 in response to a Query for AWOS [LAB-27], the Analyzer will require that the OML^O33 be received in an Analyzer-specific period of time. If the time period elapses, the Analyzer will assume that the query has failed and may notify the user that no response was received.

When the OML^O33 is sent in response to a Query for AWOS [LAB-27] for a single specimen, it will only contain the AWOSs or Negative Query Response related to that specimen. If the OML message contains the Order Control Code “DC”, the Analyzer will evaluate the Negative

Query Response. The Analyzer will respond only with the MSH and MSA segments in the ORL^O34 to acknowledge receipt of the Negative Query Response.

A Negative Query Response for an unrecognized specimen is considered an unexpected situation. An unrecognized Negative Query Response might be received because:

- the response was received after the query time-out period elapsed
- the Analyzer Manager erroneously retransmitted the response and the Analyzer is no longer tracking a query for that specimen
- the Analyzer Manager erroneously sent the response to the Analyzer

In this situation, the Analyzer will respond with an **Application Acknowledgement: Reject** in the ORL^O34 by setting MSA-1 to "AR" and reporting the appropriate specimen container values in the ERR segment.

3.28.5 Security Considerations

None.

3.29 AWOS Status Change [LAB-29]

3.29.1 Scope

This transaction is used by the Analyzer to send test results and AWOS status changes to the Analyzer Manager.

3.29.2 Actor Roles

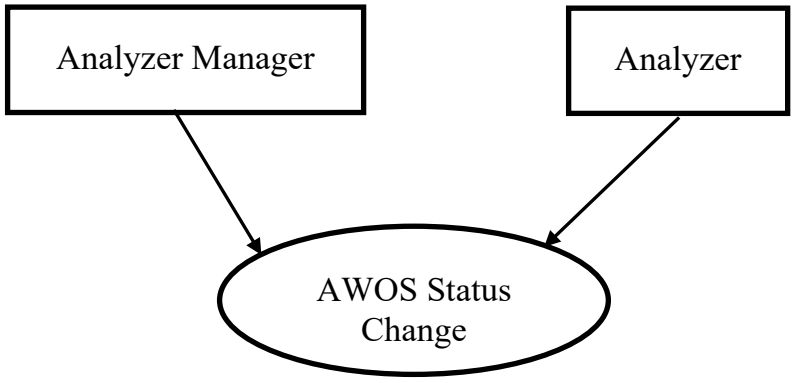

Figure 3.29.2-1: Use Case Diagram

Table 3.29.2-1: Actor Roles

Actor:	Analyzer Manager
Role:	Receives AWOS status changes and the corresponding test results from the Analyzer.

	Manages the status of the AWOS and of its parent Work Order.
Actor:	Analyzer
Role:	Notifies the Analyzer Manager of the status change of an AWOS, sending test results fulfilling this AWOS.

3.29.3 Referenced Standards

HL7 v2.5.1:

- chapter 2 “Control”: generic segments and data types,
- chapter 3 “ADT”: PID & PV1 segments,
- chapter 7 OUL^R22 message, OBR, OBX and SPM segments,
- chapter 13 “Clinical Laboratory Automation”: SAC, INV & TCD segments.

3.29.4 Messages

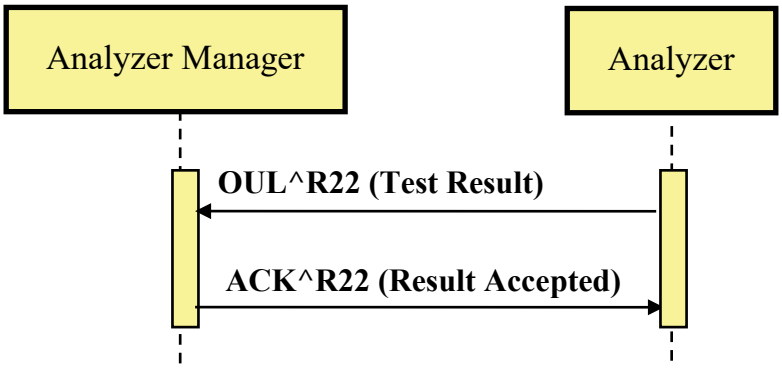

Figure 3.29.4-1: AWOS Status Change

3.29.4.1 Message OUL^R22 and its acknowledgement ACK^R22

3.29.4.1.1 Trigger Events

The Analyzer sends test results corresponding to one or more AWOSs.

3.29.4.1.2 Message Semantics

The message OUL^R22 contains zero or more observations for one or more AWOS for one or more specimens. Each specimen is in one container.

If the patient is known, then all results/specimens in the message must be for one patient.

3.29.4.1.2.1 OUL^R22 Message Static Definition

Table 3.29.4.1.2.1-1: OUL^R22

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
[	-- PATIENT begin	LAW_PAT_DEM[1] : (RE/X)	[0..1]	
[PID]	Patient Identification	R	[1..1]	3
[{NTE}]	Notes and comments (for Patient)	RE.AN	[0..*]	2
[	-- VISIT begin	LAW_PAT_DEM[1] : (RE.AN/X)	[0..1]	
[PV1]	Patient Visit	R	[1..1]	3
]	-- VISIT end			
]	-- PATIENT end			
{	--- SPECIMEN begin	M	[1..*]	
SPM	Specimen information	M	[1..1]	7
[{ OBX }]	Observation Result (for Specimen)	RE.AN	[0..*]	7
[{	--- CONTAINER begin	M	[1..1]	
SAC	Container information	M	[1..1]	13
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, … of QC specimen)	LAW_CONTRIB_SUB: (C (R/X)[2]/X)	[0..1]	13
}]	--- CONTAINER end			
{	--- ORDER begin	M	[1..*]	
OBR	Observation Order	M	[1..1]	7
[ORC]	Common Order	M	[1..1]	4
[{NTE}]	Notes and comments (for Order)	RE.AN	[0..*]	2
[{	TIMING_QTY begin	LAW_AWOS_PRIORITY: (R/X)	[0..1]	
TQ1	Timing Quantity	R	[1..1]	4
}]	TIMING_QTY end			
[{	--- RESULT begin	(C(M/RE.AN)/X)[3]	[0..*]	
OBX	Observation Result	M	[1..1]	7
[TCD]	Test Code Detail	LAW_DILUTIONS, LAW_PRIORITY, LAW_POOL_AN: (R/X)	[0..1]	13
[{INV}][4]	Detailed Substance information (e.g., reagents used for testing)	LAW_CONTRIB_SUB: (RE/X)	[0..*]	13
[{NTE}]	Notes and comments	RE.AN	[0..*]	2
}]	--- RESULT end			

Segment	Meaning	Usage	Card.	HL7 chapter
}	--- ORDER end			
}	--- SPECIMEN end			

Note 1: Option LAW_PAT_DEM CANNOT be used in combination with LAW_POOL_NOAN

Note 2: Predicate: Usage is Required when SPM-11 is “Q”. Otherwise usage is Not Supported.

Note 3: Predicate: Usage is Mandatory if field ORC-5 "Order Status" of the above ORC segment is valued with "CM". Usage is Required if Available from Analyzer if field ORC-5 “Order Status” of the above ORC segment is valued with “IP”. Otherwise usage is Not Supported.

Note 4: Usage of the INV segment is pre-adopted from HL7 v2.9, as proposed by HL7 CR-115-735.

The message conveys the observation results for one or more specimens. Each specimen is in one container and there may be one or more observation results for each container.

MSH-9 Message Type (MSG) SHALL have its three components respectively valued to "OUL", "R22", and “OUL_R22”.

MSH-21 Message Profile Identifier SHALL be populated with at minimum one occurrence of “LAB-29^IHE”.

The PATIENT and VISIT segments groups are optional and may be used to convey patient information.

The SPECIMEN group is mandatory and SHALL be used to convey specimen and specimen container information.

SPM-11 Specimen Role (CWE) SHALL be coded “Q” (Control specimen) in the case of a QC AWOS, “P” (Patient) in the case of a patient AWOS, and “L” (Pooled patient specimens) in the case of a pooled patient specimen AWOS.

The optional OBX segment in the SPECIMEN group may be used to document the condition of the specimen.

The CONTAINER segment group is mandatory and SHALL be used to provide the specimen container information.

Either SAC Container Identifier or SAC-4 Primary Container Identifier SHALL be provided. If SAC-3 Container Identifier and SAC-4 Primary Container Identifier are not known or applicable, then SAC-3 SHALL be populated with NULL (""). The Analyzer may populate the remaining fields of the SAC segment with additional container information, such as carrier information in SAC-10/11.

The INV segment usage in the CONTAINER segment group is conditional. When SPM-11 is set to the value of “Q”, INV may be populated with details about the control material. Otherwise the usage is not supported.

The ORDER group is mandatory and SHALL be used to provide order information.

The OBR segment is mandatory and SHALL be used to transmit information about the requested test.

- OBR-2 Placer Order Number SHALL contain the AWOS ID for orders transmitted to the Analyzer by the Analyzer Manager. For orders created at the Analyzer, the field SHALL contain the NULL ("") value.
- The optional OBR-3 Filler Order Number may be used by the Analyzer to provide a unique identifier for the observation.
- OBR-4 Universal Service Identifier SHALL contain the identifier for the test that was ordered.
- The optional OBR-16 Ordering Provider and OBR-17 Order Callback Phone Number fields may be populated to provide additional information about the order.

The ORC segment is mandatory and SHALL be used to transmit information about the status of the order.

- ORC-1 Order Control SHALL be populated with the code "SC".
- ORC-2 Placer Order Number is not populated because OBR-2 Placer Order Number is used to carry the AWOS ID.
- ORC-5 Order Status is populated with the status of the order to indicate if all observations have been completed by the Analyzer for the AWOS.
- ORC-8 Parent is used to send the parent AWOS ID(s) for a reflex test initiated by the Analyzer. See Section B.4 Reflex Initiated at the Analyzer in Appendix B for more details.

The TQ1 segment is optional and may be used to report the priority status of the order.

The RESULT segment group contains the observation results for the AWOS represented by the above (OBR, ORC) pair. The segment group is omitted if ORC-5 is not valued with either “IP” or “CM”. The segment group may further be omitted when ORC-5 is “IP” and the Analyzer has no observations to report yet. For example, in the scenario where an Analyzer wishes to send a [LAB-29] message at the start of a run to inform the Analyzer Manager about the estimated result completion time, but has no observations to report yet, this segment may be omitted.

The OBX segment is used to carry the observation results and supporting clinical information.

- OBX-3 will be used to identify the observation and OBX-4 will be used to identify each observation run. See Section B.3 Observation Identification in Appendix B for more details.
- OBX-29 identifies if the OBX segment contains a result, supporting clinical information, answer to a question asked at specimen collection time, or answer to an order entry question. The Analyzer Manager may discard segments that are not identified as results.

- The other OBX fields are used to convey information about the observation result. See Section C.7 OBX Segment in Appendix C for more details.

The optional TCD segment may be used to provide dilution information. The Analyzer Manager SHALL reject the message if the value of TCD-1 does not match the value of OBX-3.

The optional INV segment for this group may be used to provide details about contributing substances used to produce the result.

The optional NTE segments following the PID, ORC, and OBX segments may be used to provide human-readable notes and comments about the patient, order, and result respectively. The NTE segments after the PID and ORC segments may be notes that have been received from the Analyzer Manager during order download or they may be notes and comments entered at an Analyzer that supports order entry. For comments generated at the Analyzer, NTE-2 SHALL be populated with "Z" (for Analyzer) as specified by C.5 in Appendix C. The contents of NTE-3 SHALL not be considered interpretable by a machine.

3.29.4.1.2.2 ACK^R22 Message Static Definition

Table 3.29.4.1.2.2-1: ACK^R22

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
MSA	Message Acknowledgement	M	[1..1]	2
[{ERR}]	Error	C (R/X)[1]	[0..*]	2

Note 1: Predicate: Usage is Required when MSA-2 is not equal to "AA". There may be multiple repetitions when multiple errors have been discovered. Otherwise usage is Not Supported.

MSH-9 Message Type (MSG) SHALL have its three components respectively valued to "ACK", "R22" and "ACK".

MSH-21 Message Profile Identifier SHALL be populated at minimum with one occurrence of "LAB-29^IHE".

3.29.4.1.3 Expected Actions

The Analyzer notifies the Analyzer Manager of the test results using the OUL^R22 message. The Analyzer Manager accepts and registers information, and responds to the Analyzer with the ACK^R22 message.

The Analyzer Manager SHALL correlate all observations with a known AWOS ID to the originating Work Order.

The Analyzer Manager SHALL use OBX-3 and OBX-4 to uniquely identify each **Observation Result**, **Supplemental Result**, and run. See Section B.3 Observation Identification in Appendix B for more details.

The Analyzer Manager SHALL accept unsolicited observations, which are indicated by OBR-2 Placer Order Number populated with a NULL ("") value. It is up to the Analyzer Manager to evaluate the observation and associate it with an existing AWOS, create a new AWOS for a Work Order, or ask the operator to manually link the observation to an AWOS.

3.29.5 Security Considerations

None.

Appendices

Appendix A – Constraints on Data Types Specific to LAW Transactions

The data type constraints defined in PaLM TF-2x: Appendix A apply to LAW Transactions, with the following exceptions.

A.1 EI – Entity Identifier

LAW Transactions do not follow the data type constraints for EI defined in PaLM TF-2x:A.2 because the information defined in the Namespace ID, Universal ID, and Universal ID Type components are not useful for the Analyzer. The Analyzer Manager is expected to maintain the detailed information associated with an Entity Identifier for communication with other systems.

A standard length of 50 for the Entity Identifier component is used. This length supports GUID identifiers.

For all uses the EI data type, the sub-components used are identified as part of the field and component descriptions. In most cases, only EI.1 Entity Identifier is required.

A.2 EIP – Entity Identifier Pair

LAW Transactions do not follow the data type constraints for the EIP data type defined in PaLM TF-2x: A.3 because there is no need for the Analyzer to populate EIP.2 Filler Assigned Identifier with an Analyzer generated identifier.

For all uses of the EIP data type, the usage of the EIP.1 and EIP.2 components and sub-components are identified as part of the field and component descriptions. The EI data type sub-components SHALL conform to Section A.1 above.

A.3 ED – Encapsulated Data

In order to align the usage of the ED data type with MIME media types and subtypes established in accordance with IETF RFC2046 (http://ietf.org/rfc/rfc2046.txt), LAW Transactions pre-adopt the values in the following HL7 tables from HL7 v2.8:

- HL7 Imported Table 0834 MIME Types for ED.2 Type of Data (ID).
- HL7 External Table 0291 Subtype of Referenced Data for ED.3 Data Subtype (ID).

Appendix B – Messaging Details Specific to LAW Transactions

The following sections provide additional messaging details for LAW Transactions.

B.1 Specimen Identification

The Analyzer matches one or more AWOSs to a specimen container in order to perform tests on the specimen carried by the specimen container. In order to identify a specimen container, the fields of the SAC – Specimen Container Detail segment are used. The SAC segment is also used to carry additional container information, such as container volume. The SAC segment is mandatory for [LAB-28] and [LAB-29].

The following SAC elements, predicates, and rules will be used for container identification:

- SAC-3 Container Identifier is a conditional element for [LAB-28] and [LAB-29]. It is assumed this is a value from the container bar code, container RFID tag, or other container identification mechanism.
- SAC-4 Primary (parent) Container Identifier is a conditional element for [LAB-28] and [LAB-29]. It is assumed this is a value from the bar code, RFID tag, etc. for a parent container.
- The predicate for both SAC-3 and SAC-4 is that SAC-3, SAC-4, or both must be populated.
- If SAC-3 is populated, then it is considered to be the container identifier to use when matching an AWOS to the container. SAC-4 may also be populated if the container contents were obtained from a parent container.
- In [LAB-28], if only SAC-4 is populated, then SAC-10/11 (carrier/carrier location) or SAC-13/14 (tray/tray location) must be populated to identify the container/tray location. SAC-4 identifies the parent container, while the location carrier/tray location information identifies the specific container/tray location for testing.
- In [LAB-29], SAC-10/11 (carrier/carrier location) and SAC-13/14 (tray/tray location) may be populated by the Analyzer to provide additional container information to the Analyzer Manager. For example, the Analyzer Manager may have identified the container using SAC-3 in the [LAB-28] message. In the [LAB-29] message, the Analyzer may populate SAC-10/11 along with SAC-3 to inform the Analyzer Manager of the specific carrier and location that contained the container.

Other SAC Fields may be populated as well.

Refer to HL7 v2.5.1 Chapter 13, Section 13.4.3.3 for more details.

Table B.1-1 defines how the Analyzer Manager uses the SAC segment to identify a specimen originally provided in a specimen container with ID 987654 for the following scenarios, where each column in the table represents one of the scenarios (only required fields are shown):

- The specimen is contained in the Primary Container.

- The specimen is an aliquot container with barcode 987654A.
- The specimen is an aliquot container with no barcode that is in Position 3 of the Carrier with identifier 12345.
- The specimen is an aliquot in the location at row 1, column 8 (also known as location A-8) of the tray with identifier 8523.
- The specimen is an isolate (a pure colony of a microorganism) with identifier ISO123.

Table B.1-1: Specimen Identification Scenarios

SAC Fields	Primary container	Aliquot container w/barcode	Aliquot container without barcode in rack	Aliquot in tray	Isolate
SAC-3 Container Identifier	987654	987654A	-	-	ISO123
SAC-4 Primary (parent) Container Identifier	-	987654	987654	987654	987654
SAC-10 Carrier Identifier	-	-	12345	-	
SAC-11 Position in Carrier	-	-	3	-	
SAC-13 Tray Identifier	-	-	-	8523	
SAC 14 Position in Tray	-	-	-	1^8	
SAC-15 Location	-	-	-	A-8	

B.2 Device Identification

Information about the equipment used to produce an observation is included in the AWOS Status Change [LAB-29] message. Many labs compare testing from the same analyzer model/method for inter-lab quality control and proficiency testing, so the Analyzer will provide vendor name (manufacturer), Analyzer model, and unique instrument identifier (manufacturer serial number) to facilitate these activities.

Also, an Analyzer may be composed of multiple device modules, so the message will support vendor specific fields that may be used to describe a hierarchical representation of the equipment, e.g., module of an instrument, instrument consisting of modules, cluster of multiple instruments, etc.

In addition, there are also regulatory requirements related to the "Universal Device Identification", which will be supported. The Universal Device Identifier (UDI) is:

- coded according to ISO 15459-3:2006(E): Information Technology – Unique identification – Part 3: Common rules for unique identifiers (GS1, HIBCC)
- created and maintained by the manufacturer
- consisting of the concatenation of the Device Identifier (DI) and the Production Identifier (PI)
    - DI (static): manufacturer, make, model

- PI (dynamic, presence depending on risk class): serial number, lot number, expiration date

Therefore, fields for carrying the UDI and UDI type will be supported as optional fields.

OBX-18 Equipment Instance Identifier is used to carry the device information. This field is repeatable and is of type EI, which has the subcomponents Entity Identifier, Namespace, Universal ID, and Universal ID Type.

OBX-18 is repeatable in v2.5.1. The first instance is mandatory and will be used to carry the instrument model, manufacturer, and optional UDI information.

Table B.2-1: First Instance of Element OBX-18 Equipment Instance Identifier

Sub-Component	Usage	Comment
Entity Identifier	R	Model
Namespace	R	Manufacturer
Universal ID	O	UID when populated
Universal ID Type	O	ISO when populated

The second instance of OBX-18 is also mandatory and will be used to carry the serial number.

Table B.2-2: Second Instance of Element OBX-18 Equipment Instance Identifier

Sub-Component	Usage	Comment
Entity Identifier	R	Serial Number
Namespace	R	Manufacturer
Universal ID	X	
Universal ID Type	X	

The optional third and subsequent instance of OBX-18 will be used to carry vendor information about the configuration of the equipment (cluster of modules, etc.) or site specific identification.

Table B.2-3: Subsequent Instances of Element OBX-18 Equipment Instance Identifier

Sub-Component	Usage	Comment
Entity Identifier	R	Vendor/site specific
Namespace	R	Vendor/site specific
Universal ID	X	
Universal ID Type	X	

Note: The Namespace component is of data type IS, so the length is constrained.

B.3 Observation Identification

When fulfilling an AWOS, for each **Observable Entity** (test performed or computed) of the AWOS, an Analyzer may:

- Produce a single observation (referred to as an **Observation Result**)
- Produce multiple **Observation Results** with distinct Observation Identifiers (e.g., results associated with a hematology complete blood count AWOS)
- Produce multiple **Observation Results** with the same Observation Identifier (e.g., multiple organisms identified in a microbiology "organism identification" AWOS)
- Capture supplemental information as images, graphs, and raw values (referred to as a **Supplemental Result**)
- Perform multiple runs of the same test (reruns) resulting in groups of results (**Observation Run**), where each group contains related **Observation Results** and **Supplemental Results**

It is important that the Analyzer provide sufficient details in the messaging so that the Analyzer Manager can correctly distinguish results for the same observation (e.g., multiple organisms), group results from the same run, and distinguish between **Observation Results** and **Supplemental Results**. The **AWOS Fulfillment** structure looks as follows, using the HL7 message elements of brackets ([…]) to represent optional items and braces ({…}) to identify repeatable items:

-- **AWOS Fulfillment** begin
{-- **Observable Entity** (test) begin
{-- **Observation Run** begin
{-- **Observation** begin
Observation Result
[{**Supplemental Result**}]
-- **Observation** end}
-- **Observation Run** end}
-- **Observable Entity** (test) end
-- **AWOS Fulfillment** end

B.3.1 HL7 Message Elements

For each **AWOS Fulfillment**, an OBR and ORC segment pair is sent containing the following information:

- OBR-2 Placer Order Number contains the AWOS ID that associates the observation with the AWOS.
- OBR-4 Universal Service Identifier contains the identifier for the requested battery or test. See Section 2.3.1 for more details on populating this field.
- ORC-5 "Order Status" is the status of the AWOS. Its possible values are:
  - "**SC**": the AWOS is **scheduled** on the Analyzer. The specimen has not reached the Analyzer yet.
  - "**IP**": The first run of the AWOS is **in process** by the Analyzer with the specimen. There may be some results available or none.
  - **"CM"**: Completed - the Analyzer has finished its work for the AWOS. The results may have been produced or not. No additional result is expected for this AWOS. Nonetheless, a correction of some of the reportable results produced for this AWOS may still be sent by the Analyzer, in which case the AWOS status will remain "CM".
  - **"CA"**: The AWOS has been cancelled per request of the Analyzer Manager. Cancellation can happen only before the process of the AWOS has started, when the AWOS is created or scheduled.

The possible transitions of the status of an AWOS are represented on Figure C.8-1, in Section C.8 of Appendix C.

Separate OBX segments are used to carry each **Observation Result** and **Supplemental Result**:

- OBX-3 Observation Identifier identifies the **Observation Result** or **Supplemental Result**. See Section 2.3.1 for more details on populating this field. In some cases, the value of OBX-3 will be the same as OBR-4 because the identifier for the AWOS is the same as the identifier for the observation.
- OBX-4 Observation Sub-ID contains a run number when multiple runs of an AWOS are performed. Each run of an AWOS will have a unique positive integer identifier. This applies for runs reported in the same message as well as across messages. The first run will be “1”, the second run “2”, and so on. A run is either an instance of the same test performed multiple times because the Analyzer performs reruns, or it is an instance of a progress of tests (such as in Microbiology) that are performed leading to the reportable observation.

  Conditionally, it can also contain a group number and a sequence number in order to distinguish between multiple OBX segments with the same Observation ID organized under one OBR. This is a frequent case in mass spectrometry, where the result can have two identification results with different probability. Or, when the interpretation of a susceptibility result is dependent on the source site or route of administration, which the analyzer may not have.

Optionally, it can also contain a group number and/or a sequence number in order to further classify multiple OBX segments reported for the AWOS. When used in this manner, the OBX segments may have the same or different Observation IDs. For example, this can be used to identify analyzer-dependent groups of results for the AWOS. Each OBX could be assigned to a group identified by a common group numerical value, such as group “1”, group “2”, and so on. In order for the additional information to be processed, the Analyzer and Analyzer Manager vendors must agree on how the Analyzer Manager should interpret the grouping and sequence information.

- OBX-11 "Observation Result Status" is the status of an observation produced by a run of the AWOS. It is interpreted as follows:
  - "**P**" represents a **preliminary result** in a progression of results leading to the reportable result (such as the status of cultures in Microbiology).
  - "**R**" (**entered, not verified**) is used when the Analyzer has performed multiple runs for an AWOS, has selected the best run whose result is flagged "F", and is also reporting the results produced by the other runs for traceability. The results of these other runs are flagged "R" to inform the Analyzer Manager that these are not candidate to be reportable. The only candidate result is the one flagged "F".
  - "**F**" marks a **final** result of an Observation Run. The result is a candidate to be reported to the ordering provider. In case of multiple runs for an AWOS, if the results of all runs are flagged "F", all of them are candidates and the decision to choose the best one is left up to the Analyzer Manager. Conversely, if the results of all runs are flagged "R" but one flagged "F", this one is the only candidate.
  - "**C**" represents a **correction** of a result previously sent as final. The correction stays in the same Observation Run.
  - "**X**" means that the Analyzer was **not able to produce any result** for this observation in this Observation Run. There will be no results for the observation in this run. If this is the only run, this observation will have no result.

The possible transitions of the status of an observation, no matter how many runs are performed for the AWOS, are represented on Figure C.7-1, in Section C.7 of Appendix C.

The following two tables summarize these important fields that are used to identify an observation.

Table B.3.1-1: Fields Used to Identify Observation Instances

OBR-2 Placer Order Number	OBR-4 Universal Service Identifier	OBX-3 Observation Identifier	OBX-4 Observation Sub-ID
AWOS ID	The identifier for the requested battery or test	Unique ID for each observation result. In some cases will be the same as OBR-4	Positive integer for the Run Number. Optionally, group number and sequence number.

Table B.3.1-2: Possible statuses of an observation in a run of an AWOS

Status of the AWOS (ORC-5)	Possible observation result statuses (OBX-11)
SC: Scheduled	No observation available for this AWOS, in any run. No OBX provided by the Analyzer.
CA: Cancelled	
IP: In process	No observation, or some observations with any of these statuses: P – Preliminary result. R – for a result that is not a candidate to be reported upstream. F – Final, for a result candidate to be reported upstream. C – Correction of a result in the same reportable run. X – Result could not be obtained for this run of the observation
CM: Completed	R – for a result that is not a candidate to be reported upstream. F – Final, for a result candidate to be reported upstream. C – Correction of a final result in the same reportable run. X – Result could not be obtained for this run of the observation

Notes:

The cancellation of an AWOS can only happen before the process has started. In other words an Analyzer accepts to cancel an AWOS only when its status is "SC".

There cannot be any preliminary result in a completed (“CM”) AWOS.

A correction of a final observation (OBX-11 = "C") can still be sent by the Analyzer for an AWOS that was previously declared as completed (ORC-5 = "CM").

B.3.2 Related Observations of a Run

No restrictions are placed on the **Observation Results** or **Supplemental Results** in a message, except as follows.

Some **Observation Runs** include related observations of more than one data type. A common example is an **Observation** that includes a quantitative result and a qualitative result. In this case, the **Observation** is sent in more than one OBX segment. For example, one segment of numeric (NM) data type contains the quantitative value and another segment of coded (CE) data type contains the qualitative result.

When more than one OBX segment is used to send related observations, different codes must be used in OBX-3 for each observation so that OBX-3 and OBX-4 are unique across OBXs. The unique OBX-3 codes may be preexisting, or they can be generated in a number of ways:

- LOINC already supports unique codes for many observations so these can be used as-is.
- Vendors can append a suffix for vendor defined codes and discuss these values in their implementation guide. This effectively creates a unique observation identifier.
  - Suffixes can be any alpha-numeric sequence 75.C, 75.CONC, 75-2, etc.
  - Any separator can be used except those already used as HL7 delimiters.
  - Specific values such as “I”, “A” can be assigned to qualitative observations to establish the type of observation (e.g., interpretation, abnormality).
  - Rolling numbers such as 1, 2, and 3 may also be used to differentiate observations.

Although the above example used an OBX segment of data type CE to transmit a qualitative result, the OBX-8 field is strongly recommended for interpretations and flags rather than using a separate OBX segment. By using OBX-8, a vendor is following a standard convention for reporting interpretations and also using a standard vocabulary for the interpretation. The LAW Profile recommends the subset of codes from HL7 Table 0078 pre-adopted from HL7 v2.8.2 that is shown in Table C.7-16 in Section C.7. However, an Analyzer may extend the set with codes from a vendor-defined coding system.

Qualitative results can also be sent in a separate OBX as a string. However, using an OBX with the ST data type to report an interpretation requires the Analyzer Manager and the Analyzer to agree on how to interpret the code. When using a string, a non-standard vocabulary is used thus additional coordination between vendors is necessary.

Supplemental Results, such as raw result values, can also be sent as related observations of a run, and should be reported following the guidance in Section B.3.6 Transmitting Supplemental Results. Each **Supplemental Result** requires a unique OBX-3 value, and the techniques described above can be used for distinguishing these results as well. The LAW alternate identifier information in Section 2.3.1provides guidance on establishing the supplemental result type that is standard across vendors.

When sending related observations of a run, the value of OBX-4, OBX-11, OBX-16, OBX-18, and OBX-19 should be the same for all OBX segments. The observations are all part of the same run, and therefore these values should be consistent for all of the related observations.

B.3.3 Transmitting Observations

Each **Observation Result** or **Supplemental Result** is transmitted in a separate OBX segment. The ORC-5, OBX-4, and OBX-11 segment fields are used to identify the AWOS status, group results from the same run, and provide the status of an observation. Table B.3.3-1 describes the contents of these fields based on scenarios that may occur on an Analyzer. For this discussion, it is assumed that the Analyzer is reporting only one type of observation for the AWOS (i.e., one OBX segment per run).

Table B.3.3-1: Examples of Order and Result Status values

Situation	ORC-5 Order Status	OBX-4 Observation Sub-ID	OBX-11 Result status
The Analyzer reports the result of a single run. A value could not be obtained for the observation. The Analyzer considers the AWOS to be complete.	CM	1	X
The Analyzer reports the result of a single run. There is no intent to perform additional runs. The Analyzer considers the AWOS to be complete.	CM	1	F
The Analyzer is sending the observations in multiple messages. Observations '1' to 'n-1' are marked 'R' as not candidate for reporting because the Analyzer has made some determination that they should not be reported and it intends to perform additional runs. The AWOS is still in process on the Analyzer until the result of run 'n' is sent. The Analyzer marks the result in the last run as the only candidate reportable result.	IP CM	1..(n-1) n	R F
The current observation is part of a set of multiple runs and the analyzer considers all of them as candidates for reporting, leaving the choice up to the Analyzer Manager. All runs are reported in the same message. The AWOS is completed on the Analyzer.	CM	1..n	F
The current observation is part of a set of multiple runs for which the Analyzer selects one of the runs as the best candidate. Results of all runs are sent in the same message. The AWOS is completed on the Analyzer.	CM	m 1..n – {m}	F for the results of the selected run R for the results of the other runs
The Analyzer is correcting one of the results of a run previously sent as the reportable one for this test.	CM	The distinct result identifier of the OBX	C

B.3.4 Sample Messages for Single and Multiple Runs

The following is a sample message showing the transmission of a single run with multiple **Observation Results**:

```
MSH|...
PID|...
OBR||111111||85027^Hemogram and platelet count|...
ORC|SC||||CM||||20120530182101
OBX|1|NM|11156-7^LEUKOCYTES^LN|1|8.2|10*3/mm3^^UCUM|||||F|||20120530182101
OBX|2|NM|11273-0^ERYTHROCYTES^LN|1|4.08|10*3/mm3^^UCUM|||||F|||20120530182101
```

The following is a sample message showing the results of a run, but the results are not considered technically valid. The Analyzer will perform additional runs.


```
MSH|...
PID|...
OBR||432156||85027^Hemogram and platelet count|...
ORC|SC||||IP||||20120530182101
OBX|1|NM|11156-7^LEUKOCYTES^LN|1|8.2|10*3/mm3^^UCUM|||||R|||20120530182101
OBX|2|NM|11273-0^ERYTHROCYTES^LN|1|4.08|10*3/mm3^^UCUM|||||R|||20120530182101
OBX|3|NM|20509-6^HEMOGLOBIN^LN|1|13.4|10*3/mm3^^UCUM|||||R|||20120530182101
OBX|4|NM|20570-8^HEMATOCRIT^LN|1|39.7|10*3/mm3^^UCUM|||||R|||20120530182101
```

The following is the subsequent message carrying the results of the technically valid run:

```
MSH|...
PID|...
OBR||432156||85027^Hemogram and platelet count|...
ORC|SC||||CM||||20120530184001
OBX|1|NM|11156-7^LEUKOCYTES^LN|2|8.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|2|NM|11273-0^ERYTHROCYTES^LN|2|4.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|3|NM|20509-6^HEMOGLOBIN^LN|2|13.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|2|39.9|10*3/mm3^^UCUM|||||F|||20120530184001
```

The message below carries the results of two runs, with one run selected as technically valid by
1465 the Analyzer.

```
MSH|...
PID|...
OBR||123456||85027^Hemogram and platelet count|...
ORC|SC||||CM||||20120530182101
OBX|1|NM|20509-6^HEMOGLOBIN^LN|1|13.4|10*3/mm3^^UCUM|||||R|||20120530182101
OBX|2|NM|20570-8^HEMATOCRIT^LN|1|39.7|10*3/mm3^^UCUM|||||R|||20120530182101
OBX|3|NM|20509-6^HEMOGLOBIN^LN|2|13.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|2|39.9|10*3/mm3^^UCUM|||||F|||20120530184001
```

The message below carries the results of two runs, and the Analyzer considers all results to be technically valid.

```
MSH|...
PID|...
OBR||987654||85027^Hemogram and platelet count|...
```



```
ORC|SC||||CM||||20120530182101
OBX|1|NM|20509-6^HEMOGLOBIN^LN|1|13.4|10*3/mm3^^UCUM|||||F|||20120530182101
OBX|2|NM|20570-8^HEMATOCRIT^LN|1|39.7|10*3/mm3^^UCUM|||||F|||20120530182101
OBX|3|NM|20509-6^HEMOGLOBIN^LN|2|13.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|2|39.9|10*3/mm3^^UCUM|||||F|||20120530184001
```

The message below carries the results of two runs, the results have been grouped, and the Analyzer considers all results to be technically valid.

```
MSH|...
PID|...
OBR||432156||85027^Hemogram and platelet count|...
ORC|SC||||IP||||20120530182101
OBX|1|NM|11156-7^LEUKOCYTES^LN|1^1|8.2|10*3/mm3^^UCUM|||||F|||20120530182101
OBX|2|NM|11273-0^ERYTHROCYTES^LN|1^1|4.08|10*3/mm3^^UCUM|||||F|||20120530182101
OBX|3|NM|20509-6^HEMOGLOBIN^LN|1^2|13.4|10*3/mm3^^UCUM|||||F|||20120530182101
OBX|4|NM|20570-8^HEMATOCRIT^LN|1^2|39.7|10*3/mm3^^UCUM|||||F|||20120530182101
OBX|1|NM|11156-7^LEUKOCYTES^LN|2^1|8.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|2|NM|11273-0^ERYTHROCYTES^LN|2^1|4.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|3|NM|20509-6^HEMOGLOBIN^LN|2^2|13.9|10*3/mm3^^UCUM|||||F|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|2^2|39.9|10*3/mm3^^UCUM|||||F|||20120530184001
```

The final example shows a subsequent message carrying the correction to the previously reported observations for AWOS 432156 from the example above. Note that only the values to be corrected are transmitted because each observation is uniquely identified by the values of OBX-3 and OBX-4. The message is interpreted as the values for run number two (specified by OBX-4) of the observations specified by each OBX-3 are to be corrected.

```
MSH|...
PID|...
OBR||432156||85027^Hemogram and platelet count|...
ORC|SC||||CM||||20120530184001
OBX|1|NM|11156-7^LEUKOCYTES^LN|2|8.5|10*3/mm3^^UCUM|||||C|||20120530184001
OBX|2|NM|20509-6^HEMOGLOBIN^LN|2|13.5|10*3/mm3^^UCUM|||||C|||20120530184001
```


B.3.5 Sample Messages for Microbiology with Two Analyzers

In the following example two Analyzers are used to perform the tests on an isolate. One is performing the microorganism identification, and the other one is performing the antibiotic susceptibility testing (AST). Both of them report their observations for the same isolate identified ISO123. The original blood specimen collected from the patient was identified 012345.

The AST AWOS (AW1) and the microorganism identification AWOS (AW2) have been ordered separately by the Analyzer Manager.

Results of the microorganism identification

```
MSH|^~\&|VITEK-MS|MICRO-AREA|AM|MICRO-AREA|201307081558||OUL^R22^OUL_R22|...
PID|...
PV1||I|...
SPM|1|ISO123^AM1|012345|BLDV|...
SAC|1||ISO123|012345
OBR|1|AW2||ID^microorganism identification panel^BMX|...
ORC|SC|||REQ001|CM||||20130808112844|...
OBX|1|CE|11475-1^MICROORGANISM IDENTIFIED^LN|1|3092008^Staphylococcus aureus^SCT
|||A|95.0||F|||20130708181136||PHYS1||Vitek-MS^bioMerieux^0000139C426D
OBX|2|CE|564-5^COLONY COUNT^LN|1|MO^Moderate^99VitekMS|||A|||F|||20130708181136|...
```

Results of the antibiotic susceptibility testing

```
MSH|^~\&|VITEK2|MICRO-AREA|AM|AM|201307081558||OUL^R22^OUL_R22|...
PID|...
PV1||I|...
SPM|1|ISO123^AM1|012345|BLDV|...
SAC|1||ISO123|012345
OBR|1|AW1||ID^AST panel^BMX|...
ORC|SC|||REQ001|CM||||20130808112844|...
OBX|1|NM|28-1^Ampicillin^LN|1|32|ug/mL^^UCUM||R|||F|||20130708181136|...
OBX|2|NM|20-8^Amoxicillin+Clavulanate^LN|1|2|ug/mL^^UCUM||S|||F|||20130708181136|...
OBX|3|NM|383-0^Oxacilline^LN|1|15|ug/mL^^UCUM||R|||F|||20130708181136|...
OBX|4|NM|375-6^Ofloxacine^LN|1|8|ug/mL^^UCUM||R|||F|||20130708181136|...
...
```


B.3.6 Transmitting Supplemental Results

When transmitting **Supplemental Results,** LAW codes are provided as part of the identification information along with a vendor-specific code in OBX-3 Observation Identifier. The LAW code allows the Analyzer Manager to recognize the result as supplemental information. The processing of **Supplemental Results** is out of the scope of this profile. In order for the information to be processed, the Analyzer and Analyzer Manager vendors must agree on how the Analyzer Manager should interpret the information. The Analyzer Manager may choose to ignore any **Supplemental Result** it does not understand. See Section C.7 in Appendix C for more details on field OBX-3.

The following is an example of how a hematology plot might be identified in OBX-3. The LAW code identifies the result as a supplemental graph, and the vendor code identifies the observation as a WBC plot. Once the Analyzer Manager identifies the results as a **Supplemental Result**, it is now free to process and render the information based on its knowledge of the vendor-specific information.

Table B.3.6-1: Example Plot Coding

Component/Sub-Component	Value	Comment
Identifier (ST)	HEMWBC	Vendor-defined code for WBC plot
Text (ST)	WBC_PARAMETERS	Vendor-defined name for WBC Plot
Name of Coding System (ID)	VENDOR	Vendor-defined coding system identifier
Alternate Identifier (ST)	S_GRAPH	LAW Code
Alternate Text (ST)	Supplemental Graph	LAW Name
Name of Alternate Coding System (ID)	IHELAW	IHE LAW

The following sections describe the type of **Supplemental Results** covered by this profile.

B.3.7 Images as Supplemental Results

An image should be transmitted as encapsulated data, or a reference pointer to the image should be transmitted. The vendor-specific code in OBX-3 Observation Identifier should be used by the Analyzer Manager to understand how to interpret the image. The LAW code of "S_IMAGE" should be used in OBX-3.4 Alternate Identifier. See Section C.7 for additional details on field OBX-3.

- For small and medium sized images, use the HL7 "Encapsulated Data (ED)" data type with MIME content for OBX-2. The graphic may be of reduced resolution, e.g., a thumbnail to reduce the transmission throughput and storage requirements.
- For large images, use the HL7 "Reference Pointer (RP)" data type for OBX-2. It is suggested that a Uniform Resource Identifier (URI) for an HTTP(S) or FTP(S) anonymous access be used. The receiver should only have read access, and the sender is

responsible for the file management (e.g., deletion after 24 hours or any other defined retention time).

An image may be associated with a single **Observation Result**, or it may be associated with multiple **Observation Results**. Therefore, OBX-8, OBX-11, OBX-16, OBX-18, and OBX-19 should be populated in a manner that is consistent with the **Observation Result(s)** it represents.

B.3.8 Graphs as Supplemental Results

A graph could be transmitted as an array of points to plot, encapsulated data, or even structured text. For example, the HL7 "Numeric Array (NA)" data type may be used to send a series of values representing coordinates of individual points of the graphic. The NA data type may represent multidimensional arrays, e.g., X-Y or X-Y-Z plots. The vendor-specific code in OBX-3 Observation Identifier should be used by the Analyzer Manager to understand how to interpret the graph points. The LAW code of "S_GRAPH" should be used in OBX-3.4 Alternate Identifier. See Section C.7 for additional details on field OBX-3.

A graph may be associated with a single **Observation Result**, or it may be associated with multiple **Observation Results**. Therefore, OBX-8, OBX-11, OBX-16, OBX-18, and OBX-19 should be populated in a manner that is consistent with the **Observation Result(s)** it represents.

B.3.9 Raw Values as Supplemental Results

The "raw values" associated with an **Observation Result** are the measurement values used to calculate the "cooked value", e.g., photometer absorbance values for various wave lengths used for calculation of the concentration based on a calibration curve. The vendor-specific code in OBX-3 Observation Identifier should be used by the Analyzer Manager to understand how to interpret the raw values. The LAW code of "S_RAW" should be used in OBX-3.4 Alternate Identifier. See Section C.7 for additional details on field OBX-3.

When transmitting "raw values", the Analyzer sends OBX segment(s) that follow the OBX segment containing the "cooked" value. The raw values are associated with the cooked values, so the OBX segments have the same values for OBX-8, OBX-11, OBX-16, OBX-18, and OBX-19.

Raw values can be sent as a single raw value, a series of values/series of vectors, or structured text with similar semantics.

- For a single raw value, use the HL7 "Numeric (NM)" data type for OBX-2.
- For a series of values / series of vectors of values, use the HL7 "Numeric Array (NA)" data type for OBX-2 so that the values can be transmitted using multidimensional arrays.
- For structured text, use the HL7 "String (ST)" or "Text Data (TX)" data type for OBX-2 to send structured representations such as XML or JSON (see XML examples below). Using notations such as these instead of HL7 delimiters permits explicit description of the structure and avoids the "unintended" introduction of new data types potentially leading to conformance problems. Text needing to use any of the encoding characters

defined in MSH-2 Encoding Characters must use HL7 escape sequences as defined in HL7 v2.5.1: chapter 2 (2.7.1 Formatting Codes).

The following examples show how to use multidimensional arrays or structured text (XML) to send raw values. Please note that the structured text examples have been formatted for ease of reading. Extra whites space, include new lines, would not be in the transmitted text.

Table B.3.9-1: Examples of Raw Values

Raw value example	XML notation (OBX-2 = ST or TX)	Delimiter notation (OBX-2 = NA)
Structure raw value: Calibrator – Linear Curve Parameters	<DataTable Description="Linear CurveParameters"> <tr pos="1" Description="Absorbance 1"> <td pos="1">0.3456</td> </tr> <tr pos="2" Description="K Factor"> <td pos="1">1.6543</td> </tr> </DataTable>	0.3456^1.6543
Data Series raw value: Signal data	<DataTable Description="Raw data" > <tr Description="RawResult 1 - WaveLength 340" pos="1"> <td pos="1">0.1</td> <td pos="2">0.2</td> <td pos="3">0.3</td> <td pos="4">0.4</td> <td pos="5">0.1</td> <td pos="6">0.1</td> <td pos="7">0.1</td> <td pos="8">0.1</td> </tr> <tr Description="RawResult 1 - WaveLength 376" pos="2"> <td pos="1">0.1</td> <td pos="2">0.2</td> <td pos="3">0.3</td>	0.1^0.2^0.3^0.4^0.1^0.1^0.1^0.1 ~0.1^0.2^0.3^0.4^0.1^0.1^0.1^0.1 ~0.1^0.2^0.3^0.4^0.1^0.1^0.1^0.1 ~0.1^0.2^0.3^0.4^0.1^0.1^0.1^0.1 ~0.1^0.2^0.3^0.4^0.1^0.1^0.1^0.1 ~0.1^0.2^0.3^0.4^0.1^0.1^0.1^0.1

Raw value example	XML notation (OBX-2 = ST or TX)	Delimiter notation (OBX-2 = NA)
	<td pos="4">0.4</td> <td pos="5">0.1</td> <td pos="6">0.1</td> <td pos="7">0.1</td> <td pos="8">0.1</td> </tr> <tr Description="RawResult 1 - WaveLength 800" pos="12"> <td pos="1">0.1</td> <td pos="2">0.2</td> <td pos="3">0.3</td> <td pos="4">0.4</td> <td pos="5">0.1</td> <td pos="6">0.1</td> <td pos="7">0.1</td> <td pos="8">0.1</td> </tr> <tr Description="RawResult 2 - WaveLength 340" pos="13"> <td pos="1">0.1</td> <td pos="2">0.2</td> <td pos="3">0.3</td> <td pos="4">0.4</td> <td pos="5">0.1</td> <td pos="6">0.1</td> <td pos="7">0.1</td> <td pos="8">0.1</td> </tr> <tr Description="RawResult 2 - WaveLength 376" pos="14"> <td pos="1">0.1</td> <td pos="2">0.2</td> <td pos="3">0.3</td>	

Raw value example	XML notation (OBX-2 = ST or TX)	Delimiter notation (OBX-2 = NA)
	<td pos="4">0.4</td> <td pos="5">0.1</td> <td pos="6">0.1</td> <td pos="7">0.1</td> <td pos="8">0.1</td> </tr> <tr Description="RawResult 2 - WaveLength 800 " pos="24"> <td pos="1">0.1</td> <td pos="2">0.2</td> <td pos="3">0.3</td> <td pos="4">0.4</td> <td pos="5">0.1</td> <td pos="6">0.1</td> <td pos="7">0.1</td> <td pos="8">0.1</td> </tr> </DataTable>	

B.3.10 Vendor Specific Supplemental Results

For vendor-specific **Supplemental Results** not addressed by this profile, any allowable HL7 data type for OBX-2 may be used. A vendor-specific code in OBX-3 Observation Identifier should be populated with a vendor-specific code, and the LAW code of "S_OTHER" should be used to populate OBX-3.4 Alternate Identifier. In order for the Analyzer Manager to process this type of result, the Analyzer will need to provide the Analyzer Manager vendor with additional details about the result. See Section C.7 in Appendix C for additional details on field OBX-3.

B.3.11 Retransmitting Results

The usage of the OBR and OBX segments and fields allow an Analyzer Manager to identify results that have been retransmitted. For results associated with orders generated by the Analyzer Manager, the OBR-2 Placer Order Number (contains the AWOS ID), OBR-4 Universal Service Identifier (requested order), OBX-3 Observation Identifier (result identifier), and OBX-4 Observation Sub-ID (run number) fields can be used to clearly identify a result that has already been received. For results associated with orders generated at the Analyzer, no AWOS ID is

provided in OBR-2 but additional fields such as SAC-3 Container Identifier (sample identification) and ORC-8 Parent (parent AWOS IDs for a reflex) can also be used.

B.3.12 Observation Result Stored Externally

An AWOS may create large volumes of results that are not appropriate for return through the OUL message, e.g., whole slide images, genetic sequencing results, or flow cytometry list mode data. This data may be stored by the Analyzer in a separate or specialized storage system that provides temporary or persistent data access for follow-on AWOS or other applications.

As the primary **Observation Result**, the OBX segment will use the RP Data Type to encode a pointer to the stored results.

The Analyzer indicates whether the results are stored in a persistent repository by setting the OBR-49 value to “RE” (see Section C.6 in Appendix C). If OBR-49 is absent, or does not have the value “RE”, the storage is temporary, and it is the responsibility of the Analyzer Manager to access the results prior to the expiration of the locally-defined retention time.

If the storage is temporary, it is suggested that a Uniform Resource Identifier (URI) for an HTTP(S) or FTP(S) anonymous access be used in the OBX-5; the connection may use node authentication in accordance with the IHE IT Infrastructure Audit Trail and Node Authentication Profile.

In addition to the primary **Observation Result**, the message may include **Supplemental Results**, including thumbnail images or graphical representations.

B.4 Reflex Initiated at the Analyzer

A reflex is a test ordered based on the evaluation of one or more observation results for one or more AWOS (see PaLM TF-1: 5.2.9). If the Analyzer decides a reflex is necessary, then details about the reflex must be transmitted to the Analyzer Manager. The following segment fields are used to provide information about the reflex observation result.

- OBR-2 Placer Order Number is set to NULL ("") because the reflex is initiated at the Analyzer and thus the AWOS ID does not exist.
- OBR-11 Specimen Action Code is set to "G", to indicate the observation is a reflex test. This is the only situation where field OBR-11 is used in the LAW Profile.
- ORC-8 Parent carries the parent-child relationship between the reflex and the parent AWOS(s). The field is repeatable and is populated with the parent AWOS ID(s).

To determine if a reflex is needed, Analyzers may use the ORC-4 Placer Group Number in AWOS Broadcast [LAB-28] to identify Work Order related (parent) AWOSs to evaluate. In the AWOS Status Change [LAB-29] message containing the reflex observation, these Analyzers may also populate ORC-4 to clearly identify that the reflex is related to the Work Order.

B.5 Message Identification and Acknowledgement

The connection between the Analyzer and Analyzer Manager is assumed to be a simple point-to-point connection with no routing applications managing the messages between the two systems. Therefore, the MSH-3 through MSH-6 fields are considered laboratory specific values, and their usefulness will vary from laboratory to laboratory. The Analyzer and Analyzer manager should provide the capability for the laboratory to define values for these fields. When constructing a triggered message, the sending application will use the laboratory-defined values. If no values are configured then the field will be empty.

Table B.5-1: MSH-3 to MSH-6 Population for Triggered Message

Field	Value
MSH-3 Sending Application (HD)	Laboratory defined value
MSH-4 Sending Facility (HD)	Laboratory defined value
MSH-5 Receiving Application (HD)	Laboratory defined value
MSH-6 Receiving Facility (HD)	Laboratory defined value

When generating an acknowledgement message, the sending application will use the values provided in the in-bound message. A receiving actor will not check the inbound values against the configured values. The configured values are only used to populate outbound messages.

Table B.5-2: MSH-3 to MSH-6 Population for Acknowledgement Message

Field	Value
MSH-3 Sending Application (HD)	MSH-5 from triggered message
MSH-4 Sending Facility (HD)	MSH-6 from triggered message
MSH-5 Receiving Application (HD)	MSH-3 from triggered message
MSH-6 Receiving Facility (HD)	MSH-4 from triggered message

The sending application SHALL populate field MSH-15 with value "NE" and field MSH-16 with value "AL", thus instructing the receiving application to send an "application acknowledgement" (message specific or general) in all cases (communication error, unavailability of the safe storage for the message, application acceptance of the message, etc.). In that way, the desired behavior of the receiving application is the same as in the original acknowledgement mode.

As stated by Section E.3.2.3 “Acknowledgement Modes” in Appendix E to the *IHE Technical Frameworks General Introduction* published on this page, a receiving application SHALL send back an application acknowledgement with MSA-1 valued to one of the following codes:

- AA: The message has been accepted and integrated.

- AE: Application error. A message error occurs when malformed HL7 messages are received. Examples include missing or out of order segments, incorrect data types, or unsupported table values. It SHALL not be sent again without correcting the error.
- AR: Application rejection. The message has been rejected by the receiving application due to an invalid MSH segment or inconsistent message content. It SHALL not be sent again without correcting the content.

Implementers of this profile SHALL read Appendix E to the *IHE Technical Frameworks General Introduction* published on this page, and particularly Section E.3.2.3 to check the behavior rules for acknowledgement, and the rules to build the acknowledgement message and its MSH, MSA and ERR segments, in error situations.

See Section C.4 in Appendix C" for additional details on the usage of the fields in the MSH segment.

B.6 MLLP Connections

The LAW Profile requires the use of the network connections defined in PaLM TF-2x: 2.2.4. As described in the section, two network connections are required to implement communication supporting trigger events for both actors. Therefore, two network connections are required to implement bi-directional communication supporting AWOS Transfer (see Sections 5.1 and 5.2 of PaLM TF-1) for more details about LAW Profile transactions and options. One network connection will support the Query for AWOS [LAB-27] and AWOS Status Change [LAB-29] transactions from the Analyzer, while the other network connection will support the AWOS Broadcast [LAB-28] transaction from the Analyzer Manager.

In addition, it is up to the sending application to decide if a persistent or short short-lived network connection will be used. An actor application is allowed to open a network connection, send a transaction, receive an acknowledgement, and then close the connection. When using a short-lived connection, an actor application does not establish a connection with the other actor application until it has a transaction to send. Therefore, an application SHALL not assume all network connections will be established prior to sending messages. An application should listen for an inbound connection, and then either establish the outbound connection immediately if a persistent outbound connection will be used or wait until it has a message to send if short-lived outbound connections will be used. Finally, an application using persistent outbound connection must handle cases where the connection is closed by the receiving application, as discussed in Section E.3.2.1 of Appendix E to the *IHE Technical Frameworks General Introduction* published on this page.

As an example, consider the scenario where an Analyzer and Analyzer Manager exchange [LAB-27], [LAB-28], and [LAB-29] transactions and short-lived network connections are used by the applications. Both the Analyzer and Analyzer Manager applications SHALL listen for inbound connections upon application startup. When a specimen container arrives at the Analyzer it will open an outbound network connection to the Analyzer Manager, send the Query for AWOS, receive the message acknowledgement from the Analyzer Manager on the same

connection, and close the connection. After some period of time, the Analyzer Manager will open an outbound network connection to the Analyzer, send the AWOS Broadcast, receive the message acknowledgement, and close the connection. Finally, once the observation results are available the Analyzer will open another outbound network connection, send the AWOS Status Change, receive the message acknowledgement, and close the connection.

The same behavior can be implemented by either actor application using persistent network connections as well. An application using persistent connection establishes the outbound network connection at application startup, does not close the connection after sending a message, and monitors the connection in case it is closed.

B.7 Error Handling

The LAW Profile uses Application Acknowledgements to address message and application level errors that occur when messages are exchanged between the Analyzer and Analyzer Manager. The HL7 Enhanced Acknowledgment Mode allows a receiving application to not accept a message because the message contains an error or to reject the contents of the message for processing. In addition, the ORL^O34 Laboratory Order Response supports accepting and rejecting individual AWOS Requests, while the RSP^K11 Query Response supports accepting or rejecting a query request. The use of these mechanisms by the LAW Profile is discussed below.

The only guidance provided on application behavior when a message error is detected, a message is rejected, or request is rejected is the receiving application will capture the situation in a log and/or notify the user in some manner. In addition, it is also expected that the application will support connection/message recovery logic through the use of retries, user intervention, etc. when appropriate.

B.7.1 Receive a Malformed Message

A message error occurs when malformed HL7 messages are received. Examples include missing or out of order segments, incorrect data types, or unsupported table values.

If a receiving application detects an error in a trigger message, an **Application Acknowledgement: Error** is reported in the acknowledgement response by setting MSA-1 to "AE". The application will report the location(s) causing the error in the ERR segment.

If an error is detected in an Application Acknowledgement message, the receiving application SHALL ignore the acknowledgement and assume the transaction has failed.

B.7.2 Receive a Message with Incorrect Message Control Content

The HL7 uses message control information in the exchanged messages. See HL7 v2.5.1: chapter 2, Section 2.9 for additional details. Examples of an invalid content include an unsupported MSH-9 Message Type, MSH-12 Version ID, or MSH-21 Message Profile Identifier. Another example would be the receipt of an acknowledgement and MSA-2 does not match the value of MSH-10 from the originating trigger message.

If a receiving application detects invalid message control content in a trigger message, an **Application Acknowledgement: Reject** is reported by setting MSA-1 to "AR". The application will report the location(s) causing the message to be rejected in the ERR segment.

If a receiving application detects invalid message control content in an Application Acknowledgement, it SHALL ignore the acknowledgement and assume the transaction has failed.

B.7.3 Reject an AWOS Request

After receiving an AWOS Broadcast message containing several AWOS requests, an Analyzer might reject an individual AWOS Request. The Analyzer may not be able to support the specific request temporarily due to inventory configuration, or permanently because it is not a request (test) the Analyzer can perform. These situations may occur as part of the normal laboratory workflow, although they should occur infrequently.

In addition, an AWOS Broadcast message may contain inconsistent information such as:

- A request using an unsupported specimen type
- a request to cancel an unknown AWOS ID
- the receipt of an AWOS ID that has already been used

Although these situations indicate possible defects in the Analyzer Manager, these AWOS Requests will also be individually accepted or rejected so that valid requests may be processed.

The ORL^O34 Laboratory Order Response will be used to individually accept/reject AWOS Requests. MSA-1 will be set to **Application Acknowledgement: Accept** to indicate the OML^O33 message was accepted. The ORC-1 Order Control field will be used by the Analyzer to indicate if each AWOS Request has been accepted or rejected.

B.7.4 Receive a Negative Query Response for an Unknown Query

An AWOS Broadcast message containing a Negative Query Response for an unrecognized specimen is considered an unexpected situation. This situation indicates defects in the Analyzer Manager software, so the entire message will be rejected. For more details see Section 3.28.4.1.3.

The ORL^O34 Laboratory Order Response will be used to report an **Application Acknowledgement: Reject** by setting MSA-1 to "AR". The application will report the specimen information causing the message to be rejected in the ERR segment.

B.7.5 Receive an AWOS Request Acknowledgement with Inconsistent Content

An example is a response for an AWOS ID that was not in the AWOS Request.

If the Analyzer Manager detects inconsistent data in an ORL^O34 Laboratory Order Response, the Analyzer Manager will ignore the acknowledgement and assume the transaction has failed.

B.7.6 Receive an AWOS Status Change with Inconsistent Content

The Analyzer Manager must check that the AWOS Status Change content is consistent. For example, the values in the SPM, SAC, and OBR segments should be consistent with an OML^O33 message the caused the OUL^R22 message to be sent. If the OBR-4 Universal Service ID in OUL^R22 does not match the value sent in OML^O33, then the Status Change message should be rejected. Another example is if the AWOS ID in the OUL^R22 message is not known by the Analyzer Manager. These are unexpected situations that should not occur as part of the normal laboratory workflow.

The General Acknowledgement response for the OUL^R22 message does not support accepting or rejecting individual AWOS status changes, so the entire message must be rejected. Therefore, if the Analyzer Manager detects an OUL^R22 with inconsistent content, the Analyzer Manager SHALL report an **Application Acknowledgement: Reject** by setting MSA-1 to "AR". The Analyzer Manager will report the inconsistent location(s) in the ERR segment.

B.7.7 Reject a Query

Although very unlikely, it may be necessary for an Analyzer Manager to reject a query. For reasons other than a message error (covered above) or message rejection due to invalid message header (covered above), the Analyzer Manager will make use of the QAK-2 Query Response Status to indicate the query is rejected or an error occurred when processing the request.

B.7.8 Receive a Query Acknowledgement with Inconsistent Content

If the Analyzer Manager detects inconsistent data in an RSP^K11 AWOS Query Acknowledgment, the Analyzer Manager will ignore the acknowledgement and assume the transaction has failed.

Examples include the values in QAK-1 and QPD-2 do not match, or the value in the received QAK-1 does not match the value sent in QPD-2 of the QBP^Q11 message.

B.7.9 Management of Patient Data

The Analyzer Manager is considered the source of truth for all patient data.

If an Analyzer receives an AWOS Broadcast [LAB-28] message containing inconsistent patient data for a known patient based on the identifier in PID-3 Patient Identifier List, then it must assume that the Analyzer Manager has updated the patient information and it should update its local copy. The Analyzer may want to notify the operator that the patient data has been updated.

The Analyzer Manager may not retransmit an AWOS request to correct patient data because the Analyzer will individually reject an AWOS request that uses a previously seen AWOS ID. When the Analyzer Manager needs to correct patient data associated with AWOS request, the Analyzer Manager must cancel the original AWOS request and send the Analyzer a new AWOS request with the correct patient data.

The PID segment is used by the Analyzer to provide applicable patient demographic information associated with the observation, and is not intended to update the patient record. If an Analyzer Manager receives an AWOS Status Change [LAB-29] message containing inconsistent patient data for the AWOS, it should ignore the information sent by the Analyzer. The Analyzer Manager may want to notify the operator that inconsistent patient data has been received from the Analyzer.

B.7.10 Receive Unknown Message Content

Data may be received that is not even in the form of an HL7 message. For example, if significant communication errors have occurred the entire message may be garbled. Or, possibly a connection was made to a non-HL7 peer. In an extreme case, it may be that a malicious peer is attempting to comprise the receiver. In this instance, the receiving system should ignore the transmission and manage the receipt of the data in a manner that does not comprise the application (e.g., causes an internal software buffer over run).

B.8 Ordering multiple replicates of the same battery or test

The LAW Profile intentionally supports only one approach of ordering a particular number of runs for a given battery or test — the Analyzer Manager SHALL submit an individual AWOS for each run. From the Analyzer's point of view, all those orders are independent from each other; the Analyzer Manager may consider grouping them explicitly using ORC 4 "Placer Group Number".

As opposed to specifying the number of runs as a parameter of a single common test order, submitting multiple orders provides higher flexibility and control. In particular, each such order (AWOS) can be individually accepted, rejected, or cancelled, can have its own state, preliminary and supplemental results, human-readable comments, etc.

Moreover, the presence of only one unified approach for ordering test runs simplifies the development of both Analyzer and Analyzer Manager Actors.

Appendix C – Common HL7 Message Segments for LAW Transactions

The following segment definitions supersede for LAW Transactions the common segment definitions from PaLM TF-2x: Appendix C.

Cardinalities and usages are defined to clarify differences when segments are sent by the Analyzer Manager versus the Analyzer.

C.1 ERR Segment

HL7 v2.5.1: chapter 2 (2.15.5 ERR - Error Segment).

The ERR segment is used to add error information to acknowledgment messages. This segment is sent only when the accompanying MSA segment, MSA-1 acknowledgement code is 'AR' or 'AE'. For additional information, see Section E.3.2.3 "Acknowledgement Modes" in Appendix E to the *IHE Technical Frameworks General Introduction* published on this page.

Table C.1-1: ERR Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
2	18	ERL	RE	RE	[0..*]		01812	Error Location
3	705	CWE	M	M	[1..1]	0357	01813	HL7 Error Code
4	2	ID	M	M	[1..1]	0516	01814	Severity
5	705	CWE	RE	RE.AN	[0..1]		01815	Application Error Code
8	250#	TX	RE	RE.AN	[0..1]		01818	User Message

ERR-2 Error Location (ERL), required if available.

Identifies the location in a message related to the detected error. If multiple repetitions are present, the error results from the values in a combination of places.

The field should be provided when the error is directly related to a particular HL7 segment, field, component, or sub-component. Examples include:

- a missing value
- a wrong value
- a value which references an unknown entity (e.g., unknown patient ID)
- a value with the wrong cardinality
- a value which is not consistent with other message elements or transaction invariants work value

Table C.1-2: Element ERR-2 Error Location

Component/Sub-Component	Usage	LEN	Comment
Segment ID (ST)	R	3	
Segment Sequence (NM)	R	2	
Field Position (NM)	RE	2	
Field Repetition (NM)	RE	2	
Component Number (NM)	RE	2	
Sub-Component Number (NM)	RE	2	

1850

The deeper the source of the error is (segment, field, component, sub-component), the more optional components in ERR-2 will need to be populated to precisely identify it. See HL7 v.2.5.1 Section 2.A.1.28 for further explanations.

ERR-3 HL7 Error Code (CWE), mandatory.

1855 Identifies the HL7 (communications) error code. The first component (Identifier) is supported and SHALL contain a code from the following subset of codes in HL7 Table 0357.

Table C.1-3: Subset of HL7 Table 0357 – Message error condition codes

Value	Description	Comment
100	Segment sequence error	Error: The message segments were not in the proper order, or required segments are missing.
101	Required field missing	Error: A required field is missing from a segment
102	Data type error	Error: The field contained data of the wrong data type, e.g., an NM field contained "FOO".
103	Table value not found	Error: A field of data type ID or IS was compared against the corresponding table, and no match was found.
200	Unsupported message type	Rejection: The Message Type is not supported.
201	Unsupported event code	Rejection: The Event Code is not supported.
202	Unsupported processing id	Rejection: The Processing ID is not supported.
203	Unsupported version id	Rejection: The Version ID is not supported.
207	Application internal error	Rejection: A catchall for internal errors not explicitly covered by other codes.

Table C.1-4: Element ERR-3 HL7 Error Code

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	A code from the "Value" column of the Table C.1-3
Text (ST)	RE	199	Text from the "Description" column of the Table C.1-3
Name of Coding System (ID)	R	7	Fixed "HL70357"

ERR-4 Severity (ID), mandatory.

This field identifies the severity of an application error. Knowing if something is Error, Warning or Information is intrinsic to how an application handles the content. This profile supports only the following subset of codes from the HL7 Table 0516.

Table C.1-5: Subset of HL7 Table 0516 – Error severity

Value	Description	Comment
E	Error	Transaction was unsuccessful

ERR-5 Application Error Code (CWE), required if available (Analyzer Manager), required if available from analyzer (Analyzer).

This field contains a vendor-defined code identifying the specific error that occurred.

Table C.1-6: Element ERR-5 Application Error Code (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined code
Text (ST)	O	199	Vendor-defined description
Name of Coding System (ID)	R	12	"99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

ERR-8 User Message (TX), required if available (Analyzer Manager), required if available from analyzer (Analyzer).

This field contains a vendor-defined text message that can be displayed to the application user.

C.2 INV Segment

HL7 v2.5.1: chapter 13 (13.4.4 INV- Inventory Detail Segment).

The INV segment is used to:

- Identify control material when QC results are transmitted
- Identify contributing substances (e.g., reagents) that were used to produce a result

Table C.2-1: INV Segment

SEQ	LEN	DT	Usage Analyzer	Card.	TBL#	ITEM#	Element name
1	250	CE	R	[1..1]	0451	01372	Substance Identifier
2	250	CE	R	[1..1]	0383	01373	Substance Status
3	250	CE	R	[1..1]	0384	01374	Substance Type
4	250	CE	RE.AN	[0..1]		01532	Inventory Container Identifier
12	14	TS	RE.AN	[0..1]		01383	Expiration Date/Time
16	200	ST	RE.AN	[0..1]		01387	Manufacturer Lot Number

1880

INV-1 Substance Identifier (CE), required.

This is the manufacturer-specific identifier for the substance.

Table C.2-2: INV-1 Substance Identifier

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Substance identifier code from HL7 Table 0451 or vendor-defined coding system
Text (ST)	O	199	Description of the substance identifier
Name of Coding System (ID)	R	7	Fixed “HL70451” or “99zzz” for a vendor-defined coding system (where z is an alphanumeric character)

1885 **INV-2 Substance Status (CE)**, required.

This field contains the status of the substance, and is populated with values from HL7 Table 0383.

Table C.2-3: Element INV-2 Substance Status

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Substance status code from HL7 Table 0383 or vendor-defined coding system
Text (ST)	O	199	Description of the substance status

Component/Sub-Component	Usage	LEN	Comment
Name of Coding System (ID)	R	7	Fixed "HL70383" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

In many cases the status is not applicable, as the intent of the segment in the [LAB-29] transaction is only to identify the substance, so HL7 Table 0383 is extended by this profile as shown below. The table may also be extended with vendor-defined values.

Table C.2-4: LAW Extensions to HL7 Table 0383 – Substance Status

Value	Description	Comment
NA	Not Applicable	Value added by the LAW Profile

INV-3 Substance Type (CE), required.

This field contains a value from HL7 Table 0384 that identifies the substance.

Table C.2-5: Element INV-3 Substance Type

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Type of substance (e.g., Control, Reagent, Bulk Supply, Waste) code from HL7 Table 0384 or vendor-defined coding system
Text (ST)	O	199	Description of the substance type
Name of Coding System (ID)	R	7	Fixed "HL70384" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

When used to identify control material, the field SHALL be populated with "CO". All values from HL7 Table 0384 as well as vendor-defined extensions are allowed when the segment is being used to identify contributing substances (e.g., reagents).

INV-4 Inventory Container Identifier (CE), required if available from analyzer (Analyzer).

This field identifies the inventory container, e.g., unique serial number, of a specific package instance of a specific substance. This is a manufacturer-specific identifier.

Table C.2-6: Element INV-4 Inventory Container Identifier

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Substance serial number
Text (ST)	O	199	Description of the container identifier
Name of Coding System (ID)	R	5	Vendor-defined coding system name "99zzz" (where z is an alphanumeric character)

INV-12 Expiration Date/Time (TS), required if available from analyzer (Analyzer).

This is the expiration date and time of the substance. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. Degree of precision component is not supported.

Table C.2-7: Element INV-12 Expiration Date/Time

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDDHHMMSS	R	14	Expiration Date/Time

INV-16 Manufacturer Lot Number (ST), required if available from analyzer (Analyzer).

This is the manufacturer-specific lot number of the substance.

C.3 MSA Segment

HL7 v2.5.1: chapter 2 (2.15.8 MSA – Message Acknowledgment Segment).

The MSA segment contains information sent while acknowledging another message.

Table C.3-1: MSA Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	2	ID	M	[1..1]	0008	00018	Acknowledgement Code
2	50	ST	M	[1..1]		00010	Message Control Id

MSA-1 Acknowledgment Code (ID), mandatory.

This element contains the acknowledgment code, per the HL7 message processing rules. The following subset of codes from HL7 Table 0008 is supported.

Table C.3-2: Subset of HL7 Table 0008 – Acknowledgement Code

Value	Description	Comment
AA	Original mode: Application Accept	Message processed and accepted
AE	Original mode: Application Error	Message processed and was rejected because the message was malformed (e.g., missing segments, unsupported table values)
AR	Original mode: Application Reject	Message rejected due to incorrect message control content or inconsistent message content

Note: The accompanying ERR segment to the MSA segment in the acknowledgement message will indicate the location of the error.

MSA-2 Message Control Id (ST), mandatory.

This field contains the value in MSH-10 Message Control ID from the message being acknowledged.

Note on Element Length: The maximum element length for MSA-2 has been extended to 50 characters from the HL7-prescribed length of 20 characters. This extension allows sending systems to use globally unique identifiers (such as GUIDs) for Message IDs.

C.4 MSH Segment

HL7 v2.5.1: chapter 2 (2.15.9 MSH – Message Segment Header).

The MSH segment defines the intent, source, destination, and some specifics of the syntax of a message.

Table C.4-1: MSH Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	1	SI	M	[1..1]		00001	Field Separator
2	4	ST	M	[1..1]		00002	Encoding Characters
3	227	HD	RE	[0..1]		00003	Sending Application
4	227	HD	RE	[0..1]		00004	Sending Facility
5	227	HD	RE	[0..1]		00005	Receiving Application
6	227	HD	RE	[0..1]		00006	Receiving Facility
7	26	TS	M	[1..1]		00007	Date/Time of Message
9	15	MSG	M	[1..1]		00009	Message Type
10	50	ST	M	[1..1]		00010	Message Control Id
11	3	PT	M	[1..1]		00011	Processing Id
12	60	VID	M	[1..1]		00012	Version ID
15	2	ID	C (M/X)	[0..1]	0155	00015	Accept Acknowledgement Type
16	2	ID	C (M/X)	[0..1]	0155	00016	Application Acknowledgement Type

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
18	16	ID	M	[1..1]	0211	00692	Character Set
21	427	EI	M	[1..*]	01598	01598	Message Profile Identifier

MSH-1 Field Separator (SI), mandatory.

This profile requires the HL7-recommended value of '|' (ASCII 124).

MSH-2 Encoding Characters (ST), mandatory.

This field must contain the four characters in the following order: the component separator, repetition separator, escape character, and subcomponent separator. This profile requires the HL7-recommended values:

- Component Separator: ' ^' (ASCII 94)
- Repetition Separator: '~' (ASCII 126)
- Escape Separator: '\' (ASCII 92)
- Subcomponent Separator: '&' (ASCII 38)

MSH-3 Sending Application (HD), required if available.

This field contains the laboratory-defined name of the sending application.

Table C.4-2: Element MSH-3 Sending Application (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	R	See Section 2.7

MSH-4 Sending Facility (HD), required if available.

This field contains the laboratory-defined name of the sending facility.

Table C.4-3: Element MSH-4 Sending Facility (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	R	See Section 2.7

MSH-5 Receiving Application (HD), required if available.

This field contains the laboratory-defined name of the receiving application.

Table C.4-4: Element MSH-5 Receiving Application (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	R	See Section 2.7

MSH-6 Receiving Facility (HD), required if available.

This field contains the laboratory-defined name of the receiving facility.

Table C.4-5: Element MSH-6 Receiving Facility (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	RE	See Section 2.7

MSH-7 Date/Time of Message (TS), mandatory.

This field contains the date/time that the sending system created the message. This element SHALL be reported to a precision of seconds. This is the only date/time field in the message mandating the time zone. All other time stamps in the message do not support a specific time zone and are assumed to be in the same time zone as specified in this MSH-7 element.

Table C.4-6: Element MSH-7 Date/Time of Message (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDDHHMMSS+/-ZZZZ	R	19	Time zone is used for all other time stamps in the message

MSH-9 Message Type (MSG), mandatory.

This field contains the message type, trigger event, and the message structure ID for the message.

Table C.4-7: Element MSH-9 Message Type

Component/Sub-Component	Usage	Comment
Message Code (ID)	R	
Trigger Event (ID)	R	
Message Structure (ID)	R	

MSH-10 Message Control Id (ST), mandatory.

This field contains a number or other identifier that uniquely identifies the message. Each message should be given a unique identifier by the sending system. The receiving system will echo this ID back to the sending system in the Message Acknowledgment segment (MSA).

Note on Element Length: The maximum element length for MSH-10 has been extended to 50 characters from the HL7-prescribed length of 20 characters. This extension allows sending systems to use globally unique identifiers (such as GUIDs) for Message IDs. HL7 v2.6 increased the length to 199.

MSH-11 Processing ID (PT), mandatory.

This field indicates whether to process the message as defined in HL7 Application (level 7) Processing rules. Only a subset of values from HL7 Table 0103 is supported.

Table C.4-8: Element MSH-11 Processing ID

Component/Sub-Component	Usage	Comment
processing ID (ID)	R	

Table C.4-9: Subset of HL7 Table 0103 – Processing ID

Value	Description	Comment
P	Production	Message processed

MSH-12 Version ID (VID), mandatory.

Accepts values starting with the character string '2.5'. Later minor releases such as '2.5.1' are also supported. All other values will cause the message to be rejected.

Table C.4-10: Element MSH-12 Version ID

Component/Sub-Component	Usage	Comment
Version ID (ID)	R	

MSH-15 Accept Acknowledgment Type (ID), conditional.

This field identifies the conditions under which accept acknowledgements are required to be returned in response to a message. In the LAW Profile accept acknowledgements are never used and MSH-15 will contain the value "NE". In that way, the desired behavior of the receiving application is the same as in the original acknowledgement mode.

Predicate: Usage is Mandatory in the event triggered message. Otherwise usage is Not Supported.

Table C.4-11: Subset of HL7 Table 0155 – Accept/application acknowledgment type

Value	Description	Comment
NE	Never	Never send accept acknowledgments

MSH-16 Application Acknowledgment Type (ID), conditional.

This field identifies the conditions under which application acknowledgements are required to be returned in response to a message. Application acknowledgements are always required, so MSH-16 will contain the value "AL".

Predicate: Usage is Mandatory in the event triggered message. Otherwise usage is Not Supported.

Table C.4-12: Subset of HL7 Table 0155 – Accept/application acknowledgment type

Value	Description	Comment
AL	Always	Application acknowledgments are always required

M**SH-18 Character Set (ID)**, mandatory.

This field contains the character set for the entire message. This profile requires the subset of values from HL7 Table 0211 listed below. Some countries, for example Japan, may explicitly extend this subset at the national level. A system implementing the LAW Profile must be able to support UNICODE UTF-8, even if some other character set is required at a national level.

Table C.4-13: Subset of HL7 Table 0211 – Alternate character sets

Value	Description	Comment
UNICODE UTF-8	UCS Transformation Format, 8-bit form	UTF-8 is a variable-length encoding; each code value is represented by 1, 2 or 3 bytes, depending on the code value. 7 bit ASCII is a proper subset of UTF-8. Note that the code contains a space before UTF but not before and after the hyphen.

Though the field is repeatable in HL7, only one occurrence (i.e., one character set) is supported for the LAW Profile. The character set specified in this field is used for the encoding of all of the characters within the message.

MSH-21 Message Profile Identifier (EI), mandatory.

According to ITI TF-2x, the field contains one field repetition with a value representing the IHE transaction identifier, in the form <domain>-<transaction number>^IHE" (e.g., "LAB-27^IHE"), as shown below. Additional vendor specific identifiers may also be provided.

Table C.4-14: Element MSH-21 Message Profile Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	First repeat: <domain>-<transaction number> Subsequent repeat: additional IHE profile Identifiers or vendor defined
Namespace ID (IS)	R	20	First repeat: IHE Subsequent repeat: Vendor defined

C.5 NTE Segment

HL7 v2.5.1: chapter 2 (2.15.10 NTE – notes and comments segment).

The LAW Profile limits the use of this segment to human-readable comments to exchange between the operator of the Analyzer Manager and operator of the Analyzer. All comments are considered to be an internal remark.

Table C.5-1: NTE Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
1	4	SI	R	R	[1..1]		00096	Set ID - NTE
2	8	ID	R	R	[1..1]	0105	00097	Source of Comment
3	120#	FT	R	R	[1..1]		00098	Comment
4	250	CE	RE	RE.AN	[0..1]		01318	Comment Type

NTE-1 Set ID - NTE (SI), required.

This field contains the sequence number for the comments.

Within LAW Transactions, the sequence number is set to '1' for each first occurrence of the NTE segment within a Segment Group. All occurrences of the NTE segment that immediate follow are sequentially numbered.

NTE-2 Source of Comment (ID), required.

This field contains the source of the comment, and is populated with values from HL7 Table 0105 below.

Table C.5-2: HL7 Table 0105 – Source of Comment

Value	Description	Comment
A	Analyzer Manager is the source of the comment	From Table C.2-2 in PaLM TF-2x:C.
Z	Analyzer	Extension added for the LAW Profile

NTE-3 Comment (FT), required.

This field contains the text of the comment. The text may be formatted.

NTE-4 Comment Type (CE), required if available (Analyzer Manager), optional (Analyzer).

This field contains the type associated with the comment. The LAW Profile considers this to be vendor-specific information. This field SHALL be populated as described by the table below.

Table C.5-3: Element NTE-4 Comment Type (CE)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Vendor-defined code
Text (ST)	199	RE	Vendor-defined description
Name of Coding System (ID)	12	R	"99zzz…" identifier for a vendor-defined coding system

C.6 OBR Segment

HL7 v2.5.1: chapter 4 (4.5.3 OBR – Observation Request Segment).

This segment is used to transmit information specific to an order for a diagnostic study or observation. The primary use of this segment is to identify the test/analysis to be run by the Analyzer on the specimen.

Table C.6-1: OBR Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card	TBL #	ITEM #	Element name
2	50[1]	EI	M	M	[1..1]		00216	Placer Order Number (AWOS ID)
3	50[1]	EI	X	RE.AN	[0..1]		00217	Filler Order Number
4	250	CE	M	M	[1..1]		00238	Universal Service Identifier
11	1	ID	X	LAW_REFLEX (RE/X)	[0..1]	0065	00245	Specimen Action Code
16	250	XCN	RE	X	[0..1]		00226	Ordering Provider
49	2	IS	RE	LAW_RESULT_EXT (RE/X)	[0..1]	0507	01647	Result Handling

Note 1: The maximum field length has been extended to 50 characters from the HL7 defined length of 22, allowing globally unique identifiers (such as GUIDs).

OBR-2 Placer Order Number (EI), mandatory.

Each ordered battery/test is assigned to a unique Order, identified by a unique AWOS ID. The Placer Order Number is generated by the Analyzer Manager and should be unique across all OBR segments across all messages. For the Analyzer, if the AWOS ID does not exist, then this field is populated with NULL (""). This happens when sending results for:

- AWOS manually entered on the Analyzer;
- Reflex tests scheduled by the Analyzer in a new AWOS distinct from the original AWOS. In this case the original AWOS(s) is (are) referenced as the parent AWOS in field ORC-8.

The use of NULL ("") by the Analyzer should not be interpreted as requirement to delete AWOS information from AWOS data records maintained by the Analyzer Manager.

Note on Element Length: The maximum element length for OBR-2 has been established as 50 characters to allow globally unique identifiers (such as GUIDs) for AWOS IDs.

Table C.6-2: Element OBR-2 Placer Order Number (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	AWOS ID

OBR-3 Filler Order Number (EI), required if available from Analyzer (Analyzer).

This field is the order number associated with the Analyzer. This is a permanent identifier for an order and its associated observations.

Note on Element Length: The maximum element length for OBR-3 has been established as 50 characters to allow globally unique identifiers (such as GUIDs).

Table C.6-3: Element OBR-3 Filler Order Number (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	A unique order ID generated by the Analyzer

OBR-4 Universal Service Identifier (CE), mandatory.

This field contains one ordered battery or test. A battery is composed of one or more tests or one or more batteries. A local code or standard vocabulary, as described in Section 2.3.1, is required to ensure an unambiguous order.

Table C.6-4: Element OBR-4 Universal Service Identifier (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Test/Battery Identifier
Text (ST)	R	199	Name for the test/battery
Name of Coding System (ID)	R	12	Name of coding system "LN" for LOINC®, "JC10" for JLAC10, or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

OBR-11 Specimen Action Code (ID), not supported (Analyzer Manager), required if available (Analyzer with LAW_REFLEX).

This field is used to identify reflex orders generated at the Analyzer when reporting results for those orders. If the Analyzer-generated order is a reflex, then OBR-11 is set to "G", meaning "Generated order, reflex order".

See an example in Section B.3.5 of Appendix B.

OBR-16 Ordering Provider (XCN), required if available (Analyzer Manager), not supported (Analyzer).

This field identifies the provider (e.g., ordering physician) that ordered the test/battery on this sample.

Table C.6-5: Element OBR-16 Ordering Provider (XCN)

Component/ Sub-Component Index	Component/Sub-Component	Usage	LEN	Comment
OBR-16-1	ID number (ST)	R	15	Locally defined identifier
OBR-16-2	Family Name (FN)	O		
OBR-16-2-1	Surname (FN)	O	20#	Last Name
OBR-16-3	Given Name (ST)	O	20#	First name
OBR-16-4	Second and Further Given Names or Initials Thereof (ST)	O	20#	Multiple middle names may be included by separating them with spaces
OBR-16-5	Suffix (ST)	O	10#	A name suffix
OBR-16-9	Assigning Authority (HD)	RE	227	Unique identifier of the organization that creates the data.
OBR-16-9-1	Namespace ID (IS)	RE	20	
OBR-16-9-2	Universal ID (ST)	RE	199	
OBR-16-9-3	Universal ID Type (ID)	C (R/X)	6	Predicate: Must be populated if OBR-16-9-2 is populated; otherwise is not supported.

In most cases only OBR-16-1 is sufficient to identify the Ordering Provider when exchanging order information in the LAW transactions as the Analyzer Manager is responsible for managing the identity of providers and preventing identifier collisions. The additional fields in OBR-16 can be used when the Analyzer Manager is just passing along information or for those Analyzers where orders can be entered and the Ordering Provider information needs to be transmitted to the Analyzer Manager.

If all three sub-components of OBR-16-9 Assigning Authority are populated, they must reference the same entity.

OBR-49 Result Handling (IS), not supported (Analyzer Manager), required if available (Analyzer with LAW_RESULT_EXT).

This field transmits information regarding the handling of the result. The value is specified in the User-Defined Table 0507.

Table C.6-6: IHE-Lab User-Defined Table 0507 – Result Handling

Value	Description	Comment
RE	Result stored in repository	Result is persisted externally

The presence of this field with the value "RE" in an OUL^R22 indicates that the Analyzer has stored the result data in a persistent object repository, and it is accessible via the reference pointer in the subsequent OBX segment.

C.7 OBX Segment

HL7 v2.5.1: chapter 7 (7.4.2 OBX – Observation/Result Segment), with some pre-adoptions from 2.6, 2.8.1 and 2.8.2.

The OBX segment is used to transmit a single observation or observation fragment.

Table C.7-1: OBX Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM #	Element name
1	4	SI	M	M	[1..1]		00569	Set ID – OBX
2	2	ID	C (M/X)	C (M/X)	[0..1]	0125	00570	Value Type
3	250	CWE	M	M	[1..1]		00571	Observation Identifier
4	20	OG[1]	RE	M	[0..1]		00572	Observation Sub-ID
5	99999	Varies	M	M	[1..*]		00573	Observation Value
6	250	CE	C (M/X)	C (M/X)	[1..1]		00574	Units

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM #	Element name
7	70	ST	RE	RE.AN	[0..1]		00575	Reference Range
8	5	CWE	M	M	[1..*]	0078	00576	Interpretation Codes
9	5	NM	X	LAW_MASS_SPEC (RE/X)	[0..1]		00577	Probability
11	1	ID	M	M	[1..1]	0085	00579	Observation Result Status
14	14	TS	RE	X	[0..1]		00582	Date/Time of the Observation
16	250	XCN	M	M	[1..*]		00584	Responsible Observer
18	427	EI	M	M	[2..*]		01479	Equipment Instance Identifier
19	14	TS	M	M	[1..1]		01480	Date/Time of the Analysis
21	427	EI	RE	RE.AN	[0..1]		02180	Observation Instance Identifier[2]
29	4	ID	M	M	[1..1]	0936	03432	Observation Type[3]

Note 1: This datatype was pre-adopted from HL7 v2.8.2.

Note 2: This field was pre-adopted from HL7 v2.6.

Note 3: This field was pre-adopted from HL7 v2.8.1.

OBX-1 Set ID (SI), mandatory.

This field contains the sequence number of the observations.

Within the LAW Profile, the sequence number is set to '1' for the first occurrence of the OBX segment in a segment group representing an AWOS. For example, the field is set to one in the first occurrence of the OBX segment in an instance of the ORDER segment group of the [LAB-29] transaction. Subsequent occurrences of the segment within that ORDER segment group are sequentially numbered.

OBX-2 Value Type (ID), conditional.

This field contains the format of the observation value in OBX-5.

Predicate: Usage is Mandatory if OBX-5 (Observation Value) is not NULL (""). Otherwise, usage is Not Supported.

The profile supports the following subset of values from HL7 Table 0125.

Table C.7-2: Subset of HL7 Table 0125[1] – Value Type

Value	Description	Comment
CE	Coded Entry	Used to report a coded qualitative result or a coded exception (reason why the test failed to produce the requested measurement)
ED	Encapsulated Data	Used to report graphs, images, etc.
EI[1]	Entity Identifier	Use for references to observation instance identifiers
NM	Numeric	Numeric result
NA[1]	Numerical Array	n-dimensional set of values
RP	Reference Pointer	Reference to a location of the result, such as a reference to a large image
SN	Structured Numeric	Used when result is above or below dynamic range of the assay (> or <)
ST	String	Used to report a result in structured (e.g., XML) or unstructured text, limited to less than 200 characters so can only be used for short strings
TX	Text Data	Used to report a result in structured (e.g., XML) or unstructured text, can be used for long strings

Note 1: The content of table 0125 is drawn from HL7 2.5.1 with two additions pre-adopted from HL7 2.8.2: data types EI (Entity Identifier) and NA (Numerical Array).

OBX-3 Observation Identifier (CWE), mandatory.

This field contains one observation reported by the Analyzer. A local code or standard vocabulary, as described in Section 2.3.1, is required to ensure an unambiguous observation.

Table C.7-3: Element OBX-3 Observation Identifier

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Observation Identifier Code
Text (ST)	199	R	Observation Identifier Description
Name of Coding System (ID)	12	R	"LN" for LOINC®, "JC10" for JLAC10, "99zzz" for a vendor-defined or local-defined coding system (where z is an alphanumeric character)
Alternate Identifier (ST)	20	C(RE/X)	Either: • Supplemental result code from Table 2.3.1-5 (LAW Codes for Supplemental Results) if used for Supplemental Result • Additional Observation Identifier Code similar to OBX-3-1
Alternate Text (ST)	199	C (R/X)	Either: • Supplemental result name from Table 2.3.1-5 (LAW Codes for Supplemental Results) if used for Supplemental Result • Observation Identifier Description as for OBX-3-2

Component/Sub-Component	LEN	Usage	Comment
Name of Alternate Coding System (ID)	6	C (R/X)	Either: • Fixed "IHELAW" for Supplemental Results or • "LN" for LOINC®, "JC10" for JLAC10, or "99zzz" for a vendor-defined or local-defined coding system as defined for the Name of Coding System (OBX-3-3)
Coding System Version ID	10	X	Not used in this profile
Alternate Coding System Version ID	10	X	Not used in this profile
Original Text	199	X	Not used in this profile
Second Alternate Identifier	20	C(RE/X)	Additional Observation Identifier Code similar to OBX-3-1
Second Alternate Text	199	C (R/X)	Observation Identifier Description as for OBX-3-2
Name of Second Alternate Coding System	6	C (R/X)	"LN" for LOINC®, "JC10" for JLAC10, or "99zzz" for a vendor-defined or local-defined coding system as defined for the Name of Coding System (OBX-3-3)

Alternate components OBX-3-4 to OBX-3-6 SHALL be used only for two reasons:

- To identify supplemental result information, where OBX-3-4 "Alternate Identifier" is populated with a LAW supplemental result identifier associated with the vendor supplemental identification provided in OBX-3-1 to OBX-3-3. The condition for both OBX-3-5 "Alternate Text" and OBX-3-6 "Name of Alternate Coding System" is that OBX-3-4 "Alternate Identifier" is populated.
- To be able to send different result codes that are alternatives to the one used in OBX-3-1 to OBX-3-3 (i.e., to be able to send vendor defined information in OBX-3-1 to OBX-3-3 and LOINC, JLAC10 or other vendor/local defined codes together in OBX-3-4 to OBX-3-6). The condition for both OBX-3-5 "Alternate Text" and OBX-3-6 "Name of Alternate Coding System" is that OBX-3-4 "Alternate Identifier" is populated.

The Second Alternate components OBX-3-10 to OBX-3-12 MAY be used to send different result codes that are alternatives to the ones used in OBX-3-1 to OBX-3-3 and OBX-3-4 to OBX-3-6 (i.e., to be able to send vendor-defined information in OBX-3-1 to OBX-3-3 and LOINC defined codes in OBX-3-4 to OBX-3-6 together with JLAC10 defined codes in OBX-3-10 to OBX-3-12). The condition for both OBX-3-11 "Second Alternate Text" and OBX-3-12 "Name of Second Alternate Coding System" is that OBX-3-10 "Second Alternate Identifier" is populated.

OBX-4 Observation Sub-ID (OG), required if available (Analyzer Manager), mandatory (Analyzer).

This field ensures results from multiple runs reported by the Analyzer can be distinctly identified. Each run is uniquely identified by a positive integer, starting from "1".

Table C.7-4: Element OBX-4 Observation Sub-ID (OG: Observation Grouper)

Component/ Sub-Component	Usage	LEN	Comment
Original (ST)	R	20	Run identifier starting from "1"
Group (NM)	C(R/RE. AN)[1]	5	Group Identifier starting from "1"
Sequence (NM)	C(R/RE. AN)[1]	5	Sequence Number starting from "1"

Note 1: Predicate for OBX-4.2 and OBX-4.3: When a result message with multiple OBX segments uses the same observation ID (OBX-3) under the same OBR, OBX-4 is used to uniquely identify each observation. This is accomplished by use of OBX-4.2, which must be populated with an integer starting from "1". It creates a group of related OBXs. OBX-4.3 must be set with an integer starting from "1" for further differentiation. Otherwise, when supported by the Analyzer the fields may be used to further classify the OBX segments.

Example:

OBR|1|ORD885||5863^Spt Routine Cult^99Lab|...

ORC|SC|||REQ885|CM

OBX|1|CE| 76346-6^Microorganism identified in Isolate by MS.MALDI-TOF^LN|1^1^1|412643004^Beta hemolytic Streptococcus A^SCT||||0.5||F|...

OBX|2|CE| 76346-6^ Microorganism identified in Isolate by MS.MALDI-TOF ^LN|1^1^2|3092008^Staphylococcus aureus^SCT||||0.5||F|...

See Section B.3 for more details about the use of this field.

OBX-5 Observation Value (varies), mandatory.

This field contains the result value for the test result identified in OBX-3 Observation Identifier. The observation value SHALL be reported based on the value type specified in OBX-2.

In some cases, there may not be an observation value to report. For example, some systems may only report the normalcy/abnormality using OBX-8. OBX-5 SHALL be set to NULL ("") if there is no value to report. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete observation information from AWOS data records maintained by the Analyzer Manager.

One OBX segment should not contain the result of more than one logically independent observation, unless it is part of a list of like concepts that belong together. This requirement is included to assure that the contents of OBX-6-units, OBX-8-interpretation codes, and OBX-9-probability can be interpreted unambiguously. This means that all other OBX field values apply equally to the whole of OBX-5 noting that OBX-6 does not apply in the case of coded values.

It is important to state that ANY independent observation, that may require parent-child linking to additional tests, such as reflex testing, SHALL NOT be included in a single OBX-5 field using

repeat delimiters, nor any list elements that require variations in the values of other OBX field values.[4]

In LAW repeating OBX-5 values are only allowed for supplemental results, which are for internal lab use only.

Conformance Statement:

IHE-01: Cardinality of OBX-5 SHALL be 1..1, except when OBX-3.4 is populated with "S_RAW" or "S_OTHER", drawn from Table 2.3.1-5, then repeats are allowed.

Coded Entry (CE): The coded entry data type is used to represent coded qualitative results or exceptions. The following table defines the components of the CE data type.

Table C.7-5: Element OBX-5 Observation Value (when CE data type)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Coded result
Text (ST)	199	R	The meaning of the code
Name of Coding System (ID)	12	R	Can be an analyzer-specific coding system or a national or international terminology, depending on the observation performed and of the type of result produced.

Encapsulated Data (ED): The encapsulated data type is used to for observations that are represented as images, reports, graphs, etc. For more information refer to Sections A.3 and B3.6 through B.3.10. The following table defines the components of the ED data type.

Table C.7-6: Element OBX-5 Observation Value (when data type is ED)

Component/Sub-Component	LEN	Usage	Comment
Source Application (HD)	20	RE	Only the Namespace ID component is used. A unique name that identifies the system which was the source of the data.
Type of Data (ID)	9	R	A value from HL7 Table 0191. E.g., the value for image data is "IM"
Data Subtype (ID)	18	RE	A value from HL7 Table 0291. E.g., "JPEG"
Encoding (ID)	6	R	A value from HL7 Table 0299 Recommended value is "Base64"
Data (TX)	unlimited	R	The data representing the image or other encapsulated data being sent.

[4] Text excerpted from HL7 Chapter 7, Section 7.4.2.5 in version 2.8.2.

Entity Identifier (EI): The entity identifier data type is used for references to OBX-21 Observation Instance Identifier. This allows relationships to be established between two observation instances. The following table defines the components of the EI data type.

Table C.7-7: Element OBX-5 Observation Value (when data type is EI)

Component/Sub-Component	LEN	Usage	Comment
Entity Identifier (ST)	199	R	A unique identifier created by the assigning authority described in the following components. Specific meaning of identifier defined by each vendor.

Numeric (NM): The numeric data type is used to represent observations that include ASCII numeric characters and optionally a leading sign (+ or -) and a decimal point. If there is no sign the observation is considered positive. The following table defines the components of the NM data type.

Table C.7-8: Element OBX-5 Observation Value (when data type is NM)

Component/Sub-Component	LEN	Usage	Comment
Numeric	16	R	The numeric value of the observation.

Numeric Array (NA): The numeric array data type is used for observations that are represented as a series of numeric values (NM). A single repetition of this data type is used to represent a one-dimensional array. Multiple repetitions of this data type can be used to represent a two-dimensional array of values. For more details on usage of a numeric array refer to B.3.9. The following table defines the components of the NA data type.

Table C.7-9: Element OBX-5 Observation Value (when data type is NA)

Component/Sub-Component	LEN	Usage	Comment
Value 1 (NM)	16	R	Numeric value defined by vendor
Value 2 (NM)	16	RE	Numeric value defined by vendor
…			More vendor-defined components as needed.

Reference Pointer (RP): The reference pointer data type is used to refer to the location of an observation. This is used when the size of the observation is too large to be transmitted via this

interface. e.g., a large image file. For more information refer to Section B.3.7. The following table defines the components of the RP data type.

Table C.7-10: Element OBX-5 Observation Value (when data type is RP)

Component/Sub-Component	LEN	Usage	Comment
Pointer (ST)	999[1]	R	A unique key assigned by the system that is used to identify and access the data associated with the observation. E.g., the path to a file on a network drive or ftp server.
Application ID (HD)	227	O	A unique designator of the system that stores the data.
Type of Data (ID)	9	O	A value describing the general type of the observation. A value from HL7 Table 0191 or a vendor defined value. E.g., “IM” for image data.
Subtype (ID)	19	O	A value describing the specific type of the observation. E.g., “JPEG” or “PNG” or “”PDF”

Note 1: This length was pre-adopted from HL7 v2.6.

The following shows an example usage of the RP data type for reporting an observation. This shows an image observation with the first component of the data type populated with a URL pointing to a JPEG image. Component two is empty. Components three and four indicate it is an imaged encoded as a JPEG.

Example:

OBX|4|RP|1A10^result name^JC10|1|http://LIS_IMAGE_SYSTEM/filename_01.JPG^^IM^JPEG|…

Structured Numeric (SN): The structured numeric data type is used to transmit a numerical result that is associated with symbolic qualifications. The following table defines the components of the SN data type.

Table C.7-11: Element OBX-5 Observation Value (when data type is SN)

Component/Sub-Component	LEN	Usage	Comment
Comparator (ST)	2	R	One of the following: “>” or “<” or “>=” or “<=” or “=” or “<>”
Num1 (NM)	15	R	The 1st numeric value of the structured numeric observation.
Separator/Suffix (ST)	1	RE	One of the following: “-” or “+” or “/” or “.” or “:”

Component/Sub-Component	LEN	Usage	Comment
Num2 (NM)	15	RE	The 2nd numeric value of the structured numeric observation.

The following tables shows examples of usage of the SN data type for reporting observations.

Table C.7-12: Examples of SN Observation Values

Value	Comment
|>^100|	Observation is greater than 100.
|^100^-^200|	Observation is the range 100 through 200.
|^1^:^228|	Observation is the ratio of 1 to 128, e.g., the results of a serological test.

String (ST): The string data type is used for observations that are represented as structured or unstructured text data limited to 200 characters. The following table defines the components of the ST data type.

Table C.7-13: Element OBX-5 Observation Value (when data type is ST)

Component/Sub-Component	LEN	Usage	Comment
String Data	200	R	The string that represents the value of the observation.

Text Data (TX): The text data type is similar to the string data type except the length of the observation may be up to 65536 characters in length. The following table defines the components of the TX data type.

Table C.7-14: Element OBX-5 Observation Value (when data type is TX)

Component/Sub-Component	LEN	Usage	Comment
Text Data	65536	R	The observation represented as text.

OBX-6 Units (CE), conditional.

This field is populated with the unit of measure for the result, as described in Section 2.3.2. If there is no unit for the numerical value, then the field is set to NULL (""). The use of NULL ("")

by the Analyzer should not be interpreted as a requirement to delete observation information from AWOS data records maintained by the Analyzer Manager.

Predicate: Usage is Mandatory if OBX-2 is valued with either with “NM” or “SN”. Otherwise usage is Not Supported. The unit of measure could be unitless, such as:

- Count of RBC (red blood cells): represented in UCUM as “{rbc}”
- Percentage: represented in UCUM as “%”

Table C.7-15: Element OBX-6 Units (CE)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	RE	UCUM coded unit of measure
Text (ST)	199	R	Vendor human-readable unit
Name of Coding System (ID)	4	C (R/X)[1]	Fixed “UCUM” (value pre-adopted from HL7 v2.6)

Note 1: Predicate: Name of Coding System must be populated if Identifier is populated.

OBX-7 Reference Range (ST), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

For numeric values, the suggested format of reference ranges is lower limit-upper limit when both lower and upper limits are defined (e.g., 3.5 - 4.5)

OBX-8 Interpretation Codes (CWE), mandatory.

The data type CWE for OBX-8 is pre-adopted from HL7 v2.7. The field contains analyzer codes assigned to the result. The field is set to NULL ("") if no codes exist. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete observation information from AWOS data records maintained by the Analyzer Manager. Multiple codes can be assigned to a result, thus this field can repeat.

This field is intended to convey a categorical assessment of OBX-5 Observation Value, such as "Normal", "Abnormal", “Positive”, “Negative”, etc. This field may also be used to convey an assessment of an observation where no legitimate result may be obtained. This includes laboratory assays that are rejected due to the presence of interfering substances, specimen toxicity or failure of quality control. In addition, it may also be used to convey an analysis warning, such as not enough sample volume to be confident of the result.

This field is also used to convey the interpreted value (S, I, R, …) of antibiotic susceptibility tests (AST) performed by microbiology analyzers.

The LAW Profile recommends the following subset of codes from HL7 Table 0078, which is pre-adopted from HL7 v2.9. However, an Analyzer may extend the set with codes from a vendor-defined coding system.

Table C.7-16: Subset of HL7 Table 0078 – Interpretation Codes

Value	Description	Comment
<	Off scale low	Below assay dynamic range
>	Off scale high	Above assay dynamic range
L	Low	Below low normal
H	High	Above high normal
LL	Critically low	Below assay panic range
HH	Critically high	Above assay panic range
N	Normal	Non-numeric results
A	Abnormal	Non-numeric results
POS	Positive	
NEG	Negative	
IND	Indeterminate	
QCF	Quality control failure	
S	Susceptible	For microbiology susceptibilities only
I	Intermediate	For microbiology susceptibilities only
R	Resistant	For microbiology susceptibilities only
SDD	Susceptible-dose dependent	For microbiology susceptibilities only
IE	Insufficient evidence	For microbiology susceptibilities only

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The components of this field should be populated according to the following table.

Table C.7-17: Element OBX-8 Interpretation Codes (CWE)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Code from "Value" column of Table C.7-16 or code from a vendor-defined coding system
Text (ST)	199	RE	Text from "Description" column of Table C.7-16 or vendor-defined description
Name of Coding System (ID)	12	R	"HL70078" for HL7 values or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

OBX-9 Probability (NM), not supported (Analyzer Manager), required if available (Analyzer with LAW_MASS_SPEC).

This field is the probability associated with the result. In microbiology, for example, it can be used to identify the probability of a specific organism being identified when multiple potential organisms have been matched. It is a decimal number that must be between 0 and 1, inclusive.

OBX-11 Observation Result Status (ID), mandatory.

This field contains the status of observation, and supports a subset of values taken from HL7 Table 0085 as described below:

Table C.7-18: Subset of HL7 Table 0085 – Observation Result Status (ID)

Value	HL7 Description	Meaning in the LAW Profile
X	Results cannot be obtained	Test Exception. The reason for failure is being reported in field OBX-5. This test will not produce any result in this run.
P	Preliminary results	The result is preliminary in a progression of results leading to the final result (such as the status of cultures in Microbiology).
R	Result entered – not verified	The result of this run is not a candidate to be reported upstream.
F	Final results; Can only be changed with a corrected result	The result of this run is final and a candidate to be reported upstream. In case results of multiple runs have status "F" the choice of the right run is left up to the Analyzer Manager.
C	Record coming over is a correction and thus replaces a final result	Correction of a result previously sent as final.

See Section B.3 Observation Identification for further details on the use of this field.

Figure C.7-1 represents the possible state transitions for an observation result within an Observation Run.

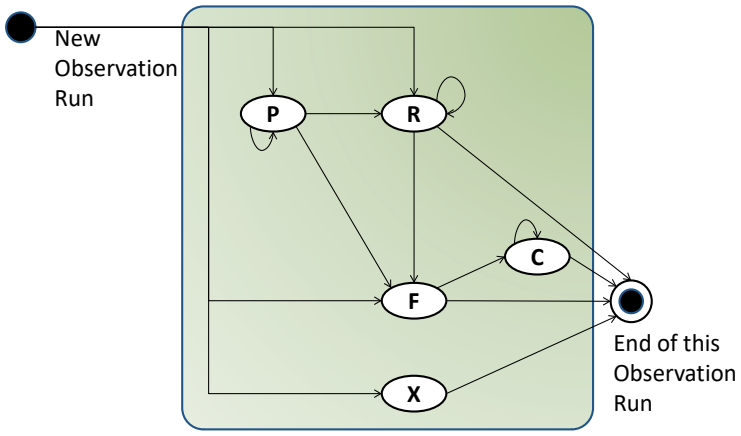

Figure C.7-1: State Transitions for an Observation Result within an Observation Run

Note: The recurring loops on statuses "P", "R" and "C" reflect the fact that a result can be revised or corrected in one of those statuses, without changing status.

Note: Each Observation Run has its own life cycle for the results it produces. However, there can be no more than one Observation Run of the same Observable Entity (test) of an AWOS, producing results in status "F" or "C".

OBX-14 Date/Time of the Observation (TS), required if available (Analyzer Manager), not supported (Analyzer).

The relevant date-time is the specimen's collection date-time. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. Degree of precision component is not supported.

Table C.7-19: Element OBX-14 Date/Time of the Observation (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDDHHMMSS	R	14	Specimen collection date/time

OBX-16 Responsible Observer (XCN), mandatory.

The first instance of this field contains the identity of the observer that causes the change of the observation result status. Subsequent repeats are vendor defined. Only the first component (ID number) of this field is necessary. If the value does not exist, then a NULL ("") value will be used for the ID number. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete observation information from AWOS data records maintained by the Analyzer Manager.

Table C.7-20: Element OBX-16 Responsible Observer (XCN)

Component/Sub-Component	Usage	Len	Comment
ID number (ST)	R	15	Locally defined identifier

OBX-18 Equipment Instance Identifier (EI), mandatory.

This field specifies the manufacturer, model, serial number/ID, and optional UID of the analyzer that performed the test. It may also contain additional vendor or site specific identifiers. See Section B.2 for more details.

Table C.7-21: Element OBX-18 Equipment Instance Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R R O	50	First repeat: Model Second repeat: Serial number Subsequent repeats: Vendor/site defined
Namespace ID (IS)	R R O	20	First Repeat: Manufacturer Second Repeat: Manufacturer Subsequent repeats: Vendor/site defined
Universal ID (ST)	O X	199	First Repeat: UID Subsequent repeats: Not supported
Universal ID Type (ID)	O X	6	First Repeat: ISO Subsequent repeats: Not supported

OBX-19 Date/Time of the Analysis (TS), mandatory.

This field contains the date and time the test processing completed. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. Degree of precision component is not supported.

Table C.7-22: Element OBX-19 Date/Time of Analysis (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDDHHMMSS	R	14	Date/time test processing completed

OBX-21 Observation Instance Identifier (EI), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field is pre-adopted from HL7 v2.6. It contains a unique identifier for this observation. This instance identifier is persistent between messages. Since the use is marked as optional a partner agreement on how to use this field is required prior to implementation to discuss, if more than

just the EI.1 component needs to be supported. Support for EI.2 or EI.3 and EI.4 is recommended to ensure global uniqueness, unless a GUID is used in EI.1.

Table C.7-23: Element OBX-21 Observation Instance Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	Observation Instance Identifier

Note on Element Length: The maximum element length for OBX-21 has been extended to 50 characters from the HL7 defined length of 22. This extension allows sending systems to use globally unique identifiers (such as GUIDs).

OBX-29 Observation Type (ID), mandatory

This field is pre-adopted from HL7 v2.8.1. It indicates the type of observation to enable systems to distinguish between observations sent along with an order, versus observations sent as the result to an order. See HL7 Table 0936 – Observation Type for valid values.

Table C.7-24: HL7 Table 0936 - Observation Type (ID)

Value	Description	Comment
AOE	Asked at Order Entry Question	Limited to responses to questions by the Analyzer/ Analyzer Manager. Pre-adopted from HL7 v2.8.2.
ASC	Asked at Specimen Collection	Limited to responses to questions by the Analyzer/ Analyzer Manager. Pre-adopted from HL7 v2.8.2.
RSLT	Result	
SCI	Supporting Clinical Information	Observations not explicitly requested to provide context or supporting information.

C.8 ORC Segment

HL7 v2.5.1: chapter 4 (4.5.1 ORC – Common Order Segment).

The Common Order segment (ORC) is used to transmit elements that are common to all of the tests ordered.

Table C.8-1: ORC Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card. Analyzer	TBL#	ITEM#	Element name
1	2	ID	M	M	[1..1]		00215	Order Control
2	50[1]	EI	X	ORL^O34 (M/X)	[0..1]		00216	Placer Order Number (AWOS ID)
4	50[1]	EIP	RE	RE.AN	[0..1]		00218	Placer Group Number
5	2	ID	X	M	[1..1]		00219	Order Status

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card. Analyzer	TBL#	ITEM#	Element name
8	200	EIP	X	LAW_REFLEX (RE/X)	[0..*][2]		00222	Parent
9	26	TS	M	X	[1..1]	0038	00223	Date/Time of Transaction
21	250	XON	RE	RE.AN	[0..1]		01311	Ordering Facility Name
27	26	TS	X	RE.AN	[0..1]		01642	Filler Expected Availability Date/Time

Note 1: The maximum field length has been extended to 50 characters from the HL7 defined length of 22, allowing globally unique identifiers (such as GUIDs).

Note 2: This usage was pre-adopted from HL7 v2.9, OO CR075-725.

ORC-1 Order Control (ID), mandatory.

This field may be considered the "trigger event" identifier for orders. The IHE PaLM Technical Framework allows only the following subset for the LAW Profile:

Table C.8-2: Subset of HL7 Table 0119 – Order Control Codes

Value	Description	Comment
NW	New Order	Event request sent by AM in OML message of [LAB-28]
OK	Notification or request accepted	Event acknowledgement sent by Analyzer in ORL message of [LAB-28], responding to OML (NW)
UA	Unable to accept order/service	Event acknowledgement sent by Analyzer in ORL message of [LAB-28], responding to OML (NW)
CA	Cancel order/ service request	Event request sent by AM in OML message of [LAB-28]
CR	Canceled as requested	Event acknowledgement sent by Analyzer in ORL message responding to OML (CA), in [LAB-28]
UC	Unable to cancel	Event acknowledgement sent by Analyzer in ORL message responding to OML (CA), in [LAB-28]
DC	Discontinue Request	Sent by AM to indicate a negative query response in [LAB-28]
SC	Status Change	Sent by Analyzer in OUL message of [LAB-29] to indicate the message is a status change

ORC-2 Placer Order Number (EI), not supported (Analyzer Manager), mandatory (Analyzer with ORL^O34).

The field is used by the Analyzer to uniquely identify an AWOS when used as part of an ORL^O34 response to the Analyzer Manager.

Table C.8-3: Element ORC-2 Placer Order Number (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	AWOS ID

Note on Element Length: The maximum element length for ORC-2 has been established as 50 characters to allow globally unique identifiers (such as GUIDs) for AWOS IDs.

ORC-4 Placer Group Number (EIP), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

Using the data type EIP for ORC-4 is pre-adopted from HL7 2.8.

The Placer Group Number represents an identification of a set of closely related batteries and/or tests for one subject ordered together and for the same diagnostic purpose. For the LAW Profile, this field contains the **Work Order identifier** that groups AWOS ordered together by the Analyzer Manager and sent to one or more Analyzers. The Work Order can encompass more than one sample from the same patient. Only the Analyzer Manager establishes a Work Order identifier, so only the first identifier of the EIP data type is supported.

In cases where AWOS are not grouped under a common Work Order, this field is empty.

Table C.8-4: Element ORC-4 Placer Group Number (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	50	Work Order Identifier

Note on Element Length: The maximum element length for ORC-4 has been established as 50 characters to allow globally unique identifiers (such as GUIDs).

ORC-5 Order Status (ID), mandatory (Analyzer).

The Analyzer uses this field to provide the status of the AWOS. The allowed values for this field within the LAW Profile are a subset of HL7 Table 0038 - Order Status as shown below:

Table C.8-5: Subset of HL7 Table 0038 – Order Status

Value	HL7 Description (Order status)	Meaning in the LAW Profile (AWOS status)
SC	In process, scheduled	The AWOS is scheduled on the Analyzer, but the Analyzer has not started the work for the AWOS. This status can be sent in ORL message of [LAB-28] in response to OML (NW) when the AWOS is accepted.

Value	HL7 Description (Order status)	Meaning in the LAW Profile (AWOS status)
IP	In process, unspecified	The process of the first run of the AWOS has started on the Analyzer with the specimen. There may be some results or none. This status can be sent in ORL message of [LAB-28] in response to OML (NW) when the AWOS is accepted. This status can be sent in ORL message of [LAB-28] in response to OML (CA) when the AWOS cannot be cancelled because the AWOS work is in process. This status can be sent in OUL message of [LAB-29] to update the AWOS Status.
CM	Order is completed	The Analyzer has finished its work for the AWOS. The results may have been produced or not. No additional result is expected for this AWOS. Nonetheless, a correction of some of the final (candidates for reporting) results produced for this AWOS may still be sent by the Analyzer, in which case the AWOS status will remain "CM". This status can be sent in ORL message of [LAB-28] in response to OML (NW) when the AWOS is accepted. This status can be sent in ORL message of [LAB-28] in response to OML (CA) when the AWOS cannot be cancelled because the AWOS work is complete. This status can be sent in OUL message of [LAB-29] to update the AWOS Status.
CA	Order was canceled	The Analyzer considers the AWOS work cancelled. This status can be sent in ORL message of [LAB-28] in response to OML (NW) when the AWOS request is rejected. An AWOS was not created by the Analyzer. This status can be sent in ORL message of [LAB-28] in response to OML (CA) when the AWOS is cancelled. The Analyzer can cancel the AWOS before the process of the AWOS has started, when the AWOS status is scheduled (“SC”).

The following diagram depicts the lifecycle of an AWOS on the Analyzer when the AWOS request is accepted.

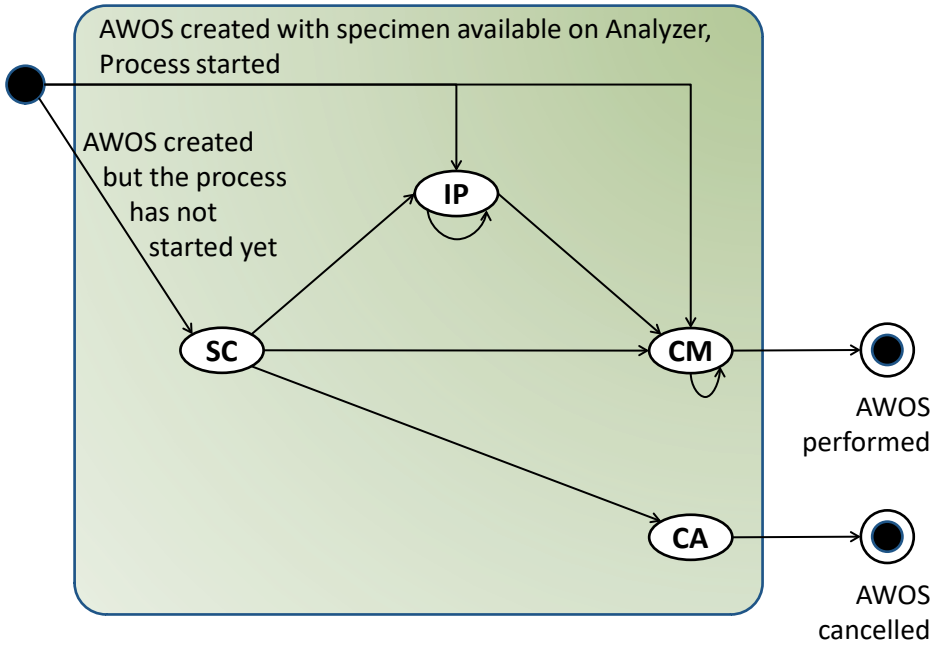

Figure C.8-1: AWOS Status transition diagram

Note: The recurring loops on statuses "IP" and "CM" reflect the fact that new or corrected results can be sent for the AWOS, without changing its status.

Note: A child AWOS (e.g., a reflex test) has its own life cycle, independent of the life cycle of the parent AWOS.

ORC-8 Parent (EIP), not supported (Analyzer Manager), required if available (Analyzer with LAW_REFLEX).

The field is used by the Analyzer to associate a reflex AWOS generated at the Analyzer to its parent AWOS(s) in OUL^R22 messages. Each instance of this repeatable field SHALL carry in its first component (Placer Assigned Identifier) the AWOS ID of a parent AWOS.

The field is made repeatable in the IHE PaLM Technical Framework pre-adoption of this repeatability stated in HL7 V2.9.

Table C.8-6: Element ORC-8 Parent (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	50	AWOS ID

Note on Element Length: The maximum element length for ORC-8 has been established as 50 characters to allow globally unique identifiers (such as GUIDs).

ORC-9 Date/Time of Transaction (TS), mandatory (Analyzer Manager), not supported (Analyzer).

This field contains the date and time of the event that initiated the current transaction as reflected in ORC-1 Order Control Code. This field is not equivalent to MSH-7 Date and Time of Message that reflects the date/time of the creation of the physical message.

It is used by the Analyzer Manager for new orders and order cancellations in the OML^O33 message.

Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. Degree of precision component is not supported.

Table C.8-7: Element ORC-9 Date/Time of Transaction (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDDHHMMSS	R	14	Date/time of initiating event

ORC-21 Ordering Facility Name (XON), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field contains the name of the facility placing the order.

Table C.8-8: Element ORC-21 Ordering Facility Name (XON)

Component/Sub-Component	Usage	LEN	Comment
Organization Name (ST)	R	50#	

ORC-27 Filler's Expected Availability Date/Time (TS), not supported (Analyzer Manager), required if available from Analyzer (Analyzer).

This field specifies the date and optional time the filler expects the results to be available. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. Degree of precision component is not supported.

Table C.8-9: Element ORC-27 Filler's Expected Availability Start Date/Time (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDD[HHMMSS]	R	8/14	Date/time results are expected to be available

C.9 PID Segment

This segment is only used with the LAW_PAT_DEM Profile Option (see Section 2.2.4.5).

The PID segment is used by all applications as the primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change frequently.

This segment allows an Analyzer to use patient demographic information for additional clinical evaluation of a test result, and to indicate when patient demographic information is applicable for the observations reported. Only a minimal set of identifying data is specified, as it is the responsibility of the Analyzer Manager to maintain patient demographic information. The scope of the PID segment in the context of LAW is the message only. Within LAW, the PID segment is not used to manage patient records, but rather to provide additional context for orders and observations.

Table C.9-1: PID Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
3	278	CX	R	R	[1..1]		00106	Patient Identifier List
5	250	XPN	R	R	[1..1]		00108	Patient Name
7	26	TS	RE	RE.AN	[0..1]		00110	Date/Time of Birth
8	1	IS	RE	RE.AN	[0..1]	0001	00111	Administrative Sex
10	250	CE	RE	RE.AN	[0..1]	0005	00113	Race
35[1]	250	CWE	RE	RE.AN	[0..1]		01539	Taxonomic Classification Code

Note 1: This usage was pre-adopted from HL7 v2.8.1

PID-3 Patient Identifier List (CX), required.

For the LAW Profile, this field contains the identifier used to uniquely identify a patient. The field is constrained to just one identifier, because it is the responsibility of the Analyzer Manager to manage multiple identifiers used by the healthcare facility (medical record number, billing number, birth registry, etc.). The Analyzer should not receive multiple identifiers for the same patient.

If the identifier is not applicable, then the field is set to NULL (""). This may occur when an Analyzer is using the PID segment to identify demographic information applicable to the observation, such as PID-7 Date/Time of Birth, but does not use or maintain the patient identifier. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete the patient identifier from patient data records maintained by the Analyzer Manager.

PaLM TF-2x: A.1 specifies the usage for CX.4 “Assigning Authority” as Required. In most cases this information is not needed when exchanging patient identification information in the LAW transactions. It is the responsibility of the Analyzer Manager to manage the list of patient identifiers and not the Analyzer, and the Analyzer is not required to persist information about the Assigning Authority.

Table C.9-2: Element PID-3 Patient Identifier List (CX)

Component/Sub-Component	Usage	LEN	Comment
ID (ST)	R	50	Locally defined
Assigning Authority (HD)	RE	227	
Namespace ID (IS)	RE	20	
Universal ID (ST)	RE	199	
Universal ID Type (ID)	C (R/X)	6	Must be populated if PID-3-4-2 is populated; otherwise is not supported

If all three sub-components of PID-3-4 Assigning Authority are populated, they must reference the same entity.

Note on Element Length: The maximum element length for PID-3-1 has been extended to 50 characters from the HL7-prescribed length of 15 characters. This extension allows sending systems to use globally unique identifiers (such as GUIDs) for patient IDs.

PID-5 Patient Name (XPN), required.

This element contains the legal name of the patient.

If the patient name is not applicable, then the field is set to NULL (""). This may occur when an Analyzer is using the PID segment to identify demographic information applicable to the observation, such as PID-7 Date/Time of Birth, but does not use or maintain the patient name. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete the patient name from patient data records maintained by the Analyzer Manager.

XPN.7 SHALL be populated with the value “L” from HL7 Table 0200 – Name type, which is the code for “Legal”.

Table C.9-3: Element PID-5 Patient Name (XPN)

Component/Sub-Component	Usage	LEN	Comment
Family Name (FN)	RE		
Surname (ST)	RE	20#	Last Name
Given Name (ST)	RE	20#	First name
Second and Further Given Names or initials Thereof (ST)	RE	20#	Multiple middle names may be included by separating them with spaces

Component/Sub-Component	Usage	LEN	Comment
Suffix (e.g., JR or III) (ST)	RE	10#	A name suffix
Name Type Code (ID)	R	1	Always "L"

PID-7 Date/Time of Birth (TS), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field contains the patient's date and optional time of birth to support neonatal patient specimens where hours/minutes is a significant criteria. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. Degree of precision component is not supported.

Table C.9-4: Element PID-7 Date/Time of Birth (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDD[HHMMSS]	R	8/14	Date/time of birth

PID-8 Administrative Sex (IS), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field contains the patient's sex. Can be blank or contain only a value from HL7 User-defined Table 0001 (see below).

Table C.9-5: HL7 User-defined Table 0001 – Administrative Sex

Value	Description	Comment
F	Female	
M	Male	
U	Unknown	

PID-10 Race (CE), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field refers to the patient's race. This value may be forbidden in some countries (e.g., France), and thus will never available in those locations. The code can be a value from HL7 User-defined Table 0005 – Race or a vendor-defined code.

Table C.9-6: Element PID-10 Race (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Value from HL7 User-defined Table 0005or vendor-defined value
Text (ST)	RE	199	Description from HL7 User-defined Table 0005 or vendor defined description
Name of Coding System (ID)	R	12	Fixed "HL70005" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

PID-35 Taxonomic Classification Code (CWE), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field is a code representing the taxonomic classification (e.g., species and/or breed) of an organism. This may include the common or scientific name in the description component, based on the coding system(s) used. If this field is not valued, a human is assumed. The code may be drawn from the organism hierarchy in SNOMED CT® or from a vendor defined code system.

Table C.9-7: Element PID-35 Taxonomic Classification Code (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined value
Text (ST)	RE	199	Description from vendor defined description
Name of Coding System (ID)	R	12	"99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

C.10 PV1 Segment

HL7 v2.5.1: chapter 3 (3.4.3 PV1 – Patient Visit Segment).

This segment is used with the LAW_PAT_DEM Profile Option (see Section 2.2.4.5).

The PV1 segment is to communicate patient location information.

Table C.10-1: PV1 Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
2	1	IS	R	R	[1..1]	0004	00132	Patient Class

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
3	80	PL	RE	RE	[0..1]		00133	Assigned Patient Location

PV1-2 Patient Class (IS), required.

This field is used by systems to categorize patients by site. The field must contain a value taken from HL7 User-defined Table 0004 Patient Class. The values defined by the standard and adopted for use by the LAW Profile are shown below.

If Patient Class information is not maintained by the Analyzer, the field should be populated with 'N'.

Table C.10-2: HL7 User-defined Table 0004 – Patient Class

Value	Description	Comment
E	Emergency	
I	Inpatient	
O	Outpatient	
P	Preadmit	
R	Recurring Patient	
B	Obstetrics	
C	Commercial Account	
N	Not Applicable	Used when the value is not maintained by the Analyzer
U	Unknown	

PV1-3 Assigned Patient Location (PL), required if available.

This field contains the patient's initial assigned location or the location to which the patient is being moved. Only the second component of this field is supported.

Table C.10-3: Element PV1-3 Assigned Patient Location (PL)

Component/Sub-Component	Usage	LEN	Comment
PV1-3-2 Room (IS)	R	16#	

C.11 SAC Segment

HL7 v2.5.1: chapter 13 (13.4.5 SAC – Specimen Container Detail Segment).

The SAC segment is used to describe the specimen container.

Table C.11-1: SAC Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
3	80	EI	C (M/X)	C (M/X)	[0..1]		01331	Container Identifier
4	80	EI	C (M/X)	C (M/X)	[0..1]		01332	Primary (parent) Container Identifier
9	250	CE	LAW_CONTAINER (RE/X)	X	[0..1]		0378	Carrier Type
10	80	EI	C (M/X)	RE	[0..1]		01337	Carrier Identifier
11	80	NA	C (M/X)	RE	[0..1]		01338	Position in Carrier
13	80	EI	C (M/X)	RE	[0..1]		01340	Tray Identifier
14	80	NA	C (M/X)	RE	[0..1]		01341	Position in Tray
15	250	CE	C (RE/X)	RE	[0..*]			Location
21	20	NM	LAW_CONTAINER (RE/X)	X	[0..1]		00644	Container Volume
22	20	NM	LAW_CONTAINER (RE/X)	X	[0..1]		01349	Available Specimen Volume
24	250	CE	LAW_CONTAINER (RE/X)	X	[0..1]		01351	Volume Units
29	20	SN	LAW_CONTAINER (RE/X)	X	[0..1]		01356	Dilution Factor

SAC-3 Container Identifier (EI), conditional.

This field identifies the container. This field is the container's unique identifier assigned by the corresponding equipment. It is expected that the Container ID here is normally encoded as the ID (barcode, RFID) on the sample container. A container may contain the primary (original) specimen or an aliquot (secondary sample) of that specimen. The field is empty when the aliquot sample is identified by a carrier (SAC-10/11) or tray (SAC-13/14) location.

When sent by the Analyzer in AWOS Status Change [LAB-29], the field must be set to NULL ("") in instances where the container identifier does not exist or is not applicable. One example is reporting a result for an order generated at the Analyzer based on a non-barcoded container. This field is set to NULL ("") and the Analyzer may identify the container by populating SAC-10/11 (carrier information) or SAC-13/14 (tray information). Another example is the creation of a reflex result from parent results associated with multiple containers. In this situation, there is no container associated with the result. The use of NULL ("") by the Analyzer should not be

interpreted as a requirement to delete container information from container data records maintained by the Analyzer Manager.

See Section B.1 for more details on specimen identification.

Predicate: The usage of SAC-3 is related to SAC-4. Either SAC-3 or SAC-4 or both must be populated.

Table C.11-2: Element SAC-3 Container Identifier (EI)

Component/Sub-Component	Usage	C.LEN	Comment
Entity Identifier (ST)	R	50	Container ID

SAC-4 Primary (Parent) Container Identifier (EI), conditional.

If this field is populated, then it identifies the primary container from which this specimen came. For primary samples this field is empty; for aliquot samples this field should contain the identifier of primary container.

See Section B.1 in Appendix B for more details on specimen identification.

Predicate: The usage of SAC-4 is related to SAC-3. Either SAC-3 or SAC-4 or both must be populated.

Table C.11-3: Element SAC-4 Primary (Parent) Container Identifier (EI)

Component/Sub-Component	Usage	C.LEN	Comment
Entity Identifier (ST)	R	50	Parent Container ID

SAC-9 Carrier Type (CE), required if available (Analyzer Manager, and Analyzer supports LAW_CONTAINER), otherwise not supported.

This field specifies the type of carrier where this container is located.

Table C.11-4: Element SAC-9 Carrier Type (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Value from HL7 User-defined Table 0378
Text (ST)	RE	199	Description from HL7 User-defined Table 0378
Name of Coding System (ID)	R	7	Fixed “HL70378”

SAC-10 Carrier Identifier (EI), conditional (Analyzer Manager), required if available (Analyzer).

This field specifies the rack identifier.

See Section B.1 in Appendix B for more details on specimen identification.

Analyzer Manager Predicate: The usage of SAC-10 is related to SAC-3, SAC-4 and SAC-13. If SAC-3 is not populated but SAC-4 is populated, then SAC-10 or SAC-13 must be populated.

Table C.11-5: Element SAC-10 Carrier Identifier (EI)

Component/Sub-Component	Usage	C.LEN	Comment
Entity Identifier (ST)	R	50	Rack ID

SAC-11 Position in Carrier (NA), conditional (Analyzer Manager), required if available (Analyzer).

This field identifies the position of the container in the carrier (e.g., 1…3…). The sub-components allow, if necessary, to transfer multiple axis information, e.g., 2-dimensional carrier (X~Y).

Analyzer Manager Predicate: Usage is Mandatory if SAC-10 is populated. Otherwise usage is Not Supported.

Table C.11-6: Element SAC-11 Position in Carrier (NA)

Component/Sub-Component	Usage	LEN	Comment
Value1 (NM)	M	16	Position within Rack as an Integer
Value2 (NM)	O	16	
Value2 (NM)	O	16	
…	O	16	

SAC-13 Tray Identifier (EI), conditional (Analyzer Manager), required if available (Analyzer).

This field identifies the tray identifier (e.g., a number of a tray or a bar code on the tray), where the sample is located.

See Section B.1 for more details on specimen identification.

Analyzer Manager Predicate: The usage of SAC-10 is related to SAC-3, SAC-4, and SAC-13. If SAC-3 is not populated but SAC-4 is populated, then SAC-10 or SAC-13 must be populated.

Table C.11-7: Element SAC-13 Tray Identifier (EI)

Component/Sub-Component	Usage	C.LEN	Comment
Entity Identifier (ST)	R	50	Tray ID

SAC-14 Position in Tray (NA), conditional (Analyzer Manager), required if available (Analyzer).

This field identifies the position of the sample in the tray. The sub-components allow, if necessary, to transfer multiple axis information, e.g., 2-dimensional tray (X^Y).

Analyzer Manager Predicate: Usage is Mandatory if SAC-13 is populated. Otherwise usage is Not Supported.

Table C.11-8: Element SAC-14 Position in Tray (NA)

Component/Sub-Component	Usage	LEN	Comment
Value1 (NM)	M	16	Position within tray as an Integer
Value2 (NM)	O	16	
Value2 (NM)	O	16	
…	O	16	

SAC-15 Location (CE), conditional (Analyzer Manager), required if available (Analyzer).

This field contains additional information about the physical location of the sample. This field must be used in combination with the physical location/position of the sample on either a carrier or a tray and is used to further clarify the location.

Analyzer Manager Predicate: Usage is Required if Available if SAC-10 or SAC-13 is populated. Otherwise usage is Not Supported.

Table C.11-9: Element SAC-15 Location (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Additional location information defined by the vendor
Text (ST)	RE	199	Vendor description
Name of Coding System (ID)	R	12	Vendor-defined coding system name “99zzz” (where z is an alphanumeric character)

SAC-21 Container Volume (NM), required if available (Analyzer Manager, and Analyzer supports LAW_CONTAINER), otherwise not supported.

This field indicates the capacity of the container in the units specified in SAC-24 Volume Units.

SAC-22 Available Specimen Volume (NM), required if available (Analyzer Manager, and Analyzer Supports LAW_CONTAINER), otherwise not supported.

This field identifies the current specimen volume available for use in this container in the units specified in SAC-24 Volume Units.

SAC-24 Volume Units (CE), required if available (Analyzer Manager, and Analyzer supports LAW_CONTAINER), otherwise not supported.

This field is populated with the unit of measure for the result, as described in 2.3.2.

Table C.11-10: Element SAC-24 Volume Units (CE)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	RE	UCUM coded unit of measure
Text (ST)	199	R	Vendor human-readable unit
Name of Coding System (ID)	4	C (R/X)[1]	Fixed "UCUM" (value pre-adopted from HL7 v2.6)

Note 1: Predicate: Name of Coding System must be populated if Identifier is populated.

SAC-29 Dilution Factor (SN), required if available (Analyzer Manager, and Analyzer supports LAW_CONTAINER), otherwise not supported.

This field identifies the factor of dilution already performed on the specimen. If a manual/offline dilution has been performed on the specimen prior to presenting it to the Analyzer, then this value will be populated with the dilution factor.

Table C.11-11: Element Dilution Factor (SN)

Component/Sub-Component	Usage	LEN	Comment
Comparator (ST)	X		
Num1 (NM)	R	1	Always '1'
Separator/Suffix (ST)	R	1	Always ':'
Num2 (NM)	R	15	Positive Number (e.g., 2, 5.5)

C.12 SPM Segment

HL7 v2.5.1: chapter 7 (7.4.3 SPM – Specimen Segment).

The SPM segment is used to describe the characteristics of a single specimen. The SPM segment relays information about the type of specimen and the date/time the specimen was received. It differs from the intent of the OBR segment in that the OBR addresses order-specific information.

It differs from the SAC segment in that the SAC addresses specimen container attributes and the ID that is normally encoded on the sample container (barcode, RFID tag, etc.).

In the case of an AWOS related to a single patient, the specimen role is "patient" (SPM-11 = P) and the specimen properties type, collection method, collection date, source site, source site modifier, and risk always represent the primary specimen that was collected from the patient, even in the case where the current specimen used by the AWOS is an aliquot or an isolate (a pure colony of a microorganism obtained after culture).

Table C.12-1: SPM Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL #	ITEM #	Element name
1	4	SI	M	M	[1..1]		01754	Set ID-SPM
2	80	EIP	LAW_SPECIMEN (RE/X)	LAW_SPECIMEN (RE.AN/X)	[0..1]		01755	Specimen ID
3	80	EIP	LAW_POOL_NOAN (R/X) LAW_SPECIMEN (RE/X)	LAW_SPECIMEN (RE.AN/X)	[0..*]		01756	Specimen Parent IDs
4	250	CWE	M	M	[1..1]	0487	01900	Specimen Type
7	250	CWE	LAW_SPECIMEN (RE/X)	X	[0..1]	0488	01759	Specimen Collection Method
8	250	CWE	LAW_SPECIMEN (RE/X)	X	[0..1]		01901	Specimen Source Site
9	250	CWE	LAW_SPECIMEN (RE/X)	X	[0..1]	0542	01760	Specimen Source Site Modifier
11	250	CWE	M	M	[1..1]	0369	01762	Specimen Role
13	6	NM	LAW_POOL_NOAN (R/X)	LAW_POOL_NOAN (R/X)	[0..1]		01763	Grouped Specimen Count
16	250	CWE	LAW_SPECIMEN (RE/X)	X	[0..1]	0489	01903	Specimen Risk Code
17	26	DR	LAW_SPECIMEN (RE/X)	X	[0..1]		01765	Specimen Collection Date/Time
18	26	TS	LAW_SPECIMEN (RE/X)	X	[0..1]		00248	Specimen Received Date/Time
27	250	CWE	LAW_SPECIMEN (RE/X)	X	[0..1]		01773	Container Type

SPM-1 Set ID (SI), mandatory.

This field contains the sequence number for the specimens.

Within the LAW Profile, the sequence number is set to '1'for the first occurrence of the SPM segment. All occurrences of the SPM that follow are sequentially numbered within a message.

SPM-2 Specimen ID (EIP), required if available (Analyzer Manager with LAW_SPECIMEN), required if available from Analyzer (Analyzer with LAW_SPECIMEN).

This field contains the specimen identifier. It may be the enterprise-wide unique specimen identifier.

Table C.12-2: Element SPM-2 Specimen ID (EIP)

Component/Sub-Component	Usage	LEN	C.LEN	Comment
Placer Assigned Identifier (EI)	R			
Entity Identifier (ST)	R		50	
Namespace ID (IS)	C (R/RE)[1]	20		
Universal ID (ST)	C (R/RE)[1]	199		
Universal ID Type (ID)	C (R/RE)[1]	6		

Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all be present.

SPM-3 Specimen Parent ID (EIP), required (Analyzer with LAW_POOL_NOAN), required if available (Analyzer Manager with LAW_SPECIMEN), required if available from Analyzer (Analyzer with LAW_SPECIMEN).

This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance.

When used with the LAW_POOL_NOAN Profile Option, this required field will contain the specimen identifiers of the specimens that were pooled.

Table C.12-3: Element SPM-3 Specimen Parent IDs (EIP)

Component/Sub-Component	Usage	LEN	C.LEN	Comment
Placer Assigned Identifier (EI)	R			
Entity Identifier (ST)	R		50	
Namespace ID (IS)	C (R/RE)[1]	20		
Universal ID (ST)	C (R/RE)[1]	199		
Universal ID Type (ID)	C (R/RE)[1]	6		

Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all be present.

SPM-4 Specimen Type (CWE), mandatory**.**

This field describes the precise nature of the entity that will be the source material for the observation. The values defined in HL7 Table 0487 – Specimen Type will be used. The Analyzer may define extensions to the table, and the Analyzer may identify a subset of specimen types that are supported.

This field is populated with a value from HL7 Table 0487 – Specimen Type if the SPM-11 Specimen Role is “P” (Patient specimen) or “L” (Pooled patient specimen). This field is populated with NULL ("") if the SPM-11 Specimen Role is “Q” (Control specimen) or “U” (Unknown specimen as part of a Negative Query Response).

For some Analyzers, the AWOS performed is not impacted by the Specimen Type. The field must also be set to NULL ("") when sent by an Analyzer if the specimen type is not applicable for the AWOS(s).

The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete specimen information from specimen data records maintained by the Analyzer Manager.

Table C.12-4: Element SPM-4 Specimen Type (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from HL7 Table 0487, code from a vendor-defined coding system.
Text (ST)	RE	199	Description from HL7 Table 0487, or vendor-defined description
Name of Coding System (ID)	R	12	Fixed “HL70487” or “99zzz” for a vendor-defined coding system (where z is an alphanumeric character)

SPM-7 Specimen Collection Method (CWE), required if available (Analyzer Manager, and Analyzer supports LAW_SPECIMEN), otherwise not supported.

This field describes the procedure or process by which the specimen was collected.

Table C.12-5: Element SPM-7 Specimen Collection Method (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from HL7 Table 0488 or a vendor-defined coding system
Text (ST)	RE	199	Description of the specimen collection method

Component/Sub-Component	Usage	LEN	Comment
Name of Coding System (ID)	R	12	Fixed "HL70488" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

SPM-8 Specimen Source Site (CWE), required if available (Analyzer Manager, and Analyzer supports LAW_SPECIMEN), otherwise not supported.

This field specifies the source from which the specimen was obtained.

Table C.12-6: Element SPM-8 Specimen Source Site (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined value
Text (ST)	RE	199	Vendor description of the specimen source site
Name of Coding System (ID)	R	12	Vendor-defined coding system name "99zzz" (where z is an alphanumeric character)

SPM-9 Specimen Source Site Modifier (CWE), required if available (Analyzer Manager, and Analyzer supports LAW_SPECIMEN), otherwise not supported.

This field contains modifying or qualifying description(s) about the specimen source site.

This field should be populated by the placer in microbiology, when the specimen source site modifier is known. Example: "LEFT" when the specimen has been collected from the left ear. More than one source site modifier maybe populated.

The IHE PaLM Technical Framework does not recommend a specific vocabulary. HL7 User-defined Table 0453 does not suggest any values.

Table C.12-7: Element SPM-9 Specimen Source Site Modifier (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined vocabulary value
Text (ST)	RE	199	Vendor description of the specimen source site modifier
Name of Coding System (ID)	R	12	Vendor-defined coding system name "99zzz" (where z is an alphanumeric character)

SPM-11 Specimen Role (CWE), mandatory.

This identifies the role of the specimen to be a Patient, Pooled Patient, QC specimen, or Unknown in support of the LAW use cases and messaging constructs. However, an Analyzer

may extend the set with additional codes for HL7 Table 0369 or codes from a vendor-defined coding system.

Table C.12-8: Subset of HL7 User-defined Table 0369 – Specimen Role

Value	Description	Comment	LAB-28	LAW_POOL_NOAN
P	Patient specimen		Permitted	Excluded
Q	Control specimen		Permitted	Excluded
L	Pooled patient specimens	Specimens from multiple patients, number of pooled specimens is provided in SPM-13	Excluded	Required
U	Unknown specimen role	Unknown specimen role; used for negative query response in [LAB-28]; requires IHELAW for the Name of Coding System	Permitted	Excluded

Table C.12-9: Element SPM-11 Specimen Role (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	A code from the "Value" column of Table C.12-8 or HL70369, or a vendor-defined coding system
Text (ST)	RE	199	Text from the "Description" column of Table C.12-8 or HL70369, or a vendor-defined description
Name of Coding System (ID)	R	12	Fixed "HL70369" or "IHELAW" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

SPM-13 Grouped Specimen Count (NM), required (LAW_POOL_NOAN), otherwise not supported.

This field identifies the number of patient specimens that were pooled, and is only used by the LAW_POOL_NOAN Profile Option.

SPM-16 Specimen Risk Code (CWE), required if available (Analyzer Manager, and Analyzer supports LAW_SPECIMEN), otherwise not supported.

This field contains any known or suspected specimen hazards, e.g., exceptionally infectious agent or blood from a hepatitis patient.

Table C.12-10: Element SPM-16 Specimen Risk Code (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Risk code from HL7 Table 0489 or from a vendor-defined coding system

Component/Sub-Component	Usage	LEN	Comment
Text (ST)	RE	199	Description of the specimen risk code
Name of Coding System (ID)	R	12	Fixed "HL70489" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

SPM-17 Specimen Collection Date/Time (DR), required if available (Analyzer Manager, and Analyzer Manager supports LAW_SPECIMEN), otherwise not supported.

The date and time when the specimen was acquired from the source. Only the start date/time component is supported (i.e., first component).

This element SHALL be reported to a precision of seconds. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. The degree of precision component is not supported.

Table C.12-11: Element SPM-17 Specimen Collection Start Date/Time (DR)

Component/Sub-Component	Usage	LEN	Comment
Range Start Date/Time	R		
YYYYMMDDHHMMSS	R	14	When the specimen was collected

SPM-18 Specimen Received Date/Time (TS), required if available (Analyzer Manager, and Analyzer supports LAW_SPECIMEN), otherwise not supported.

The specimen received date/time is the time that the specimen is received at the diagnostic service. The actual time that is recorded is based on how specimen receipt is managed and may correspond to the time the sample is logged in. This is fundamentally different from SPM-17 Specimen Collection Date/Time.

This element SHALL be reported to a precision of seconds. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. The degree of precision component is not supported.

Table C.12-12: Element SPM-18 Specimen Received Start Date/Time (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDDHHMMSS	R	14	When the specimen was received

SPM-27 Container Type (CWE), required if available (Analyzer Manager, and Analyzer supports LAW_SPECIMEN), otherwise not supported.

The container type in or on which a specimen is transported.

Table C.12-13: Element SPM-27 Container Type (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Container type code from a vendor-defined coding system
Text (ST)	RE	199	Vendor description of the container type code
Name of Coding System (ID)	R	12	Vendor-defined coding system name “99zzz” (where z is an alphanumeric character)

C.13 TCD Segment

2755 HL7 v2.5.1: chapter 13 (13.4.10 TCD – Test Code Detail).

This segment is used to provide additional details about the service request or observation.

Table C.13-1: TCD Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL #	ITEM #	Element name
1	250	CE	R	R	[1..1]		00238	Universal Service Identifier
2	20	SN	LAW_DILUTIONS (RE/X)	LAW_DILUTIONS (RE/X)	[0..1]		01420	Auto-Dilution Factor
3	20	SN	LAW_DILUTIONS (RE/X)	X	[0..1]		01421	Rerun Dilution Factor
5	20	SN	LAW_DILUTIONS (RE/X)	X	[0..1]		01413	Endogenous Content of Pre-Dilution Diluent
6	1	ID	LAW_AM_RR_CONTROL (R/X)	X	[0..1]	0136	01416	Automatic Repeat Allowed
7	1	ID	LAW_AM_RR_CONTROL (R/X)	X	[0..1]	0136	01424	Reflex Allowed
8	250	CE	LAW_AM_RR (R/X)	X	[0..1]	0389	01525	Analyte Repeat Status
9[1]	242	CQ	RE	X	[0..1]		xxxxx	Specimen Consumption Quantity
10[2]	16	NM	LAW_POOL_AN (R/X)	LAW_POOL_AN (R/X)	[0..1]		xxxxx	Pool Size

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL #	ITEM #	Element name
11[2]	250	CWE	LAW_DILUTIONS (RE/X)	LAW_DILUTIONS (RE/X)	[0..1]		xxxxx	Auto-Dilution Type

Note 1: Preadopted from HL7 v2.9 per *OO CR157-791*

Note 2: Preadopted from HL7 v2.9 per *OO CR-795*

Usage Note:

When the Analyzer supports LAW_DILUTIONS and the Analyzer Manager has decided that a new run is to be performed with a particular dilution, it creates a new AWOS for this new run and sends it to the Analyzer. The auto-dilution factor (or type) is then conveyed in field TCD-2 (or TCD-11). This behavior is the same, irrespective of whether the Analyzer supports LAW_AM_RR or not.

Conversely, TCD-3 is used by the Analyzer Manager to convey the dilution factor that the Analyzer should apply when the Analyzer decides that a new run is needed.

TCD-1 Universal Service Identifier (CE), required.

This field contains the same value as OBR-4 Universal Service Identifier when used by the Analyzer Manager in AWOS Broadcast [LAB-28]. This field contains the same value as OBX-3 Observation Identifier when used by the Analyzer in AWOS Status Change [LAB-9].

Table C.13-2: Element TCD-1 Universal Service Identifier (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Test/Battery Identifier
Text (ST)	R	199	Name for the test/battery
Name of Coding System (ID)	R	12	"LN" for LOINC®, "JC10" for JLAC10, or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

TCD-2 Auto-Dilution Factor (SN), required if available (Analyzer supports LAW_DILUTIONS), otherwise not supported.

When sent by the Analyzer Manager in AWOS Broadcast [LAB-28], this field is the value that is to be used as the factor for automatically diluting a particular specimen by an instrument for this particular test code. When sent by the Analyzer in [LAB-29] AWOS Status Change, this was the dilution factor used for the test result.

Table C.13-3: Element TCD-2 Auto-Dilution Factor (SN)

Component/Sub-Component	Usage	LEN	Comment
Comparator (ST)	X		
Num1 (NM)	R	1	Always 1
Separator/Suffix (ST)	R	1	In [LAB-28]: one of: • ":" – dilution factor is provided in TCD-2-4 • "+" – dilution factor is to be determined by the Analyzer • "-" – concentration factor is to be determined by the Analyzer In[LAB-29]: always "**:**"
Num2 (NM)	C (R/X)	15	Positive Number (e.g., 2, 5.5) This component is required, if TCD-2-3 "Separator/ Suffix" equals to "**:**"; otherwise, its usage is prohibited.

TCD-3 Rerun Dilution Factor (SN), required if available (Analyzer Manager, and Analyzer supports LAW_DILUTIONS), otherwise not supported.

This field is the value that is to be used as the factor for automatically diluting a particular specimen in case of rerun for this particular test code.

Table C.13-4: Element TCD-3 Rerun Dilution Factor (SN)

Component/Sub-Component	Usage	LEN	Comment
Comparator (ST)	X		
Num1 (NM)	R	1	Always 1
Separator/Suffix (ST)	R	1	Always :
Num2 (NM)	R	15	Positive Number (e.g., 2, 5.5)

TCD-5 Endogenous Content of Pre-Dilution Diluent (SN), required if available (Analyzer Manager, and Analyzer supports LAW_DILUTIONS), otherwise not supported.

This field is to be used when the pre-dilution diluent is not biochemically neutral in the context of the test to be performed, i.e., when it does intrinsically contain the analyte and can distort the measured value in that way. The analyte concentration in the diluent SHALL be provided in this field and taken into account when calculating the final observation result.

Table C.13-5: Element TCD-5 Endogenous Content of Pre-Dilution Diluent (SN)

Component/Sub-Component	Usage	Comment
Comparator (ST)	X	

Component/Sub-Component	Usage	Comment
Num1 (NM)	R	Always "1"'
Separator/Suffix (ST)	R	Always ":"
Num2 (NM)	R	Positive Number (e.g., 2, 5.5)

TCD-6 Automatic Repeat Allowed (ID), required if available (Analyzer Manager, and Analyzer supports LAW_AM_RR_CONTROL), otherwise not supported.

This field identifies whether or not automatic repeats are to be initiated for this particular specimen for this particular test code. Refer to *HL7 Table 0136 -Yes/no indicator* for valid values.

Table C.13-6: HL7 Table 0136 – Yes/no indicator

Value	Description	Comment
Y	Yes	Repeat/rerun is allowed
N	No	Repeat/rerun is not allowed

TCD-7 Reflex Allowed (ID), required if available (Analyzer Manager, and Analyzer supports LAW_AM_RR_CONTROL), otherwise not supported.

This field identifies whether or not automatic or manual reflex testing is to be initiated for this particular specimen. Refer to *HL7 Table 0136 -Yes/no indicator* for valid values.

Table C.13-7: HL7 Table 0136 – Yes/no indicator

Value	Description	Comment
Y	Yes	Reflex is allowed
N	No	Reflex is not allowed

TCD-8 Analyte Repeat Status (CE), required if available (Analyzer Manager, and Analyzer supports LAW_AM_RR), otherwise not supported.

This field identifies the repeat status for the analyte/result (e.g., original, rerun, repeat, reflex). Refer to the following table for valid values.

Table C.13-8: HL7 Table 0389 – Analyte repeat status

Value	Description	Comment
O	Original, first run	
R	Repeated without dilution	performed usually to confirm correctness of results (e.g., in case of results flagged as "Panic" or mechanical failures)

Value	Description	Comment
D	Repeated with dilution	performed usually in the case the original result exceeded the measurement range (technical limits)
F	Reflex test	This test is performed as the consequence of rules triggered based on other test result(s)

Table C.13-9: Element TCD-8 Analyte Repeat Status (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Analyte repeat status code from "Value" column of Table C.13-8
Text (ST)	R	199	Text from "Description" column of Table C.13-8
Name of Coding System (ID)	R	7	Fixed "HL70389"

TCD-9 Specimen Consumption Quantity (CQ), required if available (Analyzer Manager), not supported (Analyzer).

This field is pre-adopted from HL7 v2.9.

This field determines how much of the specimen is to be consumed in each run of the given test; for some types of equipment, observation accuracy depends on this parameter. Quantity units from the UCUM coding system SHALL be used.

Table C.13-10: Element TCD-9 Specimen Consumption Quantity (CQ)

Component/ Sub-Component Index	Component/ Sub-Component	Usage	LEN	Comment
TCD-9.1	Quantity (NM)	R	16	Specimen quantity
TCD-9.2	Quantity Units (CE)	R	225	Specimen quantity units
TCD-9.2.1	Identifier (ST)	R	20	Coded unit of measure
TCD-9.2.2	Text (ST)	O	199	Textual description
TCD-9.2.3	Name of coding system (ID)	R	4	Fixed "UCUM" (value pre-adopted from HL7 v2.6)

TCD-10 Pool Size (NM), required (LAW_POOL_AN), otherwise not supported.

This field is pre-adopted from HL7 v2.9, and is only used with LAW_POOL_AN.

Only positive integer values are allowed.

In AWOS Broadcast [LAB-28] (in the group OBSERVATION_REQUEST), this field defines the maximal size of the pool the given specimen may be combined into (or "1", if pooling of the given specimen is not allowed).

In AWOS Broadcast [LAB-28] (in the group OBSERVATION) and AWOS Status Change [LAB-29], this field contains the actual size of the pool the given specimen has been combined into (or "1", if the specimen was not pooled).

TCD-11 Auto-Dilution Type (CWE), required if available (Analyzer supports LAW_DILUTIONS), otherwise not supported.

This field is pre-adopted from HL7 v2.9 and can be used instead of TCD-2 "Auto-Dilution Factor" or along with it. TCD-11 contains a code of the auto-dilution factor and/or the auto-dilution protocol pre-configured on the Analyzer. For example, code "D1" may mean dilution 1:20, code "D2" — 1:30, and so forth.

Table C.13-11: Element TCD-11 Auto-Dilution Type (CWE)

Component/ Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined auto-dilution type code
Text (ST)	O	199	Textual description
Name of coding system (ID)	R	12	Vendor-defined coding system ID "99zzz" (where z is an alphanumeric character)

If both TCD-2 "Auto-Dilution Factor" and TCD-11 "Auto-Dilution Type" are populated, they SHALL not contradict each other.

C.14 TQ1 Segment

HL7 v2.5.1: chapter 4 (4.5.4 TQ1 – Timing/Quantity Segment).

This segment is used to provide the priority of the service request, and is only used with the LAW_AWOS_PRIORITY Profile Option (see Section 2.2.4.10).

Table C.14-1: TQ1 Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
9	250	CWE	R	R	[1..1]	0485	01635	Priority

TQ1-9 Priority (CWE), required.

This field identifies the priority of the order. The first component (i.e., Identifier) can contain a value taken from HL7 User-defined Table 0485 (see below) or from a vendor-defined code system.

Table C.14-2: Subset of HL7 User-defined Table 0485 – Extended Priority Codes

Value	Description	Comment
R	Routine	
S	Stat	

2855 **Table C.14-3: Element TQ1-9 Priority (CWE)**

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from "Value" column of Table C.14-2 or from a vendor-defined coding system
Text (ST)	RE	199	Text from "Description" column of Table C.14-2 or vendor-defined description
Name of Coding System (ID)	R	12	Fixed "HL70485" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

Glossary

The IHE Glossary can be found as an appendix to the *IHE Technical Frameworks General Introduction* published on this page.

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