Integrating the Healthcare Enterprise

IHE Laboratory (LAB)
Technical Framework Supplement

Laboratory Analytical Workflow (LAW)

Trial Implementation

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Foreword

This is a supplement to the IHE Laboratory Technical Framework V4.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published for Trial Implementation on October 2, 2012 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Laboratory Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/laboratory/laboratorycomments.cfm.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

Replace Section X.X by the following:

General information about IHE can be found at: www.ihe.net

Information about the IHE Laboratory domain can be found at: http://www.ihe.net/Domains/index.cfm

Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm

CONTENTS

Introduction

Profile Abstract

Laboratories and their vendors spend a great deal of time and money connecting analyzers and IT systems to one another. This is a worldwide challenge that results from inconsistency in the way that data exchange standards are applied in most modern laboratory equipment.

The purpose of the new LAW profile is to improve interoperability between IVD testing systems and health informatics systems by reducing complexity and variability in the exchange of information related to patient and QC test orders and to the result thereof. The exchange of any other information is currently out of scope but could be considered in further revisions.

Summary of changes brought to LAB TF by this profile

The integration of this supplement shall bring the following changes to the LAB TF:

Volume 1:

- 1.7 Scope of changes introduced in the current year
- 1.11 Glossary: New terms
- Add a new chapter describing LAW profile
- Update LDA profile, by deprecating the Analyzer Actor and the transactions used by it.
- Appendix A: revise actors descriptions as needed
- Appendix B: revise transactions descriptions as needed
- Volume 2:
- 1.6 Scope of changes introduced in the current year
- Add new chapters for the transactions of the LAW profile
- Remove the AWOS related stuff from the LDA transactions

Open Issues

LAW-15: Support for GB18030-2005 as a Character. Determine if GB18030-2005 needs to be supported as a character set due to Chinese regulations.

LAW-18: Using UCUM in W.1A.4, OBX-6, and SAC-25. Guidance needs to be provided for using UCUM for the contents of OBX-6 and SAC-25. Additional information in section W.1A.4 could be beneficial.

LAW-22: Confirm Definition of SID-1.1 is acceptable. SID-1.1 is further decomposed into additional subcomponents so that it contains information similar to INV-1 and INV-3. Need to confirm this is acceptable as it extends the HL7 2.5.1 standard.

LAW-28: Format the Supplement Based on the Latest IHE Templates. Update content to match latest template for profile supplements.

Closed Issues

LAW-01: Patient Specimens pooling in the analytical workflow. The scope of the Laboratory TF is extended to support the use cases whereby samples from multiple patients are pooled into a single specimen. This use case happens for instance with some bio molecular diagnostic analysis. The only profile impacted by this use case is the LAW profile, in case the Analyzer Manager Actor manages the pooling of patient samples, and the analyzer has to be informed that the specimen is pooled. The specificity is that the ordering and results messages in this use case are not related to any patient, since the specimen tested is not related to a single patient. The analyzer has to be informed of the number of patients pooled in the specimen since this influences the testing (dilution of a positive sample in a pool of negative ones). This use case is described in both Volume 1 and 2 of the profile.

LAW-02: Enhanced acknowledgement versus original acknowledgement. For compatibility with implementations relying on LAB profiles, as well as with IT Infrastructure leveraged by the LAB profiles, the IHE LAB TF will stick to its original acknowledgement mode for most of its transactions. However, the enhanced acknowledgement mode shall be required in the new "Laboratory Analytical Workflow" profile. This mode will be operated as follows: The sending application shall populate field MSH-15 with value "ER" and field MSH-16 with value "AL", thus instructing the receiving application to send an "accept acknowledgement" only in case of error at this level (e.g., communication error, unavailability of the safe storage in to which the message cannot be saved) and to send an applicative acknowledgement in all other cases. Thus there shall be always one and only one acknowledgement message coming back to the sending application.

LAW-03: Broadcast mode versus Query mode for transmission of an AWOS to an Analyzer. Broadcast mode puts a storage burden on the Analyzers, as they must persist more WOSs than will actually be run on the analyzer. Additional communication between Analyzers and the Analyzer Manager is also required due to the transmission of the orders to all potential instruments and the follow up cancel message, or update message.

Query mode puts a processing and communication burden on the Analyzer Manager and Analyzers. Once the specimen is presented to the Analyzer, the query must be communicated to the Analyzer Manager and query response must be received in a timely manner. The assumption is that the Analyzer is ready to process the specimen and Analyzer throughput will be impacted by delays in the query response.

Based on an analysis of the two modes, it is recommended that Query Mode be mandatory, and Broadcast Mode left optional.

Query Mode was selected as a mandatory AWOS transmit mode for the following reasons:

- It is supported by most recent generation analyzers and is commonly used.
- It supports the Client-Server paradigm where the analyzer (client) makes a request of the server (Analyzer Manager) for information.
- It reduces the messaging overhead by eliminating unnecessary messages. A message transaction is initiated only when a sample is presented to an analyzer.
- It minimizes the messaging and storage impacts on the analyzer by eliminating the transmission of work order steps and cancellation of work order steps for tests that will not be performed by the analyzer, as well as the forwarding of updates (like patient identity correction or clinical information correction) on AWOS formerly transmitted to the Analyzer.

LAW-04: Selection of the baseline standard, HL7. HL7 version 3 has been put aside mainly for complexity and lack of adoption. The orientation will be a compromise between two goals:

- Use the state-of-the art version 2 available at time of profile release (e.g., 2.7).
- Market readiness: Use a version that the vendors are ready to implement (e.g., 2.5.1).

The consensus of the messaging team was to use v2.5.1 for the following reasons:

- The use of versions after v2.5.1 might be considered an obstacle to adoption
- The team's experience indicates that v2.5.1 contains the core elements necessary to support the Volume I use cases

LAW-05: "Sequential" versus "Overlapping" queries for AWOS on a specimen. Two messaging approaches have been identified that support an Analyzer query for pending AWOS on a specimen.

- Sequential query: The analyzer sends a query for a specimen and waits for the applicative response before sending another query for another specimen.
- Overlapping query: The analyzer does not have to wait for the response of the prior query before sending the next one.

In both approaches, the response from the Analyzer Manager comes in two messages. The first one simply acknowledges the query and notifies the intent to treat it but does not contain any

operational data. Then the effective search for existing AWOS is performed and the output is the operational response to the query, as an OML^O33 message. The two pending issues are:

- What pair of messages to be used for the query and acknowledgement (QBP/RSP or SSU/ACK), in one or the other approach or in both? The QBP/RSP message will be used for the query, since this is a query for an AWOS and not a specimen status update.
- What field is to be used to notify "no pending AWOS for this specimen" in the operational response message? The decision is to use ORC-1 with a value of DC, and no observation request segment group is provided.

LAW-06: Time of uniqueness of the AWOS identifier. The profile states (section X.2, second to last paragraph) that the Analyzer Manager must guarantee uniqueness of the AWOS ID. One possible method suggested is unique over a reasonable period of time-frame to be established by the Analyzer Manager vendor. This takes into account market-readiness and the objectives of this profile in terms of reducing the daily cost of device interfaces.

LAW-07: Use of Cancel/New rather than Update in X.2 Use Cases. The LAW profile use cases should reflect that in order to update an AWOS, the AWOS must be cancelled and a new AWOS transmitted. An update of an existing AWOS is not supported. Modifications were made to *X.2.1.a AWOS broadcast by the Analyzer Manager before specimen arrival*, *X.2.2 AWOS Query by the Analyzer at specimen arrival,* and *X.2.3 AWOS created at the Analyzer* to reflect this approach.

LAW-08: Correct Use Case Titles in Figure 5-1. The use case titles in the figure need to be corrected. For example, X.2.3 is "AWOS Created at the Analyzer". A new diagram was created that corrected the use case names and also provided an improved organization of the use case execution. The figure was designation was also changed to Figure X.2.7-1.

LAW-09: Update Figure X.6.2-1, X.6.3-1, X.6.6-1. The title if LAB-28 was changed to "Broadcast AWOS" in all X.6.x figures.

LAW-10: Correct Process Flow X.6.1 and Figure X.6.1. The process flow and diagram were updated to reflect the use the two-part message exchange (LAB-27 followed by LAB-28) for a query.

LAW-11: Correct Process Flow X.6.3 and Figure X.6.3-1. The process flow and diagram were updated to reflect the use of a Cancel followed by a New Order for an AWOS update.

LAW-12: Correct Process Flow Figure X.6.7-1 associated with Process Flow X.6.7. The diagram was corrected to use a LAB-27 followed by a LAB-28 for the query exchange. The process flow was updated.

LAW-13: Update Element Tables to be consistent across all Segments. The tables were updated to provide more consistency.

LAW-14: Define Value(s) for MSH-3. The profiles specifies only MSH 3.1 is required and it is a vendor specific value of type IS, which supports a user-defined table of legal string values.

LAW-16: Define Value(s) for MSH-21. Section W.3.4 describes that MSH-21 is populated by using MSH-21.1 and MSH-21.2 in the form "<domain>-<transaction number>^IHE". For example, "LAB-27^IHE" is used when the message represents LAB-27. All other components are removed from the element table.

LAW-17: Provide Guidance on use of OBR-29. Only the first field of EIP.1 will be populated with a Parent AWOS-IS.

LAW-19: Define Flags for OBX-8. A required set of flags that an Analyzer Manager should support is defined. In addition, it was noted that an Analyzer may extend the table with additional flags.

LAW-20: Check Completeness of Table 0085 used for OBX-11. Additional value for rerun or corrected result was added: "C – Record coming over is a correction and thus replaces a final result".

LAW-21: Provide Guidance on Supported Values for PID-10. The only guidance provided is that a user-defined table (HL7 User-defined Table 0005 - Race in the HL7 specification) should be used.

LAW-23: Confirm sub-component usage of SPM-2, SPM-3. Only SPM-2.1 and SPM-3.1 are specified to be populated. The sub-component Entity Identifier is required. Sub-components Namespace ID, Universal ID, and Universal ID Type are conditional. Either Namespace ID or both Universal ID and Universal ID Type are required.

LAW-24: Provide Additional Guidance on use of SPM-4. The use of HL7 table 0487 – Specimen Type is mandated, and the Analyzer can identify extensions to the table as well as a subset of specimen types that are supported.

L**AW-25: Update Diagram in Q.2, Q.4, R.2, R.4.** The diagrams, along with Y.2 and Y.4 were updated to use the Analyzer Manager and Analyzer actors.

370 **LAW-26: Update Diagram in R.4. T**he Order Modify exchange was removed.

LAW-27: Confirm W.1A.1, SPM-2, SPM-3, SAC-3, SAC-4 meet intent of CP 171. The message details, field definition, and field usage content related to container/specimen identification are consistent with CP 171.

Volume 1 – Integration Profiles

1.7 History of Annual Changes

Add the following bullet to the list in section 1.7

- Added the LAW Profile which supports the workflow of IVD test work order steps and the results thereof between IVD analyzers and the systems driving their work (LIS or LAS). This workflow has been removed from the LDA profile, which keeps only the workflow between automation managers and pre or post-processors.

1.11 Glossary

Add the following terms to the Glossary in section 1.11

IVD: In vitro diagnostic. This abbreviation is related to the processing of tests on in vitro specimens. A laboratory device (see term "LD") is usually an IVD device, and performs work order steps (see term "WOS").

LAW: Laboratory Analytical Workflow integration profile

Panel: Synonym for Battery (see this term)

Correct the following terms in the Glossary in section 1.11

AWOS Analytical Work Order Step: A WOS **in the LAW profile, representing a test or panel to be** performed on a specimen by an Analyzer ~~in LDA integration profile~~**, producing observations**.

LD A laboratory device: A Pre/Post processor in the LDA profile. An Analyzer in the LAW profile.

Work Order Step: A battery or test requested by the Order Filler Actor to the Automation Manager Actor

WOS: A Work Order Step (WOS) is an atomic operation on one specimen contributing to a Work Order on that specimen. The WOS is a SWOS created by the Automation Manager in the LDA profile, and an AWOS created by the Analyzer Manager in the LAW profile. In both cases the WOS is identified, bound to the specimen, and assigned to a Laboratory Device (LD).

2 Scope of the Laboratory Technical Framework

Scope of LAB TF is unchanged by this new profile.

3.1 Laboratory Profiles Synopsys of Usages and Dependencies

Replace existing section 3.1 by the following section

The synopsis below shows the integration profiles from the Laboratory Technical Framework with their usage across the organizations. The XD-LAB profile is a content profile specifying the template for electronic laboratory reports.

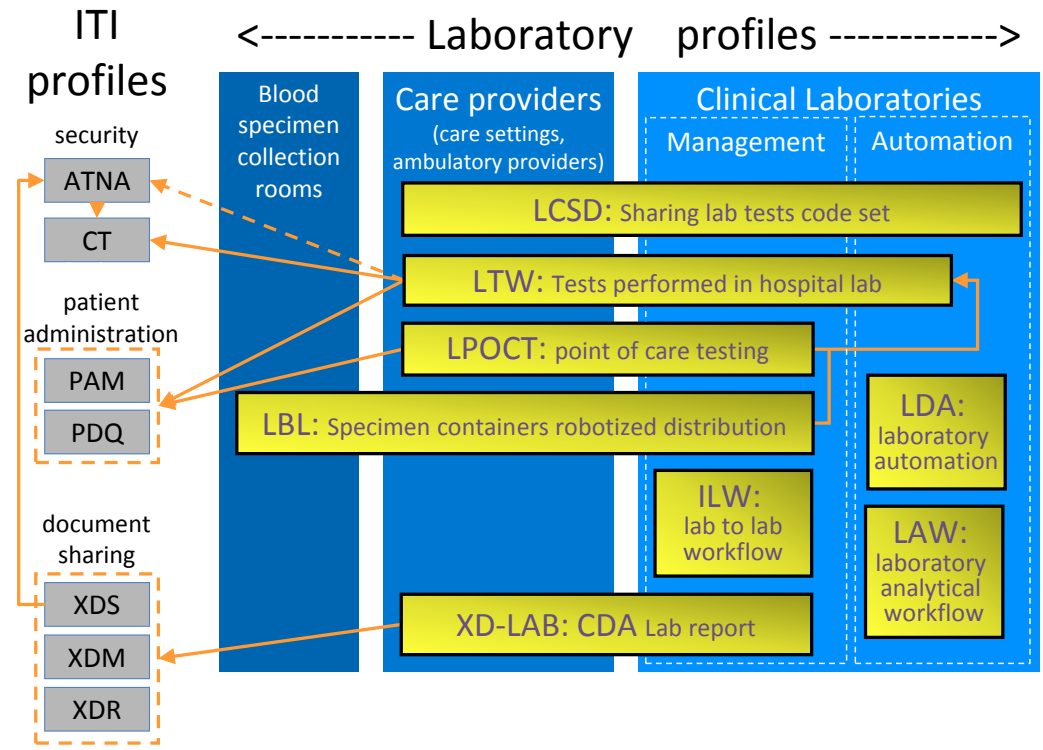


Figure 3.1-1: Laboratory Profiles Usages and Dependencies

3.2 Content Profiles for a regional healthcare community

Empty the existing section 3.2

This section is left empty in the current release of this volume.

3.3 Dependencies among Integration Profiles

Add the line of dependencies of the LAW profile into Table 3.3-1, below the LDA line. Both profiles are standalone, and can be implemented independently of any other profile.

Suppress note (1) below the table.

Integration Profile	Depends on	Dependency Type	Purpose
...			
Laboratory Device Automation (LDA)	LTW none	The system implementing the AM Actor in LDA profile shall also implement AM in LTW profile. (1)	The AM Actor is breaking Work Orders received in LTW profile into Work Order Steps for processing in LDA profile.
Laboratory Analytical Workflow (LAW)	none		

Note (1): There is no difference of capabilities for the AM actor between LTW profile and the former set of deprecated profiles LSWF and LIR.

3.4 Integration Profiles Overview

Update the 3.4.2 sub-section suppressing the word "analyzer", as follows

3.4.2 Laboratory Device Automation (LDA)

The Laboratory Device Automation (LDA) integration profile describes the workflow between the Automation Manager and a set of non-analytical laboratory equipment (pre-analytical devices, ~~analyzers,~~ post-analytical devices) involved in the testing process.

Add the 3.4.10 sub-section as follows (note that 3.4.9 is already booked by the ILW supplement)

3.4.10 Laboratory Analytical Workflow (LAW)

The Laboratory Analytical Workflow (LAW) integration profile supports the analytical workflow of IVD test work order steps and their results between IVD analyzers and the systems driving their work (LIS or LAS).

3.5.2 Usage of HL7 Standards in Laboratory Technical Framework

Complement Table 3.5.2-1 by adding a line for LAW, as follows.

Table 3.5.2-1: Versions of standard in use in the LAB TF profiles

LAB TF profile	HL7	CLSI
LTW – Laboratory Testing Workflow	2.5 & 2.5.1	
LDA – Laboratory Device Automation	2.5 & 2.5.1	
LBL – Laboratory Barcode Labeling	2.5 & 2.5.1	
LPOCT – Laboratory Point Of Care Testing	2.5	POCT1-A
LCSD – Laboratory Code Set Distribution	2.5 & 2.5.1	
XD-LAB – Sharing Laboratory Reports	CDA r2 in HL7 v3 normative edition	
LAW - Laboratory Analytical Workflow	2.5.1 (pre-adopted elements from 2.7 & 2.9)	

3.5.3 Relationships between units of work in the LAB-TF

Update section 3.5.3.4 (WOS), to reflect more precise requirements

3.5.3.4 Work Order Step (WOS, AWOS, SWOS)

Content of this section replaced by this one:

A Work Order Step (WOS) is an atomic operation requested on one specimen, contributing to a Work Order on that specimen. The WOS is created by the Automation Manager in the LDA profile, and by the Analyzer Manager in the LAW profile. In both cases the WOS is identified, bound to the specimen, and assigned to a Laboratory Device (LD). Messages related to that WOS contain the WOS identifier and properties, as well as the specimen identification (by id and/or by position) and properties. Among the WOS properties, the WOS code represents the type of atomic operation expected. This code can be omitted if this operation is unambiguously implicit for the LD.

- The WOS is a SWOS in the LDA profile. It is assigned a unique SWOS identifier by the Automation Manager, which must be memorized by the Pre/Post-processor and included in all messages related to that SWOS.
- The WOS is an AWOS in the LAW profile. It is assigned a unique AWOS identifier by the Analyzer Manager, which must be memorized by the Analyzer and included in all messages related to that AWOS. The AWOS represents an IVD test or panel. The Analyzer is expected to produce the observations corresponding to that test or panel performed on the specimen.

5 Laboratory Device Automation (LDA)

This chapter does not talk about the LAW profile! New readers to IHE LAB TF can skip it.

This chapter describes the removal of the analytical workflow from LDA profile, which will be restricted from now on, to the workflow of non-analytical laboratory devices (decapper, robotic transportation, diluter, refrigerated storage…). The analytical workflow will be taken care of solely by the LAW profile described further in section X of this supplement.

Remove from this chapter 5, all texts, shapes on figures, and other artifacts referring to the Analyzer Actor, the analytical process, AWOS, testing, tests, panels, QC testing. From now on, all these concepts are removed from LDA and transferred to the LAW profile. The sections updated are: 5.1 Scope, 5.2 Use cases, 5.6 Process Flow

5.1 Scope

Section 5.1 updated as follows:

The LDA Integration Profile supports the workflow for the automated technical section of the clinical laboratory:

The Laboratory Device Automation Integration Profile covers the workflow between an Automation Manager application (e.g., a LAS or a LIS) and a set of automated Laboratory Devices (LD) to process ~~**a Work Order, perform the tests on the related specimens and retrieve their results**~~ **various automated steps on the specimen related to a Work Order**. This processing includes the **pre-analytical process** of the specimen (sorting, centrifugation, aliquoting, transportation, decapping)~~ **the analytical process itself (run of the ordered tests on the specimen)**~~ and the **post-analytical process** (recapping, transportation, rerun, dilution, storage and retrieval).

The analytical process (testing on the analyzer and reporting back the observations) is out of the scope of the LDA profile and transferred to the LAW profile.

This LDA profile strictly addresses the workflow between Automation Managers and Laboratory Devices (LD) operated by the clinical laboratory staff. ~~**Devices operated by the clinical ward staff, are supported by another profile: LPOCT, and are therefore out of scope of LDA.**~~

The Automation Manager receives a Work Order from the Order Filler, splits it into a sequence of one or more **Work Order Steps (WOS)**, each of which is entrusted to an automated device implementing an actor (Pre/Post-processor~~**, Analyzer**~~).

A WOS is operating on one single specimen.

This profile covers various situations such as: Work Order Step downloaded before specimen arrival, Work Order Step obtained by query after specimen recognition on the device, Work Order Step manually entered on the automated device.

Except for the robotic transportation of the specimen, this profile does not address the handling of an automated device through an electromechanical interface. It only carries the Work Order Steps related information, **and** the status of these Work Order Steps~~**, and the results obtained**~~.

Among the sequence of WOS issued from a Work Order, the particular WOS that instructs the Analyzer to perform the tests is called the Analytical Work Order Step (AWOS). The other WOS of the sequence operating on the specimen do not produce observations and are called Specimen Work Order Steps (SWOS). **The LDA profile deals only with SWOS. AWOS are dealt with by the LAW profile.**

The transactions carrying the AWOS instruct the analyzer to perform a list of tests on a particular specimen. It does not say how to perform them: The electromechanical handling of an analyzer is out of scope of this profile.

The specimen may arrive on an automated device before or after the WOS referring to it has been delivered. In both cases, the specimen and the WOS (instruction) must be both present on the device in order for the step to be performed.

This LDA profile also addresses the testing of QC specimen on an Analyzer, and the upload of QC results from the Analyzer to the AM. An Analyzer can fulfill both patient specimen AWOS and QC specimen AWOS. The LTW profile supports the upload of QC results from the AM to the Order Filler. Thus the combination of both profiles enables the centralization of QC results of all the Analyzers of the clinical laboratory, on the Laboratory Information System.

In some situations, the recognition of the specimen (by its ID or position) or the WOS content can be entered manually on the LD user interface.

The primary specimen ID may be provided by one of OP, OF or LIP actors. In case a SWOS instructs an aliquoter to prepare aliquot specimen, a new ID coded on a new barcode label will be required for each aliquot produced. These IDs and labels may be provided by the Automation Manager or by the aliquoter or by a third party. The organizational details of the labeling process are out of the scope of this profile, which only recommends that barcode labels be readable (e.g., format and length of the barcode, label format) by all the LD that will perform a WOS on this specimen.

The profile includes the LD's ability to accept or reject a WOS, with the notice of specimen arrival to the Automation Manager. ~~**It also includes the ability of an Analyzer to modify the content of an AWOS, for instance adding automatically a new test, depending on the results obtained on the original tests.**~~

Observation results tracking implies the ability of each actor (Analyzer, Automation Manager) to store the raw results, before refining, converting or interpreting them This safe storage is not described in this profile.

5.2 Use cases

Update the text of section 5.2 before 5.2.1, as follows

All the use cases for patient specimen testing defined in this section start with a Work Order sent by the Order Filler to the Automation Manager. The Automation Manager splits this Work Order into a sequence of Work Order Steps, and schedules each step on a LD (aliquoter, robotic conveyer, ~~**analyzer**~~…) according to the organization of the laboratory automation.

Each WOS contains all ~~**information**~~ **data** required by the target device to perform it: container identification, specimen information, target ID, operation to perform, scheduled time…)

The Analytical Work Order Step (AWOS) also contains the list of clinical tests to perform, the patient identification, admission and clinical information, the order information…The specimen information may include the ID, position, specimen type, volume, date and time of collection, ID of collector, specimen pre-analytical status (e.g., "centrifuged", "decapped"…).

For some Analyzers which perform single test (e.g., HbA1c), or a constant panel (Blood culture, Blood cells count…), the AWOS need not mention the tests to be performed.

By definition, a **Work Order Step is related to a single specimen**. The specimen (primary or aliquot) is usually identified with a unique ID printed on a barcode label stuck to the specimen container.

The laboratory technical staff supervises the various WOS using the Automation Manager and operating all necessary LDs. The technical staff perform the technical validation of the results on the Automation Manager, which then, sends these results back to the Order Filler.

Should a specimen be damaged or lost, the Automation Manager will suspend or cancel its Work Order until the replacement specimen arrives. This section also provides two use cases for QC testing.

5.2.1 WOS downloaded on the LD before specimen arrival

Update the final part of the scenario as follows:

Final part of the scenario:

r) The LD performs the WOS on that specimen.

s) The LD notifies the Automation Manager, with the status of the performed step. In case of an AWOS on an Analyzer, this notification message contains the results and status of the performed clinical tests.

Append the following figure at the end of section 5.2.1:

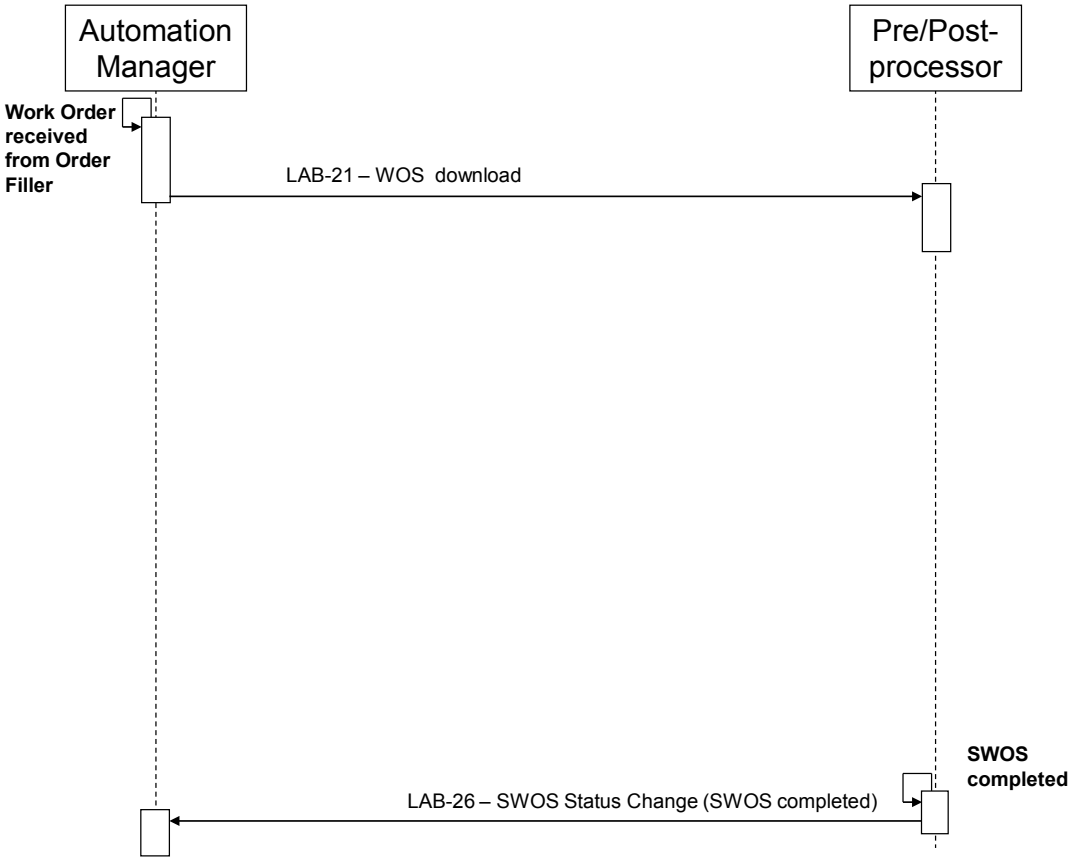


Figure 5.2.1-1: Process Flow for WOS downloaded before specimen arrival

5.2.2 Query for the WOS at specimen arrival on the LD

Append the following figure at the end of section 5.2.2:

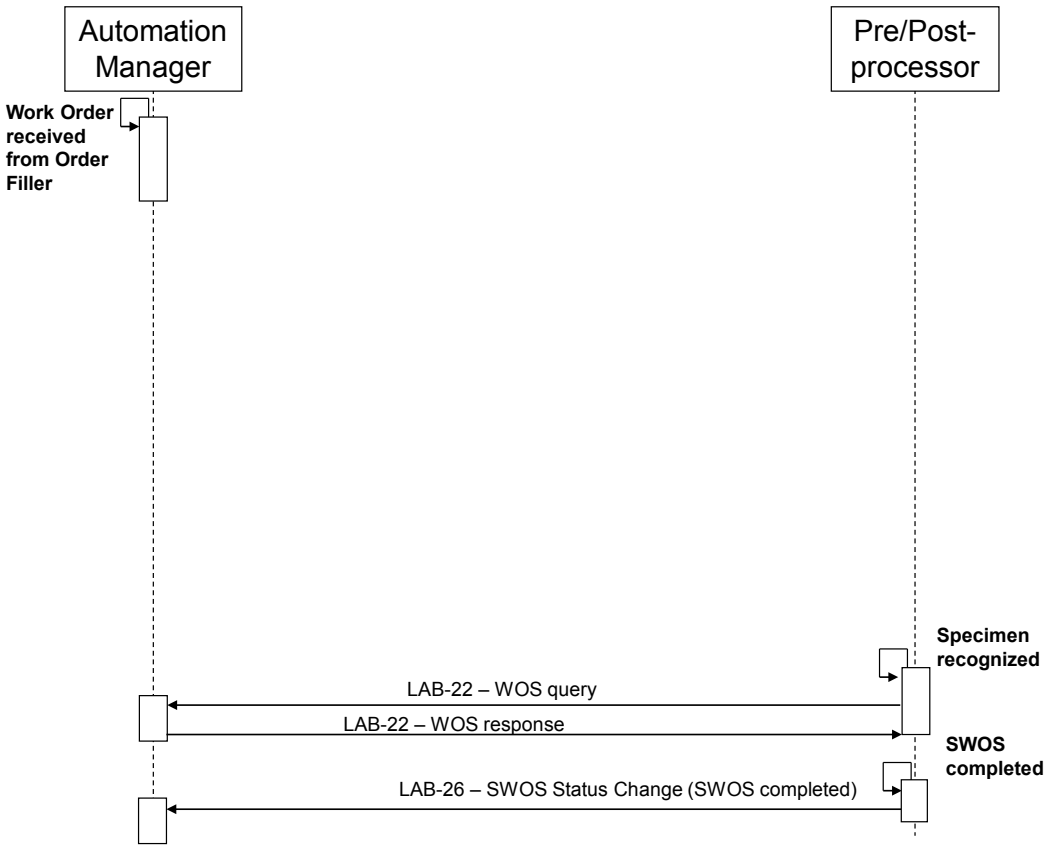


Figure 5.2.2-1: Process Flow for WOS queried at specimen arrival on the LD

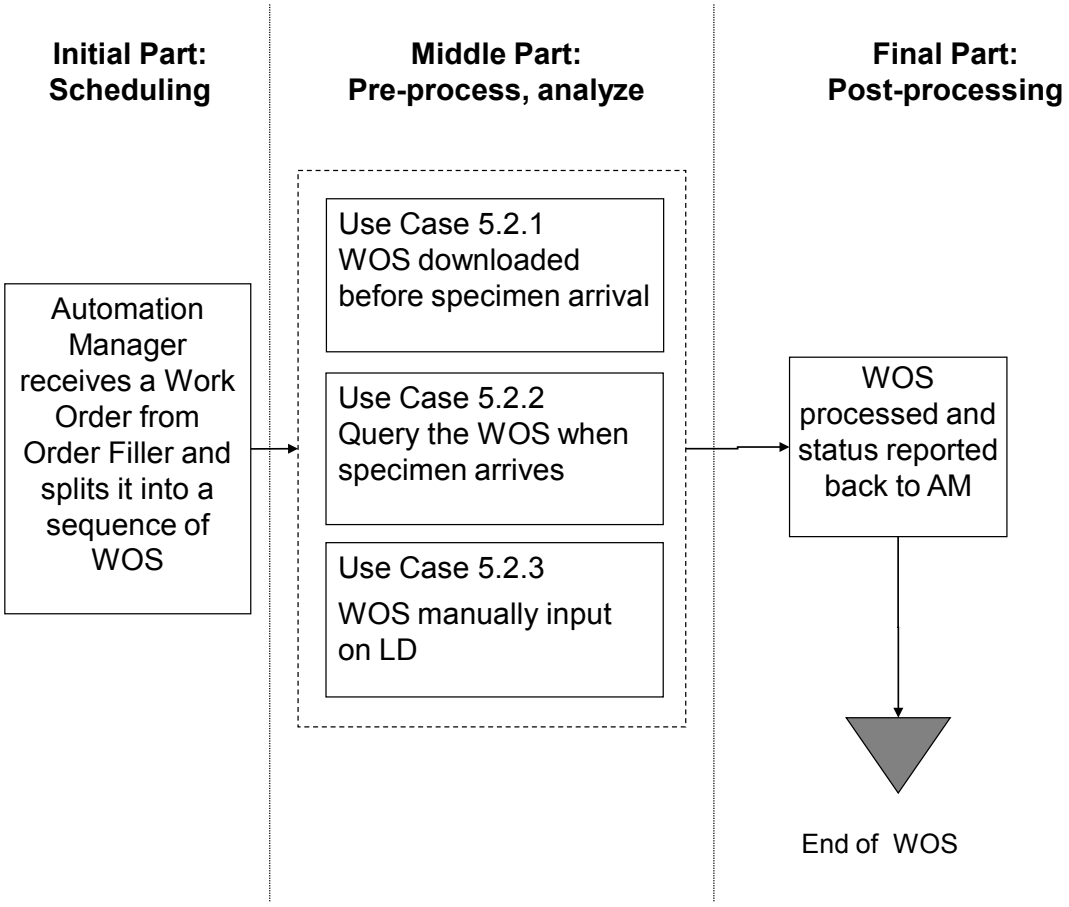
5.2.4 Rerun on the Analyzer

Remove completely the content of this section 5.2.4, including the content of subsections 5.2.4.1 through 5.2.4.3, leaving the section blank, as follows:

This section is intentionally left blank.

5.2.5 Summary of use cases on patient specimen WOS

Replace figure 5.2.5-1 by the following one:



590 **Figure 5.2.5-1: LDA use cases on patient specimen WOS**

5.2.6 QC performed on an Analyzer

Remove completely the content of this section 5.2.6, including the content of subsections 5.2.6.1
595 *through 5.2.6.3, leaving the section blank, as follows:*

This section is intentionally left blank.

5.4 Actors/Transactions

600

5.4 Actors/Transactions rewritten by removing the Analyzer Actor and related transactions as below:

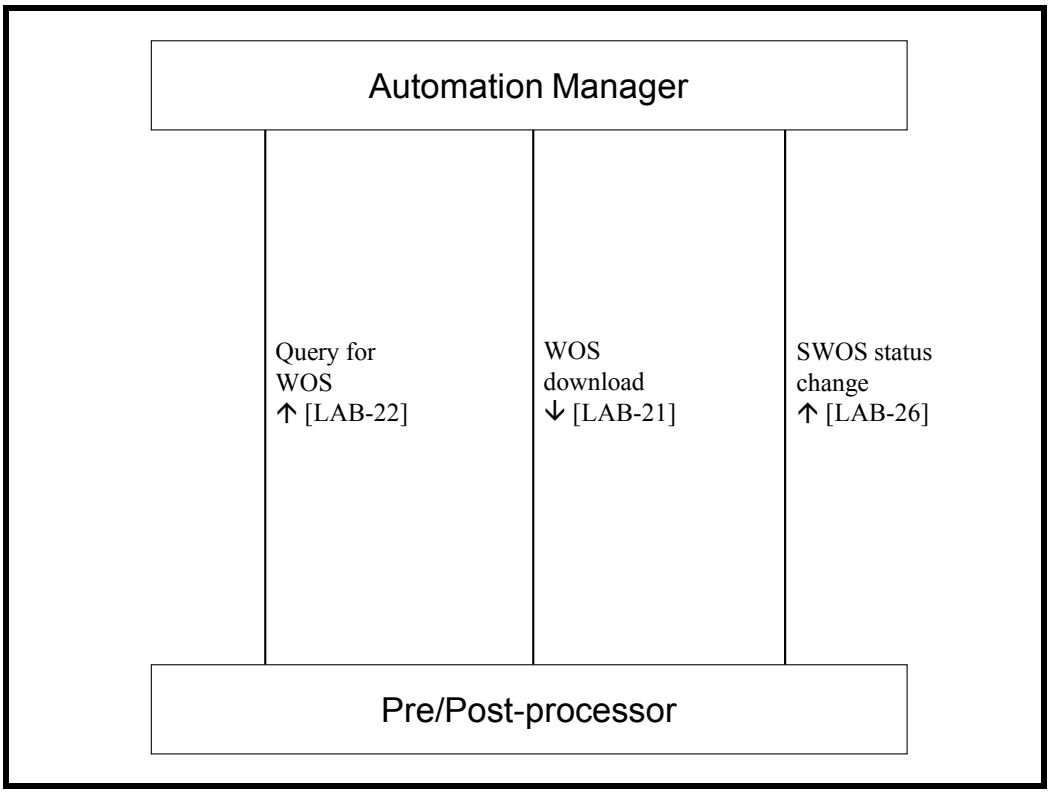


Figure 5.4-1: Laboratory Device Automation Actor Diagram

Table 5.4-1 lists the transactions for each actor involved in the LDA Profile. To claim support of this Integration Profile, an implementation of an actor must perform the required transactions (labeled "R"). Transactions labeled "O" are optional and define the profile options explained in section 5.5 below.

Table 5.4-1: LDA Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Automation Manager	LAB-21 : WOS Download	R	LAB TF-2: 9
	LAB-22 : WOS Query	R	LAB TF-2:10
	LAB-26 : SWOS Status Change	R	LAB TF-2:12
Pre/Post-processor	LAB-21 : WOS Download	O	LAB TF-2: 9
	LAB-22 : WOS Query	O	LAB TF-2:10
	LAB-26 : SWOS Status Change	R	LAB TF-2:12

5.5 LDA Integration Profile Options

5.5 Actors/Transactions rewritten by removing the Analyzer Actor and related transactions as below:

615 Options which may be selected for this Integration Profile are listed in table 5.5-1 along with the Actors to which they apply:

Table 5.5-1: Laboratory Device Automation - Actors and Options

Actor	Options	Vol & Section
Automation Manager	None	
Pre/Post-processor (1)	Query mode WOS	
	Download mode WOS	

620 **Query mode WOS:** A Pre/Post-processor implementing this option must support transaction LAB-22.

Download mode WOS: A Pre/Post-processor implementing this option must support transaction LAB-21.

625 Note 1: To claim for the LDA Integration Profile conformance, a product implementing a Pre/Post-processor Actor must support at least one of the two transactions LAB-21 and LAB-22, together with the mandatory transaction LAB-26.

~~5.6 Process Flow~~

Remove completely section 5.6

630

X Laboratory Analytical Workflow (LAW)

X.1 Scope

The LAW Integration Profile supports the analytical workflow between analyzers of the clinical laboratory and the systems managing their work.

This LAW Profile covers the workflow of "Analytical Work Order Steps" (AWOS) between an Analyzer Manager application (e.g., a LAS or a LIS) and an Analyzer (an IVD device). This workflow handles the processing of IVD tests by the Analyzer, on specimen materials. Both patient and quality control (QC) specimens are in scope.

All specialties of clinical laboratories (including blood bank testing) are in scope.

Tests performed on the point of care by the ward staff or the patient are out of scope of this profile, and addressed by the LPOCT profile instead.

An AWOS is an analytical service to be performed by an analyzer on a specimen. The AWOS is ordered by means of a code representing this analytical service. The code may represent an elementary test (e.g., "measure the glucose level of the specimen") or a panel of several elementary tests. In all cases the analytical service is expected to produce observations on the specimen that will be reported back by the Analyzer. The AWOS does not say how to perform the analytical service. The electromechanical handling of an analyzer is out of scope of this profile.

Some analyzers, such as those that perform a fixed test menu on all samples, only support the transfer of the test result. Other analyzers support both an AWOS transfer and a result transfer, or bi-directional communication. This profile covers bi-directional analyzers receiving their AWOS both in push mode (unsolicited work order steps) and in pull mode (query for one specimen, and query all). The profile also supports an AWOS manually entered at the analyzer, as well as an analyzer automatically performing a test without the need for an AWOS transfer. For bi-directional analyzers, the default behavior of the analyzer must be to operate in a query (pull) mode. Because an Analyzer Manager will communicate with a variety of analyzers, an Analyzer Manager must support bi-directional communication. An Analyzer Manager must also assume that all analyzers operate in query mode, unless configured otherwise.

The results of the tests are sent to the Analyzer Manager in push mode (automatically and/or triggered by a manual operation from the technician operating the analyzer).

The specimen may arrive on an analyzer before or after the AWOS referring to it has been delivered.

This LAW profile also addresses the testing of QC specimen on an Analyzer and the sending of QC results from the Analyzer to the Analyzer Manager.

Both the specimen and the AWOS must be present on the Analyzer for the AWOS to be performed.

The profile includes the Analyzer's ability to accept or reject an AWOS, with the notice of specimen arrival to the Analyzer Manager. It also includes the ability of an Analyzer to modify the content of an AWOS. For example, automatically adding a new reflex test to the panel or single test originally requested by the AWOS, given the preliminary results obtained.

An AWOS is bound to a single specimen unambiguously identified through a specimen container ID and/or a geographic position (carrier, tray, plate …) on the analyzer. The specimen container ID is a mandatory datum of the transactions dealing with the AWOS. Moreover, the specimen container ID is usually visible on the specimen container (e.g., as a bar-coded label sticker), so as to be read and recognized by the analyzer. More than one AWOS may be bound to the same specimen.

In addition to the specimen identification, the AWOS usually carries a number of specimen properties (e.g., specimen type, target site, specimen role (patient / QC), specimen pooled or not, dilution factor, time of specimen collection, collector…).

Observation result tracking implies the ability of each actor (Analyzer, Analyzer Manager) to store the raw results, before refining, converting or interpreting them. This safe storage is not described in this profile.

Analyzers have different capabilities related to performing tests. All Analyzers produce a test result, and therefore require a basic set of information that can be used to perform the proper test on the proper sample. Basic information required to produce the result will be mandatory. In addition, an Analyzer may provide the capability to perform a clinical evaluation of the test result. This might be accomplished automatically through the use of a rule engine, or the Analyzer might provide the capability for a user to manually evaluate the results through the user interface. In order to do so, the analyzer must receive additional, or enhanced, information from the Analyzer Manager. All enhanced information used to perform additional result evaluations will be considered optional.

X.2 Use Cases

Use cases related to patient and QC specimen testing defined in this section primarily cover Work Orders received by the Analyzer Manager. The Analyzer Manager splits this Work Order into a list of Analytical Work Order Steps (AWOS), and schedules each AWOS on an Analyzer according to the organization of the laboratory equipment. If possible, the Analyzer will produce a technically validated result and report that value to the Analyzer Manager. Optionally, the Analyzer may provide the ability to perform a clinical evaluation of the result based on enhanced information provided by the Analyzer Manager in the AWOS.

It is assumed that an Analyzer is configured to operate in either "query" (expected default) or "broadcast" mode when supporting bi-directional communication. In a "query" mode, an Analyzer queries for a list of AWOS by following use cases *X.2.2 AWOS Query by the Analyzer at specimen arrival* or *X.2.1.2 AWOS query by the Analyzer for ALL specimens before specimen arrival* for normal processing. In a "broadcast" mode, the Analyzer Manager automatically broadcasts the list of AWOS to the Analyzers by following use case *X.2.1.1 AWOS broadcast by the Analyzer Manager before specimen arrival* for normal processing. This profile does not

consider a mixed configuration of "query" and "broadcast" to be a valid mode for an Analyzer, as this greatly complicates the use cases. In addition, this profile also assumes that either Analyzers query for a given AWOS or a given AWOS is broadcast to the Analyzers. This profile considers a mix of Analyzers in "query" mode and Analyzers in "broadcast" mode that can perform the same AWOS to be out of scope, as once again it greatly complicates the use cases.

Each AWOS contains all data needed by the target device (Analyzer Actor) to perform it: specimen container identification, specimen properties, coded analytical service (test or panel) to perform …

The specimen properties may include the ID, position, specimen type, volume, date and time of collection, ID of collector, specimen pre-analytical status (e.g., "centrifuged", "decapped"…).

In case the specimen is related to a patient, the AWOS may contain patient identification and other patient administrative or clinical data relevant for the process.

In case the specimen is related to an Order Group (see this term in the glossary section 1.11 and in section 3.5.3) placed to the laboratory for this patient, the AWOS may contain the Order Group identification and some of its properties (e.g., ordering physician, date time when this order group was placed to the laboratory).

For some Analyzers that perform a single test (e.g., HbA1c) or a constant panel (Blood culture, Blood cells count…), the AWOS does not necessarily carry the code representing the test or panel to be performed.

By definition, an AWOS is related to a single specimen (this specimen can be a mixture of several patient specimen, see X.2.9). The specimen (primary or aliquot) is usually identified with a unique specimen container ID printed on a barcode label stuck to the specimen container.

The laboratory technical staff supervises the various AWOS using the Analyzer Manager and operating all necessary Analyzers. The technical staff performs the technical validation of the results on the Analyzer or on the Analyzer Manager, which then sends these results back upstream. When enhanced data has been provided, this validation may include clinical evaluation of the results.

Should a specimen be damaged or lost, the Analyzer Manager will suspend or cancel its Analytical Work Order until the replacement specimen arrives.

An AWOS could be identified by a set of attributes (e.g., Specimen, Container, Patient). However some of these could be missing (e.g. patient) or could be reused (e.g. container), so the Analyzer Manager is responsible to assign a unique identifier (called AWOS ID) to each AWOS to allow the Analyzer to unambiguously report test results associated with the AWOS independent of the nature of the patient, specimen, container, or test ordered information. The assignment of an AWOS ID requires the Analyzer to memorize the ID and use it when reporting test results to the Analyzer Manager. It is the responsibility of the Analyzer Manager to guarantee (e.g., use of unique IDs or establishing a reasonable period of time for the reuse of IDs that prevents incorrect identification of an AWOS) that the assignment of AWOS IDs can be used to uniquely identify each AWOS.

The results, or AWOS status change notifications, sent by the Analyzer generally include a number of properties attached to them (value, unit, comment, alarm, time of run, status …). The notification shall contain the AWOS ID unless it is unknown (see use case X.2.3).

X.2.1 AWOS transfer to the Analyzer before specimen arrival

In this use case the Analyzer Manager sends to the Analyzers the scheduled list of AWOS prior to the specimen arriving at the Analyzer. The delivery to the Analyzer, solicited or unsolicited, will be described in the following two sub-cases.

Since the work list is transmitted before the specimen is present on the Analyzer, in some cases it may not be known which device will receive the specimen. Laboratories may have multiple Analyzers with similar analytical capabilities for fault tolerance redundancy or to keep up with the workload. When an AWOS is scheduled on more than one analyzer, upon notification of AWOS completion by one of the Analyzers who transmits back the results, the Analyzer Manager shall cancel the other redundant AWOS awaiting execution on the other Analyzers.

X.2.1.1 AWOS broadcast by the Analyzer Manager before specimen arrival

This use case defines the expected behavior when the Analyzer Manager sends an AWOS to one or more Analyzers configured for broadcast mode.

Initial part of the scenario:

a. The Analyzer Manager creates and sends the scheduled list of AWOS to the Analyzer(s). Multiple AWOS may be grouped into a single work list provided to the Analyzer. Each AWOS represents an analytical service requested on a specimen. In response to the AWOS broadcast, the Analyzer may notify the Analyzer Manager with its intent to accept or reject an AWOS. If the Analyzer does not send a notification for an AWOS, then the Analyzer Manager can assume the Analyzer accepts the AWOS. The Analyzer commits the list of AWOS to memory.

b. An Analyzer recognizes the specimen container (through barcode ID scanning, position identification on the carrier, or manual entry) and selects the set of AWOS related to that specimen from its memory.

Final part of the scenario:

a. The Analyzer performs the AWOS (one or more) on that specimen.

b. Optionally, the Analyzer may notify the Analyzer Manager with preliminary results and status of the in progress clinical tests.

c. The Analyzer notifies the Analyzer Manager of the completion of the AWOS (one or more). This notification message contains the results of the performed tests, fulfilling one or more AWOS, with their related properties.
The Analyzer Manager must support receiving test results reported over a period of time in addition to receiving multiple test results for an AWOS at the same time. The reported test results can include both preliminary and a final result for a given test.

d. If the AWOS was sent to multiple Analyzers operating in broadcast mode, the Analyzer Manager shall notify the other Analyzers that received the AWOS to cancel the AWOS.

Exception handling:

a. In the case where the AWOS has not been received when the specimen container is recognized, then several events may occur depending upon the Analyzer's capabilities and operator's actions:

   1. The Analyzer skips this specimen.
   2. The analyzer suspends processing of the specimen and waits for the arrival of the missing AWOS.
   3. The AWOS is created at the Analyzer (transition to use case X.2.3).

b. In the time between receipt of the AWOS and the specimen recognition by the Analyzer, the content of the Order Group, Order or Work Order may be modified (correcting patient data, suppressing some tests, adding some new tests, shifting to another target Analyzer) or even canceled. Such events will require the cancellation of the original AWOS on the Analyzer Manager. Therefore, the Analyzer Manager shall notify all Analyzers that received the AWOS to cancel the AWOS.

   1. The Analyzer Manager notifies the Analyzers to cancel the AWOS
   2. Each Analyzer notifies the Analyzer Manager if the AWOS cancel is accepted. It is up to the Analyzer to evaluate the state of the AWOS and determine if cancellation is possible. If an Analyzer cannot cancel the AWOS, it should notify the Analyzer Manager that it is unable to cancel. One of the following actions will occur:

      1. If processing on the AWOS has not started, the Analyzer should notify the Analyzer Manager that the cancel was accepted and discard the AWOS.
      2. If processing on the AWOS has started but multiple results are being produced and the Analyzer can stop further processing, then it should notify the Analyzer Manager the cancel was accepted, stop processing, and notify the Analyzer Manager of the results that were completed.
      3. If processing on the AWOS has started but the Analyzer cannot stop the processing, then it should notify the Analyzer Manager that the cancel cannot be performed. The Analyzer should then transition to step b, "Final part of the scenario" of this use case.

X.2.1.2 AWOS query by the Analyzer for ALL specimens before specimen arrival

Initial part of the scenario:

a. The Analyzer queries the Analyzer Manager for all the scheduled AWOS assigned to it.

b. The Analyzer Manager responds by sending the complete AWOS work list assigned to the Analyzer, and the Analyzer updates its local work list. In response to the AWOS receipt, the Analyzer may notify the Analyzer Manager with its intent to accept or reject an AWOS. If the Analyzer does not send a notification for an AWOS, then the Analyzer Manager can

assume the Analyzer accepts the AWOS. The Analyzer commits the list of AWOS to memory.

c. Continue with step b. of the Initial part of the scenario from use case X.2.1.1.

Final part of the scenario:

Same as use case X.2.1.1.

Exception handling:

Same as use case X.2.1.1.

X.2.2 AWOS Query by the Analyzer at specimen arrival

This is the default behavior for all Analyzer Managers and Analyzers that support bi-directional communication.

Initial part of the scenario:

a. The Analyzer Manager creates the scheduled list of AWOS but does not send it to the Analyzer.

b. In the case where the Analyzer Manager receives a Work Order update or cancellation, it cancels the related AWOS appropriately, and creates a new one if needed.

c. An Analyzer recognizes the specimen container (barcode scanning, location information, or manual entry), and queries the Analyzer Manager with the specimen container ID or location information.

d. The Analyzer Manager sends the scheduled list of AWOS to the Analyzer for that specimen. Multiple AWOS may be grouped into a single work list provided to the Analyzer. Each AWOS represents an analytical service requested on the specimen. The Analyzer may notify the Analyzer Manager with its intent to accept or reject an AWOS. If the Analyzer does not send a notification for an AWOS, then the Analyzer Manager can assume the Analyzer accepts the AWOS. Note: this step is similar to step a in "Initial part of the scenario" of *X.2.1.1 AWOS broadcast by the Analyzer Manager before specimen arrival*.

Final part of the scenario:

Same as use case X.2.1.1.

Exception handling:

a. The specimen may be placed on the Analyzer, before the Work Order has been received by the Analyzer Manager, and before the AWOS exist. In that case the query in step c) is unsuccessful. The answer sent in step d) will be "unknown specimen, no pending AWOS for it", which is also known as a Negative Query Response. Several events may occur depending upon the Analyzer's capabilities and operator's actions:

    1. The Analyzer skips this specimen.

    2. The Analyzer suspends processing of the specimen and tries the query later.

3. The AWOS is created at the Analyzer (transition to use case X.2.3). NOTE: If multiple Analyzers can query for the same specimen and perform the same AWOS, then the AWOS should not be automatically created at the Analyzer. A Negative Query Response may have been received because another Analyzer queried for the specimen (see exception step c below).

b. In this use case, the AWOS to be performed on the Analyzer is sent by the Analyzer Manager just in time, when the Analyzer is ready to perform it on the specimen. Thus, all updates to the AWOS occur on the Analyzer Manager and there is no need to cancel an AWOS that has been transferred to an Analyzer.

c. Another Analyzer may have already queried for the same specimen. In this situation, any AWOS already sent to another Analyzer and accepted by that Analyzer will not be sent. If there are no AWOS to send, then the query in step c) is unsuccessful as all AWOS have been assigned to other Analyzers. The response sent in step d) will be "unknown specimen, no pending AWOS for it", which is also known as a Negative Query Response. The Analyzer skips the specimen upon receiving a Negative Query Response.

X.2.3 AWOS created at the Analyzer

Initial part of the scenario:

a. The AWOS is created at an analyzer.

1. The laboratory technical staff manually enters the AWOS on the Analyzer from information printed from the Analyzer Manager or collected by telephone in emergency cases, such as specimen id and tests to be performed.

2. The Analyzer automatically associates an AWOS default test or panel with a specimen. A default AWOS can be created as part of normal processing or because an AWOS is not available from the Analyzer so a panel of emergency tests is performed.

The AWOS ID is never entered manually on the Analyzer. It can only be obtained via a message from the AM. Therefore in both cases above the AWOS shall have a null AWOS ID.

b. The Analyzer recognizes the specimen container (through barcode ID scanning, position identification on the carrier, or manual entry) and selects the set of AWOS that was manually entered or assigned a default test or panel.

Final part of the scenario:

a. The Analyzer performs the AWOS on that specimen.

b. Optionally, the Analyzer may notify the Analyzer Manager with preliminary results and status of the AWOS in progress.

c. The Analyzer notifies the Analyzer Manager, with the status of the performed step. This notification message contains the results and status of the performed clinical tests.

d. On receiving status notifications and analytical tests results without an AWOS ID, the Analyzer Manager can handle them in different ways:

1. Use sample and test information to relate the results with the appropriate AWOS.
2. Ask the operator to manually link these orphan results to AWOS received later on.
3. Discard all AWOS with a null AWOS ID.

Exceptions handling:

a. In the case where an AWOS has not been manually entered by the time the specimen is recognized, then several events may occur depending upon the Analyzer's capabilities and operator's actions:

1. The Analyzer skips this specimen.
2. The analyzer suspends processing of the specimen and waits for the arrival of the missing AWOS.
3. The Analyzer automatically creates an AWOS default test or panel, as described in option 2) of step a) of the Initial part of the scenario for this use case, and continues with step b) of the Initial Part of the scenario for this use case.

b. It may be necessary to modify an AWOS manually entered by an operator from information provided by the Analyzer Manager (suppress tests, add test, change the target Analyzer with another Analyzer, or cancel test). Such events will result in the cancellation of the AWOS on the Analyzer Manager, which must inform the operator of those changes (through the user interface or by printing a new corrected AWOS sheet). The operator must then manually cancel the AWOS on the Analyzer, and create a new AWOS with the corrected information if applicable.

X.2.4 Rerun

An AWOS usually needs one analytic run on the Analyzer. In some circumstances the results obtained from this first run need to be controlled by subsequent runs or "reruns".

The need for a rerun may be decided:

- Immediately after the first run on the Analyzer. In that case the analyzer may send the results of the successive runs in one or more messages. The choice of the selected results among several runs can be determined:
  - On the analyzer side. In that case, two situations are possible:
    - The Analyzer reports only the selected results to the Analyzer Manager. In that case, the rerun is transparent.
    - The Analyzer reports the results from all runs to the Analyzer Manager, distinguishing each of them with the "sub-observation id" field, in order to track the Analyzer operations and to register the reagent consumption. In that case the Analyzer identifies the selected run using the "result status" field to express that this one is the final (potentially corrected) result.

- On the Analyzer Manager side. In that case, the Analyzer reports the results of all runs with the same "result status", distinguishing each of them with the "sub-observation id" field. The Analyzer Manager selects which results to report.

- During the technical validation of the Analytical Work Order with the first run results, on the Analyzer Manager application.
- During the clinical validation of the order with the first run results, on the Order Filler application.

The three use cases to be considered are described below.

X.2.4.1 Rerun decided on the Analyzer immediately after the first run

The rerun is decided automatically or manually, at the end of the first run. The reason may be:

- Results could not be obtained, due to a flaw on the Analyzer: reagent shortage, needle blocked up, calibration failure…
- Results out of range, triggering a rerun with automatic dilution of the specimen.

Initial part of the scenario:
The initial part of the scenario can be from use case X.2.1, X.2.2 or X.2.3.

Final part of the scenario:

a. The Analyzer performs the ordered step on that specimen (first run).

b. Based on the results obtained, the Analyzer schedules an additional run. The Analyzer may notify the Analyzer Manager of the results with a "preliminary" status for the first run for this AWOS, or may retain them until the additional run is performed.

c. The Analyzer performs the additional run.

d. The Analyzer notifies the Analyzer Manager, with the results and status of the additional run, or of all runs if they were not yet reported. All runs are assigned the same AWOS ID but are distinguished from one another by "observation sub-id" field. If the Analyzer has selected a run, it marks it with the appropriate result status (“final result” or “corrected final result”). Otherwise all runs have the same status "preliminary" and the Analyzer Manager will select which results to report

X.2.4.2 Rerun decided during technical validation on the Analyzer Manager

The rerun is decided during technical validation. This decision is made by the technical staff or automatically by the Analyzer Manager. A rerun decided on the Analyzer Manager will be represented by a new AWOS, with an AWOS ID distinct from the one of the previous run.

Initial part of the scenario:
The initial part of the scenario can be from use case X.2.1, X.2.2 or X.2.3

Final part of the scenario:

a. The Analyzer performs the ordered step on that specimen (first run).

b. The Analyzer notifies the Analyzer Manager, with the results and status of the first run for this AWOS.
c. The technical validation of the results is performed on the Analyzer Manager, resulting in a new run requested with the same test on the same specimen. This new run may be requested on the same analyzer or on another one (to confirm the results obtained on the first one).

The rerun picks up the scenario appropriate to the working mode of the Analyzer chosen for the second run:

- If the Analyzer targeted for the rerun is working in push mode (at least for reruns) the Analyzer Manager sends a new AWOS to it, for the same specimen and the same tests. This starts a new X.2.1 scenario (step a).
- If the Analyzer is working in query mode, the Analyzer Manager schedules the new AWOS and waits for the query from the Analyzer. This starts a new X.2.2 scenario (step a)
- If the Analyzer only supports manual entry, the Analyzer Manager prints out the scheduled rerun. This starts a new X.2.3 scenario (step a)

In addition, the rerun may generate new AWOS entrusted on Analyzers other than the targeted Analyzer.

X.2.4.3 Rerun decided during clinical validation on the Order Filler

The control (rerun) is decided during the clinical validation of the results of the whole order group, considering the clinical consistency of this whole set of results, together with normal ranges, patient's prior results, and other clinical and technical information, or technical information such as drifting or out of range quality control detected. This decision is taken by the laboratory clinical expert, or by an automated expert system assisting the clinical expert.

In this situation, the final part of the first three scenarios ends normally. After the clinical validation the Order Filler generates a new Work Order for the same patient, same specimen, requesting the Analyzer Manager to schedule the tests anew, on one of its Analyzers. This new Work Order may carry some additional tests ordered in the meantime. It may possibly require a new aliquot.

This kind of rerun is supported and described by the use case X.2.1, X.2.2 and X.2.3.

X.2.5 Reflex

An AWOS usually needs one analytic run on the Analyzer. In some circumstances the results obtained from this first run will trigger the need for one (or several) different test (i.e. a reflex test).

The need for a reflex may be decided:

- either immediately after the initial test run on the Analyzer, before uploading the results to the Analyzer Manager
- or during the technical validation of the Analytical Work Order with the first run results, on the Analyzer Manager application,

- or later, during the clinical validation of the order with the first run results, on the Order Filler application.

The three use cases are to consider are described below.

X.2.5.1 Reflex decided on the Analyzer immediately after the first run

The reflex is decided automatically or manually, at the end of the first run. For example, results in a particular range trigger a reflex of a different test on the same specimen.

This reflex decision happens before the initial test results are uploaded to the Analyzer Manager. The results of the first run may be sent either before the results from the reflex test or may be held and sent when the reflex test is complete.

The Analyzer Manager will be notified of both the initial and reflex testing in order to track the Analyzer operations and to register the reagent consumption.

Initial part of the scenario:
The initial part of the scenario can be from use case X.2.1, X.2.2 or X.2.3.

Final part of the scenario:

a. The Analyzer performs the ordered steps on that specimen.
b. Considering the results obtained, a reflex test is scheduled. The Analyzer may send the results of the parent AWOS(s) now or as part of step d).
c. After the appropriate specimen is made available, the Analyzer performs the reflex test. The reflex test is performed as a child AWOS of the original parent(s), and this child AWOS has a null AWOS ID.
d. The Analyzer notifies the Analyzer Manager with the results and status of the parent AWOS(s) (if not sent previously) and reflex test with all known information (patient, specimen, container, test, and AWOS ID(s) of the parent(s)).
e. On receiving status notifications and unexpected analytical tests results, the Analyzer Manager can handle them in different ways:
    - add the result to the AWOS if it is identified in the message;
    - link the result to the Work Order of the parent AWOS(s) in case of a child reflex AWOS;
    - use specimen and test information to link the results to an appropriate Work Order;
    - ask the operator to manually link theses orphan results to AWOS;
    - discard all AWOS with a null AWOS ID.

X.2.5.2 Reflex decided during technical validation on the Analyzer Manager

The reflex is decided during the technical validation of the results of the first run, compared with normal ranges, patient's prior results, and other clinical information, or technical information. This decision is taken by the technical staff, or automatically by the Analyzer Manager application.

Initial part of the scenario:

The initial part of the scenario can be from use case X.2.1, X.2.2 or X.2.3.

Final part of the scenario:

a. The Analyzer performs the ordered steps on that specimen.
b. The Analyzer notifies the Analyzer Manager, with the results and status for these AWOSs.
c. The technical validation of the results is performed on the Analyzer Manager, resulting in a new AWOS requested with different tests on the same specimen. This new AWOS may be requested on the same analyzer or on another one.

The execution of the reflex test follows the scenario appropriate to the operating mode of the targeted Analyzer:

- Push mode: the Analyzer Manager broadcasts a new AWOS for the same specimen and new tests. This starts a new X.2.1 scenario (step a).
- Query mode: the Analyzer Manager schedules the new AWOS and waits for the query from an Analyzer. This starts a new X.2.2 scenario (step a).
- Manual entry: the Analyzer Manager prints out the scheduled reflex. This starts a new X.2.3 scenario (step a).

X.2.5.3 Reflex decided during clinical validation on the Order Filler

The reflex is decided during the clinical validation of the results of the whole order group, considering the clinical consistency of this whole set of results, together with normal ranges, patient's prior results, and other clinical and technical information. This decision is taken by the laboratory clinical expert, or by an automated expert system assisting the clinical expert.

In this situation, the final part of the first three scenarios ends normally. After the clinical validation the Order Filler generates a new Work Order for the same patient, same specimen, requesting the Analyzer Manager to schedule the reflex tests on one of its Analyzers. It may possibly require a new aliquot.

This kind of reflex is supported and described by the first three scenarios.

X.2.6 Retransmit results from Analyzer

Usually at the completion of a run, the Analyzer notifies the Analyzer Manager one time with the status and the test results of the performed AWOS. In some circumstances the AWOS results may be sent again by the Analyzer to the Analyzer Manager. This decision to send the results again is generally made manually by the operator of the Analyzer in cases where the Analyzer Manager was unable to receive and store the results of the initial transmission, or in the case when a manual send of the results is used for testing purposes of the connection between the Analyzer and the Analyzer Manager.

In this situation, the Analyzer Manager is responsible for determining if the results are the same as it has seen previously (same AWOS, same Analyzer, same test, same results) and acting

accordingly. It shall not reject the message from the Analyzer in the case of a retransmission, but shall either record the event or ignore the retransmission, depending on application design.

X.2.7 Summary of use cases on patient specimen AWOS

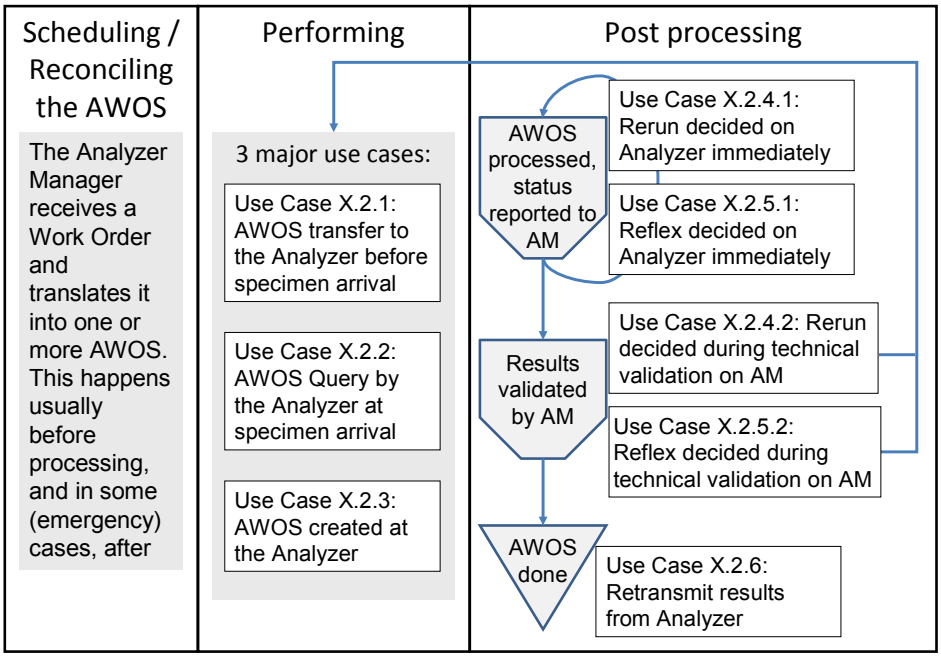


Figure X.2.7-1: LAW use cases on patient specimen AWOS

X.2.8 QC performed on an analyzer

This use case is a specialization of the following use cases:

- X.2.1.1 AWOS broadcast by the Analyzer Manager before specimen arrival
- X.2.2 AWOS Query by the Analyzer at specimen arrival
- X.2.3 AWOS created at the Analyzer
- X.2.4.1 Rerun decided on the Analyzer immediately after the first run
- X.2.4.2 Rerun decided during technical validation on the Analyzer Manager

In all these use cases the specimen is a “QC specimen”.

X.2.9 Pooling of patient specimens

This use case is a specialization of the following use cases:

- X.2.1 AWOS transfer to the Analyzer before specimen arrival
- X.2.1.1 AWOS broadcast by the Analyzer Manager before specimen arrival
- X.2.1.2 AWOS Query by the Analyzer for ALL specimens before specimen arrival

- X.2.2 AWOS Query by the Analyzer at specimen arrival
- X.2.3 AWOS created at the Analyzer
- X.2.4.1 Rerun decided on the Analyzer immediately after the first run
- X.2.4.2 Rerun decided during technical validation on the Analyzer Manager
- X.2.4.3 Rerun decided during clinical validation on the Order Filler
- X.2.5.1 Reflex decided on the Analyzer immediately after the first run
- X.2.5.2 Reflex decided during technical validation on the Analyzer Manager
- X.2.5.3 Reflex decided during clinical validation on the Order Filler
- X.2.6 Retransmit results from Analyzer

In some cases (molecular biology for example), the sample transmitted to the analyzer is mixture of several patient specimen.

- If the analyzer return a negative result all the patient specimen of the pool are considered negative.
- If the analyzer return a positive result, all the patient specimen of the pool have to be tested individually

For the preceding uses cases, the following points have to be taken in account:

- The ordering of pooled specimens assumes an Analyzer Manager capable of managing the specimen pool (e.g., by connection to a pooling device) and an Analyzer capable of measurement and calculation of the result for the pooled specimen.
- The Order sent to the Analyzer should include the following information:
  1. It is a pooled specimen.
  2. The pool size, i.e., the number of specimens used for this specific sample. This information is used in the calculation of the result (the negative specimens generally "dilute" the result of positive specimens).
  3. Optional list of specimen IDs used in the pool (for informational purpose at the Analyzer).

X.3 Systems interconnection in the laboratory

The systems: Laboratory Information System (LIS), Laboratory Automation System (LAS) and other middleware (workstations, concentrators …) Laboratory Devices (analytical, pre-analytical, post-analytical), may be interconnected in various ways, and have to support the appropriate actors of the appropriate profiles to fit their interconnection:

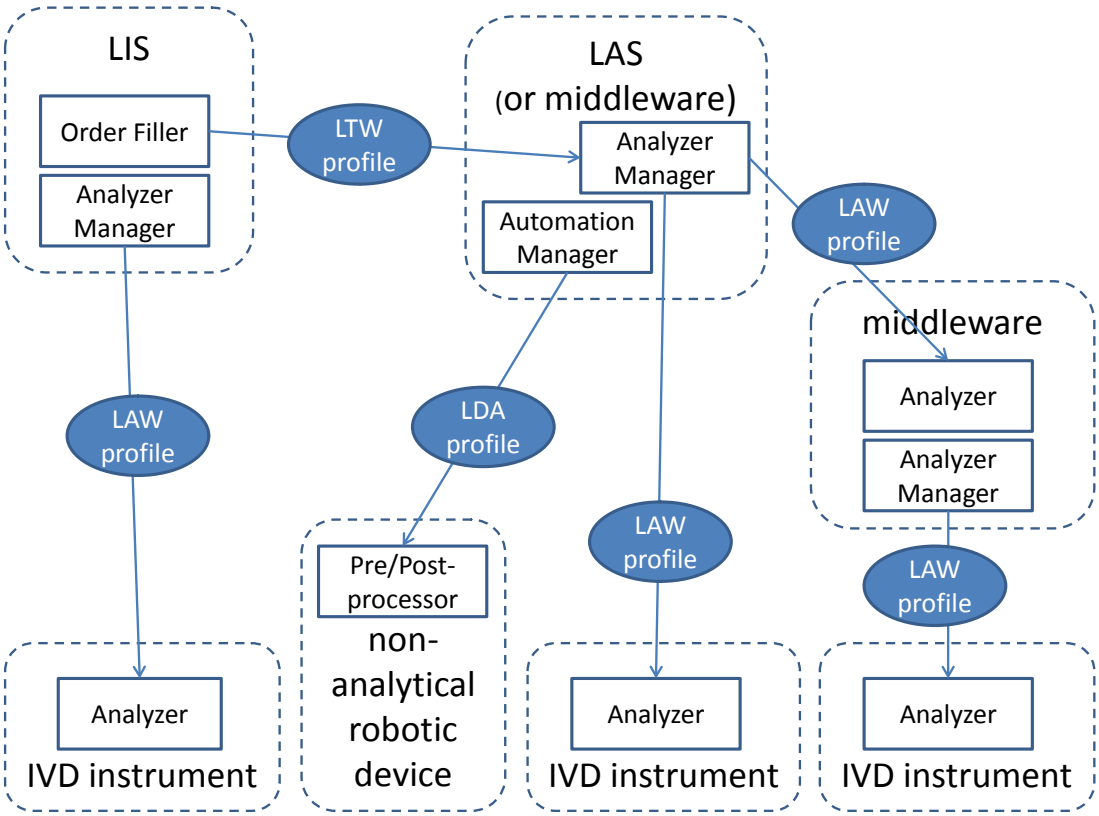


Figure X.3-1: Interconnection of systems and mapping to profile's actors

X.4 Actors/ Transactions

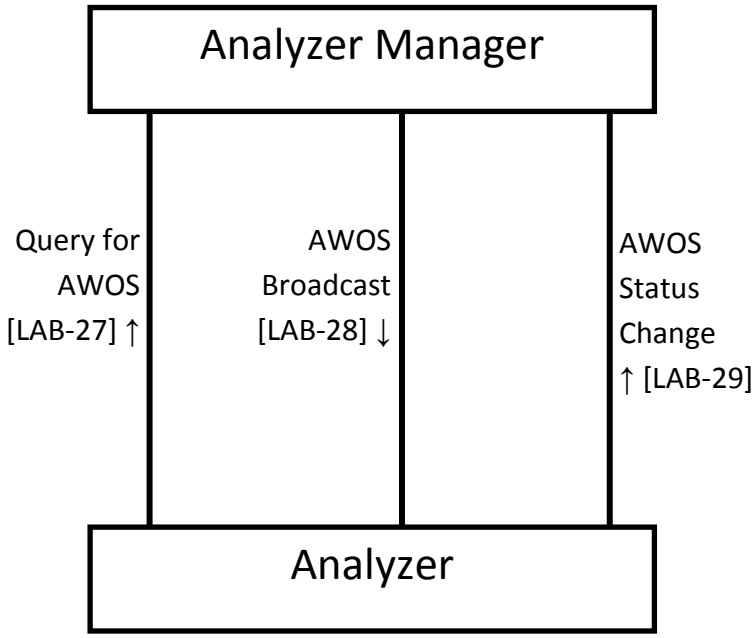


Figure X.4-1: LAW Actors/Transactions Diagram

Table X.4-1 lists the transactions for each actor involved in the LAW Profile. To claim support of this Integration Profile, an implementation of an actor must perform the required transactions (labeled "R"). Transactions labeled "O" are optional and define the profile options explained in section X.5 below.

Table X.4-1: LAW Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Analyzer Manager	LAB-27 : Query for AWOS	R[1]	Q
	LAB-28 : AWOS Broadcast	R	R
	LAB-29 : AWOS Status Change	R	Y
Analyzer	LAB-27 : Query for AWOS	O[2,3]	Q
	LAB-28 : AWOS Broadcast	O[2,3]	R
	LAB-29 : AWOS Status Change	R	Y

1 – An Analyzer Manager must support LAB-27(query) as the default mechanism for AWOS transfer.

2 – An Analyzer must support both LAB-27 and LAB-28 if supporting the bi-directional option. See X.5 below.

3 – The transaction contains enhanced data elements. It is up to the Analyzer to decide which of the enhanced elements will be supported.

X.5 LAW Integration Profile Options

Options which may be selected for this Integration Profile are listed in table X.5-1 along with the Actors to which they apply:

Table X.5-1: Laboratory Analytical Workflow - Actors and Options

Actor	Options	Vol & Section
Analyzer (1)	Bi-directional communication (AWOS Transfer)	Vol 2., Sections Q and R

Bi-directional communication: An Analyzer implementing this option must support transaction LAB-27 and LAB-28. The default configuration of the Analyzer must be to query for an AWOS with LAB-27.

X.6 Process Flow

These UML sequence diagrams present a high-level view of the process flow: Each transaction is represented by a single arrow with the initial triggering event, but without any detail on the various messages which compose the transaction. The message flow of each transaction and the description of each of its individual messages can be found in volume 2.

X.6.1 Normal process when Analyzers query at specimen arrival (default flow for bi-directional communication)

This process flow is based on use case X.2.2, with all Analyzers querying for AWOS.

a. The Analyzer Manager receives a Work Order.
   The Analyzer Manager splits this work order into a sequence of AWOS (only one in our example).
b. The Analyzer recognizes the specimen container.
c. The Analyzer sends a query to the Analyzer Manager with the recognized specimen container ID or location.
d. The Analyzer Manager replies to the query and sends an AWOS Broadcast with work to be performed.
e. Later, the Analyzer performs the test.
f. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager.

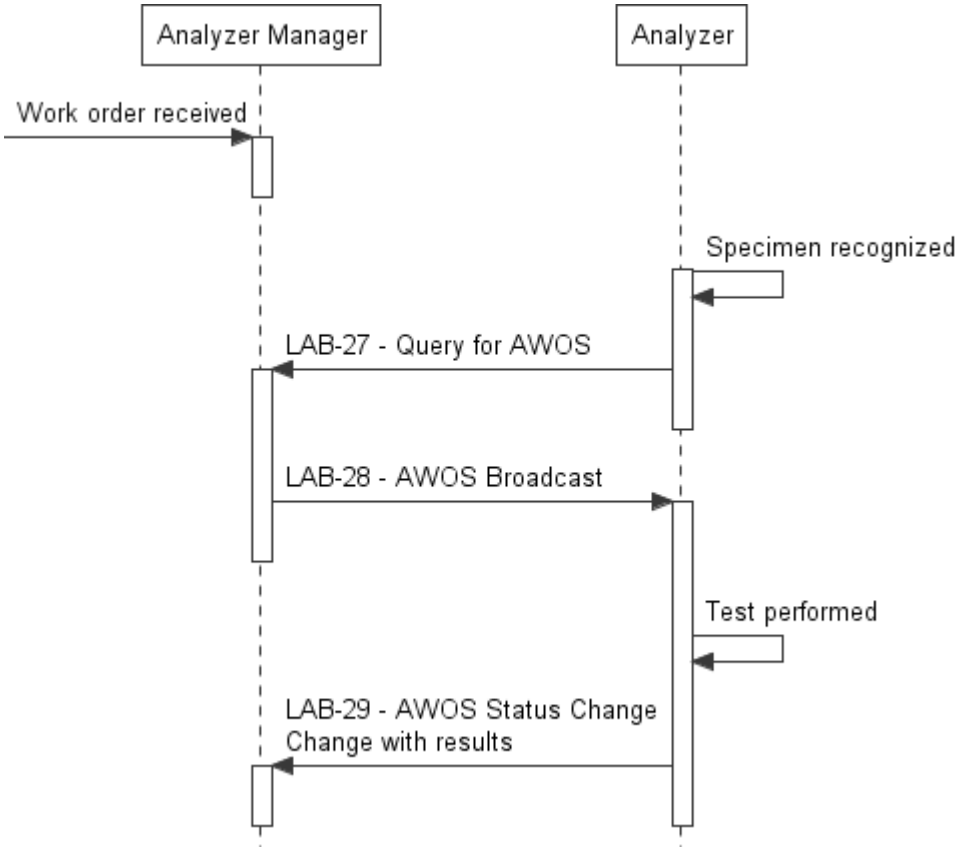


Figure X.6.1-1: Normal process when Analyzers query

X.6.2 Normal process when Analyzers receive AWOS prior to specimen arrival

This process flow is based on use case X.2.1.

a. The Analyzer Manager receives a Work Order.
   The Analyzer Manager splits this work order into a sequence of AWOS (only one in our example).
b. The Analyzer manager sends a scheduled AWOS to the Analyzer by sending an AWOS Broadcast.
c. Later, the Analyzer recognizes the specimen container and performs the test.
d. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager.

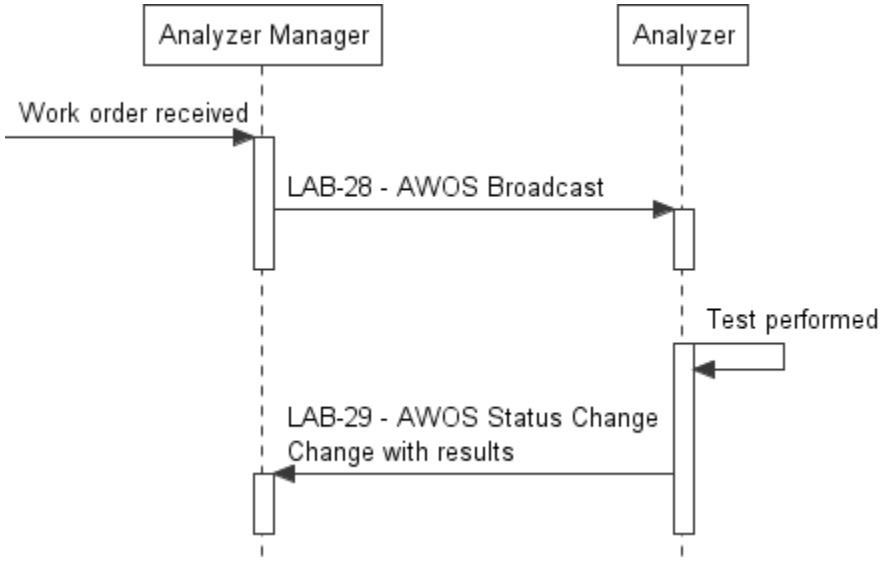


Figure X.6.2-1: AWOS received prior to specimen arrival

X.6.3 Analyzers receive AWOS update prior to specimen arrival

This process flow based on use case X.2.1 shows the update of an Analytical Work Order triggering the update of its AWOS.

a. The Analyzer Manager receives a Work Order.
   The Analyzer Manager splits this work order into a sequence of AWOS (only one in our example).
b. The Analyzer manager sends a scheduled AWOS to the Analyzer.
c. The Analyzer Manager receives an update of the Work Order. The Analyzer Manager updates the previously generated AWOS with the new information.
d. The Analyzer manager sends a cancel AWOS to the Analyzer by sending an AWOS Broadcast with order control code of "CA - Cancel order/ service request".
   This cancel is sent only to those Analyzers which are concerned with this update.
e. The Analyzer responds with a "CR- Cancel as requested" order control code.
f. The Analyzer manager sends a new scheduled AWOS to the Analyzer.
g. Later, the Analyzer recognizes the specimen container and performs the test.
h. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager.

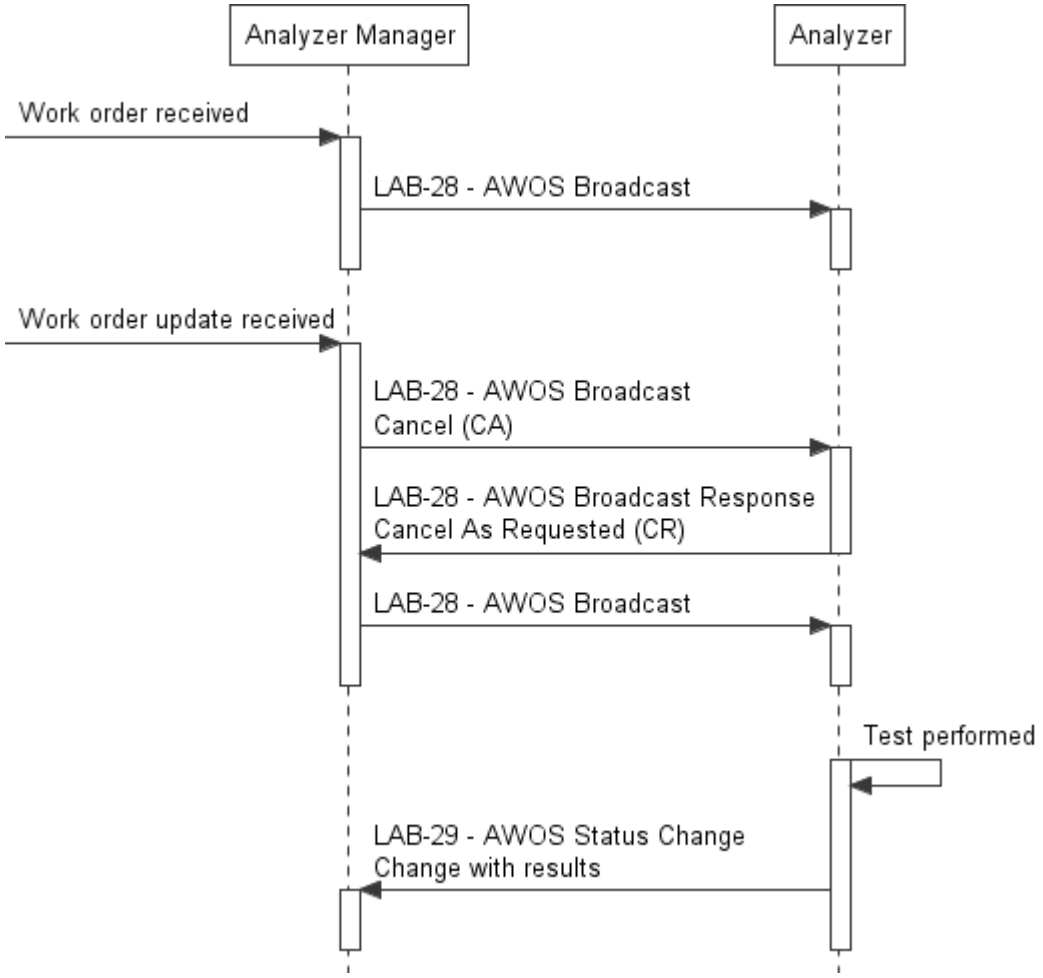


Figure X.6.3-1: AWOS update prior to specimen arrival

X.6.4 Normal process with AWOS entered manually at the Analyzer

This process flow is based on use case X.2.3, which may occur when the Analyzer has a one-way interface supporting only transaction LAB-29 to report its results.

a. The Analyzer Manager receives a Work Order.
The Analyzer Manager splits this work order into a sequence of AWOS (only one in our example).
b. The AWOS work list is printed by the Analyzer Manager.
c. The laboratory technician manually enters the AWOS on the Analyzer.
d. Latter, the Analyzer performs the test.
e. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager.

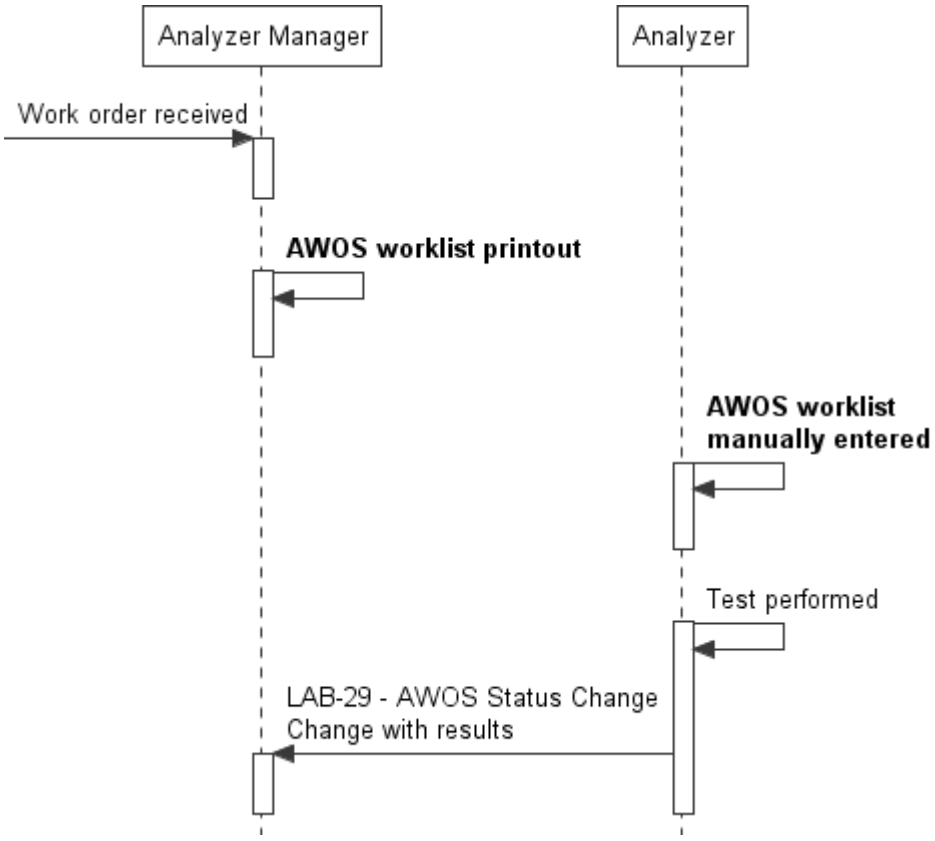


Figure X.6.4-1: Normal process with AWOS manual entry

X.6.5 Automatic rerun on the Analyzer, triggered by out of range results

This process flow is based on sub-use case X.2.4.1. Figure X.6.5-1below represents the process of the final part of the scenario.

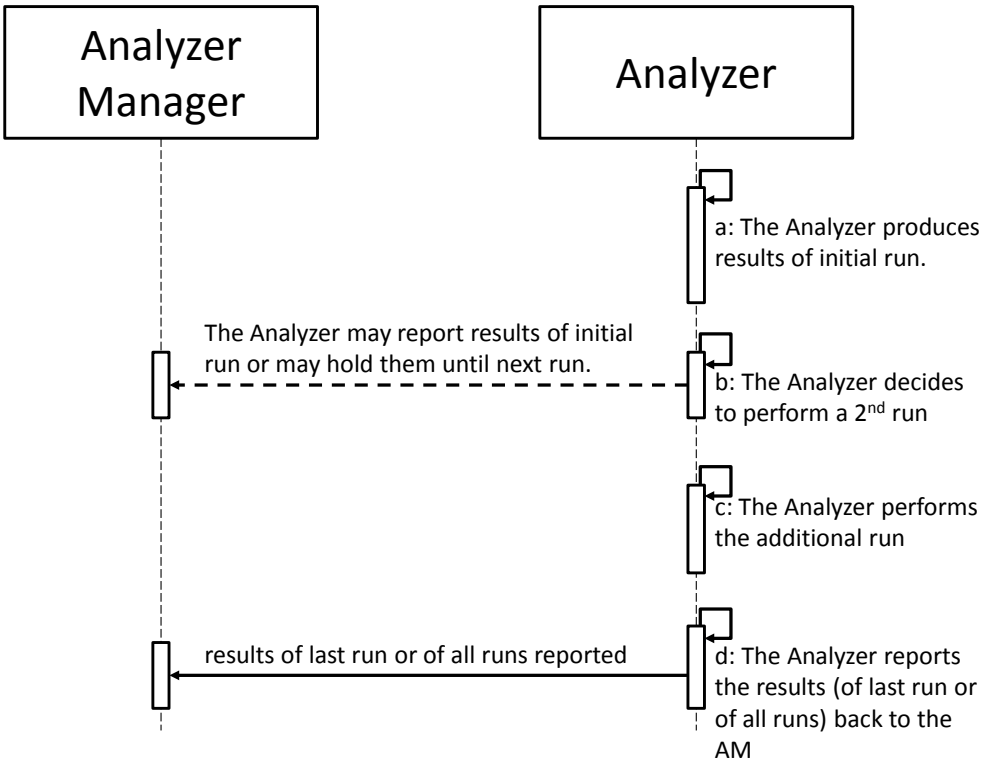


Figure X.6.5-1: Rerun decided on the Analyzer immediately after first run

X.6.6 Rerun requested by Analyzer Manager during technical validation

This process flow is based on sub-use case X.2.4.2.

a. The Analyzer Manager receives a Work Order.
   The Analyzer Manager splits this work order into a sequence of AWOS (only one in our example).
b. The Analyzer manager sends a scheduled AWOS to the Analyzer.
c. Latter, the Analyzer performs the test (1st run).
d. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager.
e. During the technical validation of the 1st run on the Analyzer Manager, a rerun is decided.
f. The Analyzer manager sends a **new** scheduled AWOS to the Analyzer.
g. Latter, the Analyzer performs the test (2nd run).
h. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager.

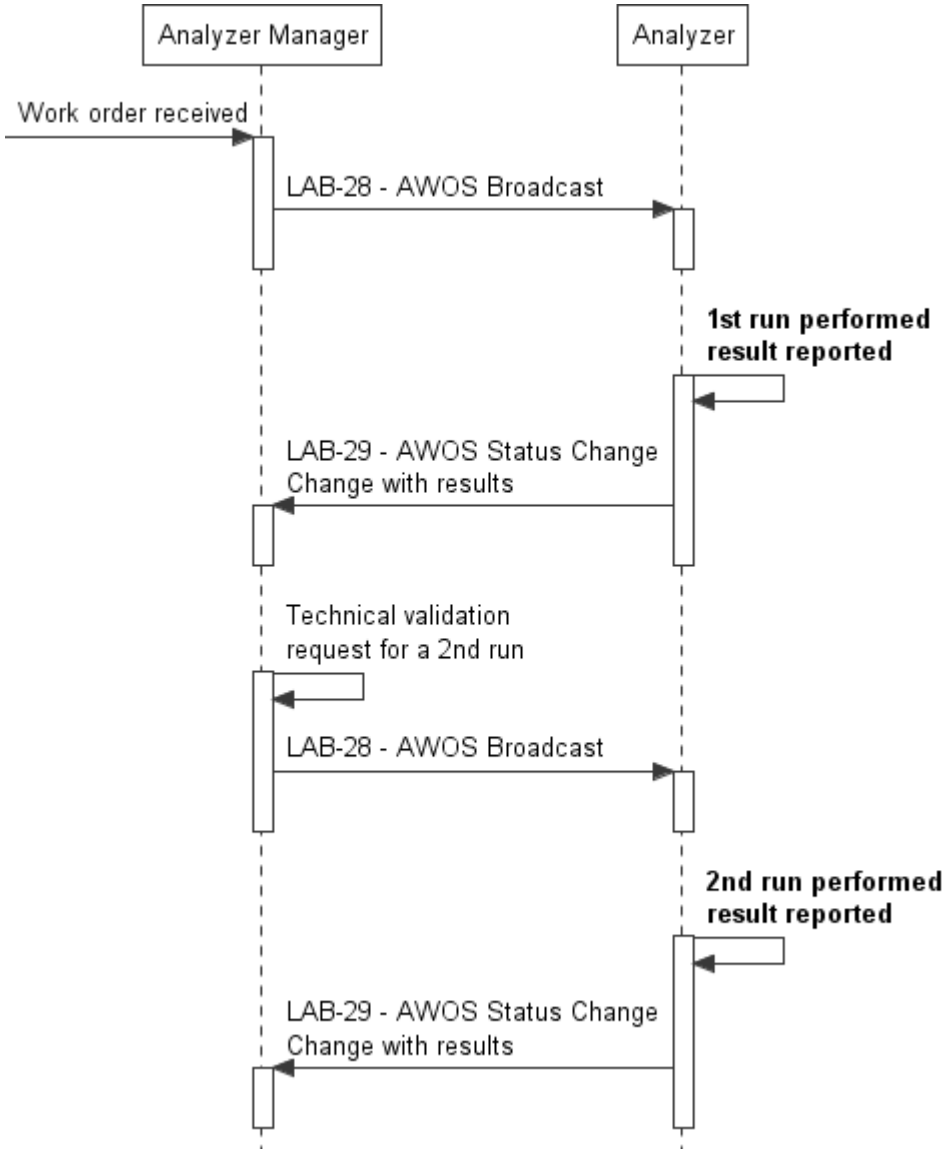


Figure X.6.6-1: Rerun decided on the Analyzer Manager at technical validation time

The request for a second run generates a new AWOS for the same specimen on the Analyzer.

X.6.7 Urgent tests performed before the arrival of the Analytical Work Order

This process flow is based on use case X.2.2 linked with use case X.2.3, in combination with the Order Filler Actor of the LTW integration profile.

a. The Analyzer recognizes the specimen container.
b. The Analyzer sends a query to the Analyzer Manager with the recognized container ID or location.
c. The Analyzer Manager does not know this ID and responds by sending an AWOS Broadcast with control code “DC - Discontinue Request”.
d. The laboratory technician manually enters the AWOS on the Analyzer.

e. Latter, the Analyzer performs the test.
f. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager. The AWOS Status Change does not contain an AWOS ID.
g. The Analyzer Manager receives a Work Order.
The Analyzer Manager splits this work order into a sequence of AWOS (only one in our example).
h. The Analyzer Manager manages the merge between the manually entered AWOS and the AWOS requested by the Order Filler (manually or based on some IDs).
i. The result is the validated and transmitted to the Order Filler.

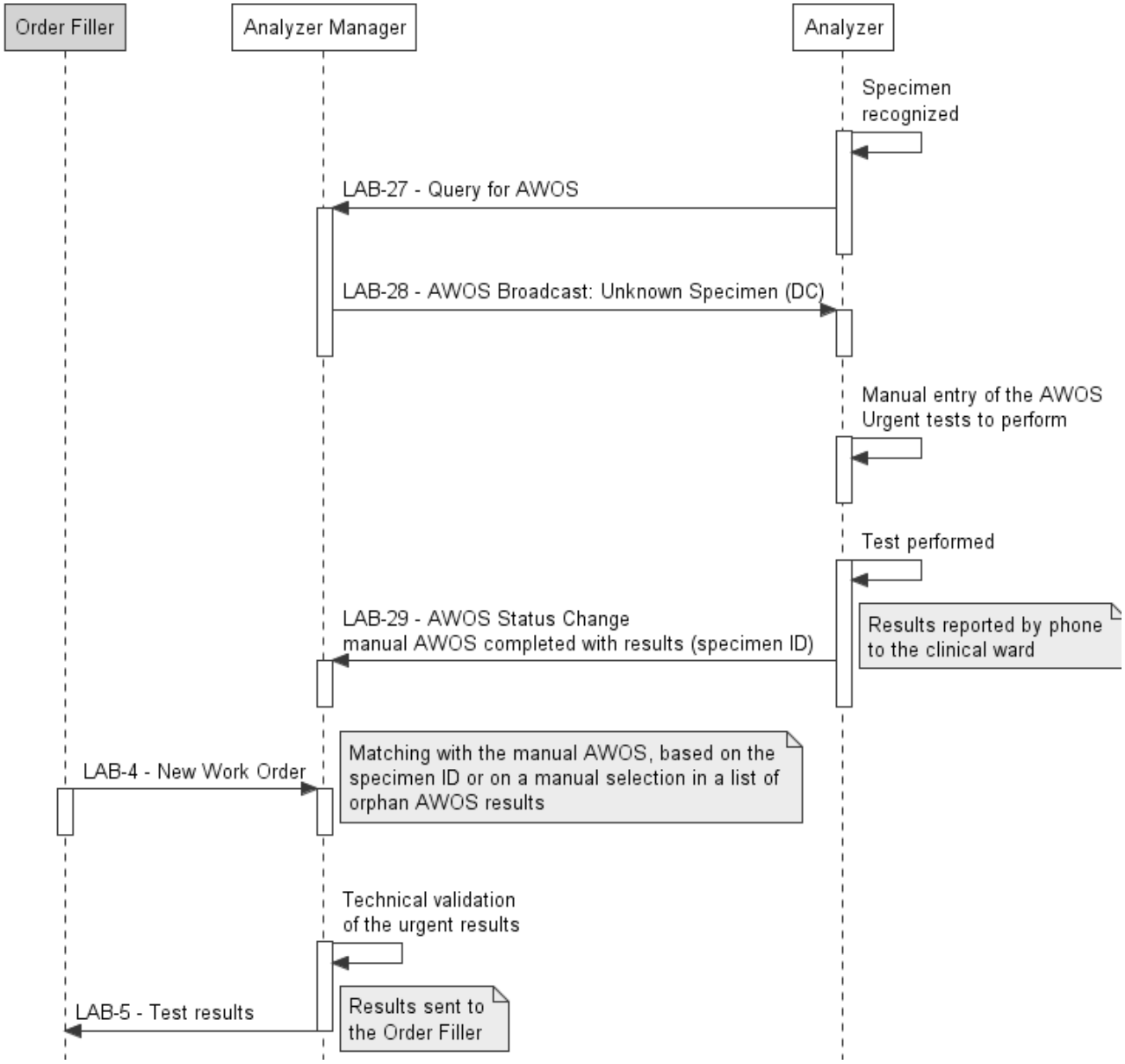


Figure X.6.7-1: Manual urgent AWOS performed and used before arrival of Work Order

X.6.8 Reflex test decided on the Analyzer

The following diagram illustrates use case X.2.5.1

a. The Analyzer performs the original AWOSs on the specimen.
b. Considering the results obtained, a reflex test is scheduled. The Analyzer may optionally send the results of the first tests.
c. The Analyzer performs the reflex test in a child AWOS of the original parent(s).

d. The Analyzer sends the results of the reflex test to the Analyzer Manager, including all known information (patient, specimen, container, test, AWOS ID if known, or AWOS ID(s) of the parent(s)).
e. The Analyzer Manager links the results of the reflex test to the appropriate AWOS and stores them.

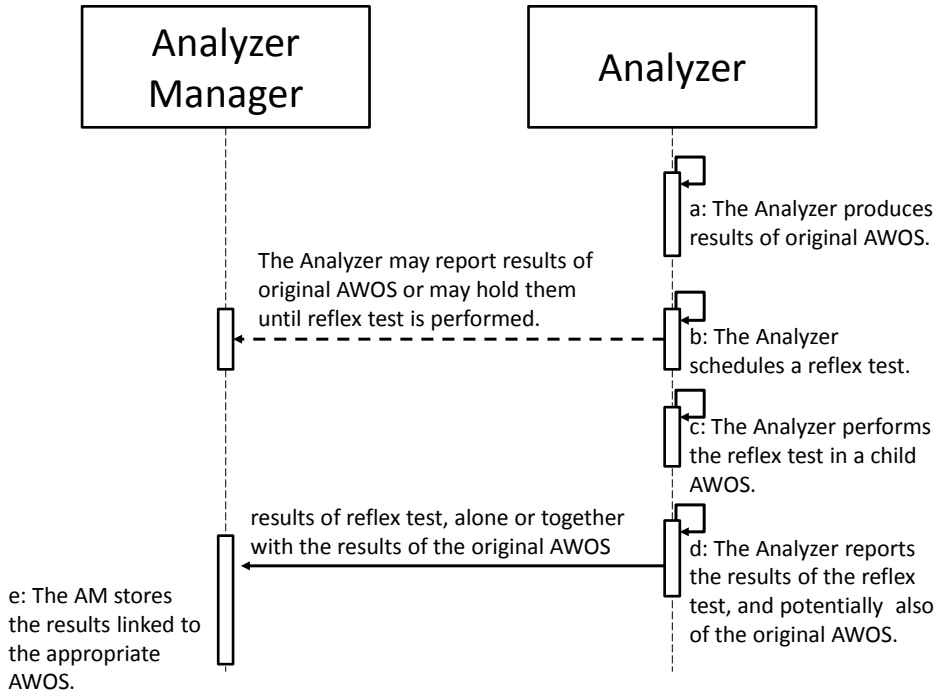


Figure X.6.8-1: Reflex decided on the Analyzer immediately after first run

X.6.9 Reflex test decided on the Analyzer Manager

The following diagram illustrates use case X.2.5.2

a. The Analyzer Manager receives a Work Order.
The Analyzer Manager splits this work order into a sequence of AWOS (only one in our example).
b. The Analyzer recognizes the specimen container.
c. The Analyzer sends a query to the Analyzer Manager with the recognized container ID or location.
d. The Analyzer Manager replies to the query with the AWOS to be performed.
e. Latter, the Analyzer performs the test.
f. To notify completion of the AWOS, the Analyzer sends an AWOS Status Change to the Analyzer Manager.
g. Considering the results obtained, the Analyzer Manager schedule a new AWOS.
h. The Analyzer sends a query to the Analyzer Manager with the recognized ID.
i. The Analyzer Manager replies to the query with the new AWOS to be performed.

j. Latter, the Analyzer performs the test.
k. To notify completion of the new AWOS (reflex), the Analyzer sends an AWOS Status Change to the Analyzer Manager.

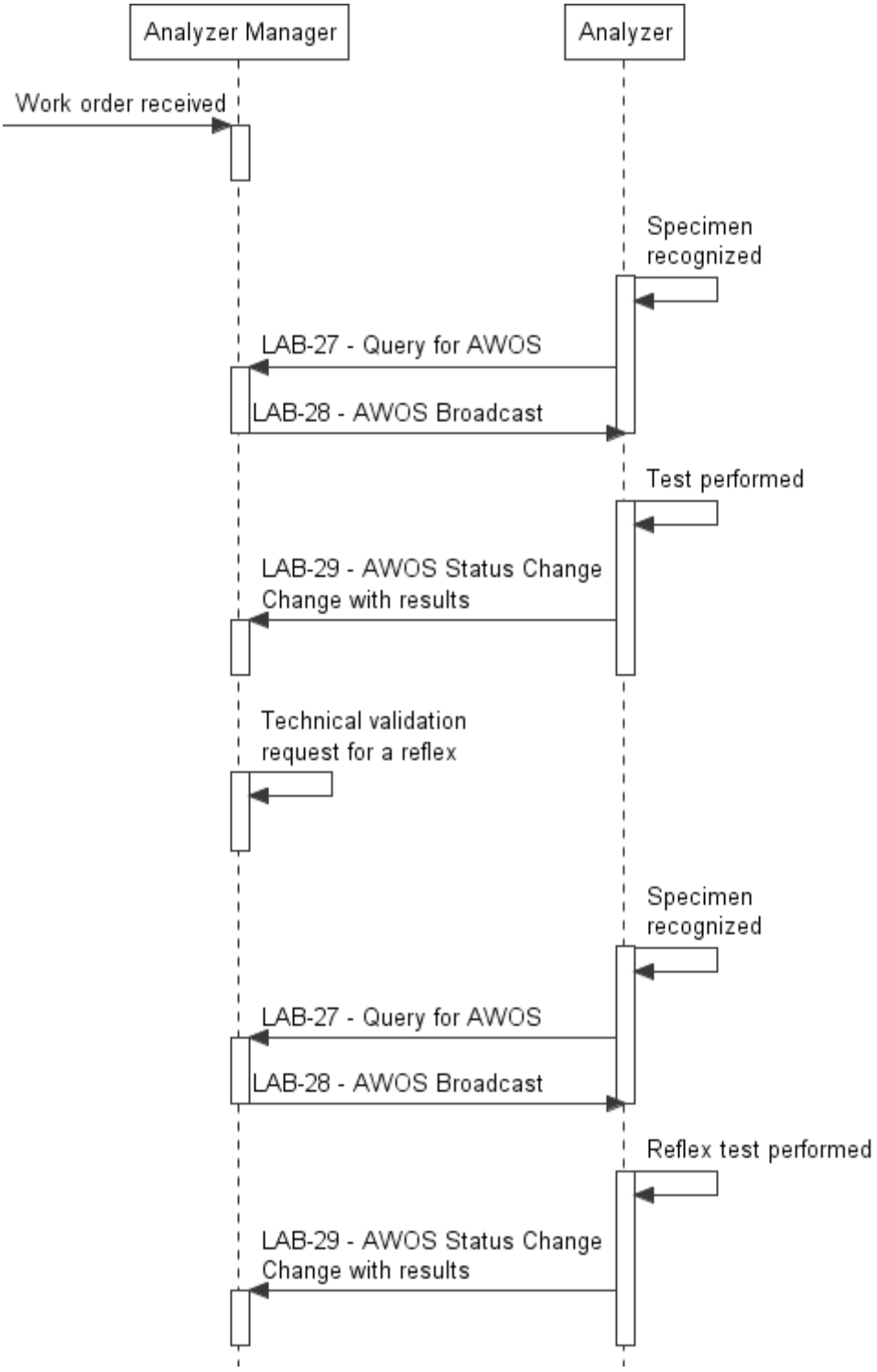


Figure X.6.9-1: Reflex decided on the Analyzer Manager at the technical validation time

Appendix A Actor Summary Definitions

Correct/Add the following terms to the Appendix A

Analyzer: An automated instrument that performs testing on biological specimens upon request from the ~~Automation~~ **Analyzer** Manager managing this instrument. Each request for testing on a specimen sent by the ~~Automation~~ **Analyzer** Manager to the Analyzer is called an Analytical Work Order Step (AWOS). The instrument sends back to the ~~Automation~~ **Analyzer** Manager the observations produced and any related conditions or events. In addition, the Analyzer may perform QC testing for its own surveillance, and also sends its QC results to the ~~Automation~~ **Analyzer** Manager. This actor is involved in the ~~LDA~~ **LAW** profile.

Automation Manager: A system or component that manages the automation in the laboratory or a part of it. Automation involves the integration or interfacing of automated or robotic transport systems, ~~analytical instruments, and~~ pre- or post-analytical process equipment such as automated centrifuges and aliquoters, decappers, recappers, sorters, and specimen storage and retrieval systems. This actor receives work orders from the Order Filler. It manages the processing of the ordered tests on the appropriate devices, and sends technically validated results back to the Order Filler. ~~This actor must be considered even if it manages a small part of the analytical process; e.g. if it manages one single analytical instrument.~~ Multiple Automation Managers can be related to one Order Filler. This actor is involved in the LTW and LDA profiles.

Analyzer Manager: An Automation Manager that manage the analytical part of the laboratory. This actor is involved in the LAW profiles.

Appendix B Transaction Summary Definitions

Correct/Add the following terms to the Appendix B

[LAB-21] WOS Download: This transaction contains the messages used to download a Work Order Step (WOS) from the Automation Manager to the ~~Analyzer or~~ Pre/Post-processor, according to a "push method". It includes "new WOS", "update WOS", "cancel WOS" and the related applicative acknowledgements. This transaction is used with ~~Analyzers and~~ Pre/Post-processor which work in download mode.

[LAB-22] WOS Query: This transaction contains the message used by the ~~Analyzer or~~ Pre/Post-processor to query the Automation Manager with one or more specimen (or location) identifiers, and the reply message from the Automation Manager delivering one or more WOS dedicated to each of these specimen. This transaction implements the "pull method" for requesting WOS.

~~**[LAB-23] AWOS Status Change:** This transaction contains the messages used by the Analyzer to report the status of an AWOS (such as "specimen arrived", "first run failed", "second run~~

~~started", "AWOS complete"…) and to send the tests results when the AWOS is complete. It also includes the related applicative acknowledgements from the Automation Manager.~~

[LAB-27] AWOS Query: This transaction contains the message used by the Analyzer to query the Analyzer Manager for one specimen (or location). The Analyzer Manager will follow the exchange with a LAB-28 that delivers one or more AWOS dedicated to the specimen or indicates there is no work to perform. This transaction implements the "pull method" for requesting AWOS, which is the default behavior.

[LAB-28] AWOS Broadcast: This transaction contains the messages used to broadcast an Analytical Work Order Step (AWOS) from the Analyzer Manager to the Analyzer, according to a "push method". It includes "new AWOS", "cancel AWOS" and the related applicative acknowledgements.

[LAB-29] AWOS Status Change: This transaction contains the messages used by the Analyzer to send the tests results when the AWOS is complete. It also includes the related applicative acknowledgements from the Analyzer Manager.

Volume 2 - Transactions

1 Introduction

1.6 History of Annual Changes

Add the following bullet to the list in section 1.6

- Added the LAW Profile which supports the workflow of IVD test work order steps and the results thereof between IVD analyzers and the systems driving their work (LIS or LAS). This workflow has been removed from the LDA profile, which keeps only the workflow between automation managers and pre or post-processors.

2 Conventions

Replace second paragraph of section 2.4.4 Acknowledgment Modes with the following paragraph:

For the IHE Laboratory Technical Framework, applications that receive HL7 messages shall send acknowledgements using the HL7 original acknowledgement mode as defined in HL7 v2.5 chapter 2, 2.9.2. The enhanced acknowledgement rules are not supported, except for the LAW profile.

3 Common HL7 Message Segments for IHE LAB TF

3.2 NTE- Notes and Comment Segment

Table 3.2-2 Modify the meaning for the value "A" to "Automation Manager or Analyzer Manager is the source of the comment."

Delete 11 Transaction LAB-23: AWOS Status Change

W IHE LAW Common Segment Definitions

Profiling conventions, messaging details, and segments that have common definitions across the LAW transactions are discussed below.

W.1 HL7 Profiling Conventions

At the message and segment level, the same usage conventions as defined in section 2.3 will be used, with the following exceptions.

W.1.1 Basic Interface Message Elements

A new usage coded value will be used, which is a more restrictive version of the "**R**: Required" coded value, for the message elements that are part of the basic interface required to produce technically valid results.

M: Mandatory. This code identifies a mandatory element that must be provided by the sender. A sender must be capable of providing the element. A receiver will raise an error if a required element is absent. A receiver must process the required information according to the defined use case behavior. A value must always be provided for a mandatory field. It is acceptable to send a NULL value in a mandatory field to indicate no value to report. See section 2.4.3 for a discussion of empty and nullified fields. The segment definitions will indicate when a NULL value is acceptable. An application will report an application error (MSA-1 = "AE") in the message acknowledgment if a value for a mandatory field is not provided.

W.1.2 Enhanced Interface Message Elements

The following coded values will be used for data elements that are part of the enhanced interface that supports additional Analyzer capabilities.

O: Optional. Used for the data elements of the enhanced interface elements that can be sent by the Analyzer. Those Analyzers supporting the interface will identify which of the optional elements are supported. Analyzers may decide to support none, some, or all of the optional elements. An Analyzer may produce a refined conformance profile changing supported elements to **RE (Required if Available)** and unsupported elements to **X (Not supported)**. Analyzer Managers will not raise an error if an optional data element is transmitted by an Analyzer.

RE: Required if Available. Used for the data elements of the enhanced result interface elements that are sent by the Analyzer Manager. As per the RE definition, the Analyzer will ignore these data elements of it does not support the enhanced interface.

W.1.3 All Message Elements

The definition for conditional usage has been modified to require defining the usage for the true and false outcomes of the condition predicate. This definition is similar to the definition used by HL7 v2.7.1 for conditional usage.

C (a, b): Conditional. 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", "RE", "O" or X":
- If the condition predicate associated with the element is false, follow the rules for "**b**" which shall be one of "M", "RE", "O" or X".

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

W.2 Messaging Details

The following sections provide additional messaging details.

W.2.1 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 a mandatory segment for LAB-28 and LAB-29. For this profile, the specimen container identifier is considered to be the value read from the container barcode, or other container identification mechanism (e.g., RFID).

The following SAC elements and predicates defined in HL7 v2.5.1 Chapter 13 will be used by the Analyzer to identify a container:

- SAC-3 Container Identifier is a conditional element for LAB-28 and LAB-29. It is assumed this is the value read from the container bar code, RFID tag, etc. for the container
- SAC-4 Primary (parent) Container Identifier is a conditional element for LAB-28 & LAB-29. It is assumed this is a value read from the container 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. If SAC-3 is populated, then SAC-4 may also be populated if the container contents were obtained from a parent container.
- If only SAC-4 is populated, then SAC-10/11 (carrier/carrier location) or SAC-13/14 (tray/tray location) will be used to identify the container/tray location. SAC-4 identifies the parent container, but the location carrier/tray location information identifies the specific container/tray location for testing. Either SAC-10/11 or SAC-13/14 must be populated if only SAC-4 is populated.

Refer to HL7 v2.5.1 Chapter 13 for more details.

Table W.2.1-1 defines how the SAC segment identifies a specimen originally provided in a specimen container with ID 987654 for the following scenarios, where each column in the table represents a scenario:

- 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.

Table W.2.1-1: Specimen Identification Scenarios

SAC Fields	Primary container	Aliquot container w/barcode	Aliquot container without barcode in rack	Aliquot in tray
SAC-3 Container Identifier	987654	987654A	-	-
SAC-4 Primary (parent) Container Identifier	-	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

W.2.2 Device Identification

Information about the equipment used to produce the observation is included in the AWOS Status Change 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 the use of multiple device identifiers. The repeating of this field allows for the hierarchical representation of the equipment (lowest level first), 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 should be supported. The Universal Device Identifier (UDI) should be:

- coded according to ISO 15459 (GS1, HIBCC)
- created and maintained by the manufacturer
- consist of the concatenation the Device Identifier (DI) and 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 W.2.2-1: 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 W.2.2-2: 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 manufacturer or site specific information to allow for the identification of the hierarchical configuration of the equipment (cluster of modules, etc.) and site specific identification.

Table W.2.2-3: Third and Subsequent Instance of Element OBX-18 Equipment Instance Identifier

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

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

W.2.3 Universal Service Identifier

The usage of LOINC(r) test codes for OBX-3 Observation Identifier, OBR-4 Universal Service Identifier, and TCD-1 Universal Service Identifier is strongly recommended. The value of the "Name of Coding System" in the case of LOINC is "LN".

W.2.4 Units of Measure

The Unified Code for Units of Measure (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.

W.2.5 Observation Identification

For an AWOS, the Analyzer performs one or more observation "runs" and generates one or more observation results for each run. Each run will be identified by a unique Run_ID. In addition, there may be alternate representations and raw values associated with an observation result. Each representation will be identified by a unique Representation_ID. It is important that the Analyzer provide sufficient details about each observation result so that the Analyzer Manager can correctly associate the result with the correct AWOS and observation run.

The observation hierarchy looks as follows, using the HL7 message elements of braces ([…]) to represent optional items and brackets ({…}) to identify repeatable items:

Observation

{Observation Result}

[{Alternate Representation}]

[Raw Values]

For each **Observation**, an OBR and ORC segment is sent with the following information:

- OBR-2 Placer Order Number contains the AWOS ID to associate the observation with the AWOS.
- OBR-4 Universal Service Identifier contains the identifier for the requested battery or test.
- ORC-5 Order Status contains the AWOS Status that indicates if all observations for the AWOS have been completed or if there are more observation instances to follow in subsequent messages.

Separate OBX segments are used to carry each **Observation Result** and the **Alternate Representation** or **Raw Values** associated with an Observation Result:

- OBX-2 Value Type contains the format of the observation value.
- OBX-3 Observation Identifier uniquely identifies the observation result. For example, a LOINC code may be used to identify the observation.
- OBX-4 Observation Sub-ID identifies a run in the format <Run_ID.Representation_ID>. Each observation run is assigned a unique numerical value starting with "1". When an

observation has alternate representations or raw values, a "dot" numerical value is added to the Run ID to uniquely identify each representation with a Representation_ID. For example, "1.1", "1.2", and so on will be used to identify the alternate representations or raw values associated with run "1".

- OBX-11 Observation Result Status indicates if the Analyzer considers the observation to be preliminary "P", final "F", or corrected "C".

The following sections describe how to populate the OBR, ORC, and OBX fields when transmitting observations.

W.2.5.1 Transmitting a Single Run

When only one run is performed by the Analyzer, it populates ORC-5 with "CM" to indicate the AWOS is complete. Each observation result for the run will be contained in a separate OBX segment and contain a unique value for OBX-3. For each segment, OBX-4 is populated with "1" to indicate this is the first (and only) run for the AWOS. The Analyzer considers the observation to be final because it is the only run, so for each segment OBX-11 is populated with "F". See table W2.5.1-1 for a summary of these important field values.

Table W.2.5.1-1: Field values for a Single Observation Result

Situation	OBR-2 Placer Order Number	ORC-5 Order Status	OBX-3 Observation Identifier	OBX-4 Observation Sub-ID	OBX-11 Result status
The Analyzer reports the result of this single run as final. There is no intent to perform an additional run yet. The Analyzer considers the AWOS as completed.	AWOS ID	CM	Unique ID for each observation result	1	F

The following is a sample message showing the transmission of a single run with multiple observation results:

```
MSH|...
PID|...
OBR|1|432156|123|85027^Hemogram and platelet count|...
ORC|OK||||CM||||20120530182101
OBX|1|NM|11156-7^LEUKOCYTES^LN|1|8.2|10*3/mm3|||||F|||20120530182101
OBX|2|NM|11273-0^ERYTHROCYTES^LN|1|4.08|10*3/mm3|||||F|||20120530182101
```

W.2.5.2 Transmitting Multiple Runs

If the Analyzer Manager decides another run, or rerun, is necessary then a new AWOS is sent to the selected Analyzer. The results of this rerun fulfill the new AWOS, which is distinct from the AWOS of the previous run. The Analyzer Manager knows that this AWOS represents a new run of a previous AWOS. The observation message does not carry any specific information to enable the processing of the rerun observation.

However, for reruns decided on the Analyzer and reported to the Analyzer Manager, multiple runs are transmitted. The following segment fields identify if the AWOS is complete, distinguish the runs, and provide the status of a run.

- ORC-5 Order Status indicates if the Analyzer has completed the AWOS (value "CM") or if more results (e.g., an additional run) are to be expected for that AWOS (value "IP").
- OBX-4 Observation Sub-ID is used to identify an observation instance. Each run of an AWOS will have a unique numerical identification. This applies for runs reported in the same message and across messages. The first run will be "1", the second run "2", and so on.
- OBX-11 Result Status indicates if the current observation is selected as reportable (values "F" or "C") or if it is not selected (value "P") by the Analyzer. In the latter, another run for the same test may have been selected as the reportable one by the Analyzer (status "F") or the selection of the reportable run is left up to the Analyzer Manager (all runs have status "P"). Result Status "C" is used only to correct the observation of a previous run that was selected as reportable (value "F").

Table W.2.5.2-1 details the contents of ORC-5 and OBX-11 in the different situations that may occur with multiple runs decided by the Analyzer.

Table W.2.5.2-1: Order and result status in cases of rerun decided on the Analyzer

Situation	ORC-5 Order Status	OBX-11 Result status
The current result is reported as preliminary because the Analyzer has decided to perform an additional run that will be reported later on. The AWOS is still in process on the Analyzer.	IP	P
Having reported a result marked as preliminary because an additional run was pending for the same test, the Analyzer now reports the result of the additional run and marks it as the reportable result. The AWOS is completed on the Analyzer.	CM	F
The current result is part of a set of multiple runs for which the Analyzer leaves up to the AM the decision to select the reportable one. No more run is expected. The AWOS is completed on the Analyzer.	CM	P
Having reported a final result, the Analyzer / biotechnologist later detected a defect in the initial run and decided to perform an additional run. The now selected result of this additional run as the reportable one. The AWOS is completed.	CM	C

The following sample messages clarify the contents of the OBR, ORC, and OBX segments when transmitting multiple runs in the same message and across messages.

Message carrying the results of an initial run, with an additional run pending:

```
MSH|...
PID|...
OBR|1|432156|123|85027^Hemogram and platelet count|...
ORC|OK||||IP||||20120530182101
OBX|1|NM|11156-7^LEUKOCYTES^LN|1|8.2|10*3/mm3|||||P|||20120530182101
OBX|2|NM|11273-0^ERYTHROCYTES^LN|1|4.08|10*3/mm3|||||P|||20120530182101
OBX|3|NM|20509-6^HEMOGLOBIN^LN|1|13.4|10*3/mm3|||||P|||20120530182101
OBX|4|NM|20570-8^HEMATOCRIT^LN|1|39.7|10*3/mm3|||||P|||20120530182101
```

Subsequent message carrying the results of the run selected by the Analyzer:

```
MSH|...
PID|...
OBR|1|432156|123|85027^Hemogram and platelet count|...
ORC|OK||||CM||||20120530184001
OBX|1|NM|11156-7^LEUKOCYTES^LN|2|8.9|10*3/mm3|||||F|||20120530184001
OBX|2|NM|11273-0^ERYTHROCYTES^LN|2|4.9|10*3/mm3|||||F|||20120530184001
OBX|3|NM|20509-6^HEMOGLOBIN^LN|2|13.9|10*3/mm3|||||F|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|2|39.9|10*3/mm3|||||F|||20120530184001
```

Message carrying the results of two runs, with one run selected by the Analyzer.

```
MSH|...
PID|...
OBR|1|123456|123|85027^Hemogram and platelet count|...
ORC|OK||||CM||||20120530182101
OBX|1|NM|20509-6^HEMOGLOBIN^LN|1|13.4|10*3/mm3|||||P|||20120530182101
OBX|2|NM|20570-8^HEMATOCRIT^LN|1|39.7|10*3/mm3|||||P|||20120530182101
OBX|3|NM|20509-6^HEMOGLOBIN^LN|2|13.9|10*3/mm3|||||F|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|2|39.9|10*3/mm3|||||F|||20120530184001
```

Message carrying the results of two runs, with selection of the reported results left to the Analyzer Manager.

```
MSH|...
PID|...
OBR|1|987654|123|85027^Hemogram and platelet count|...
ORC|OK||||CM||||20120530182101
OBX|1|NM|20509-6^HEMOGLOBIN^LN|1|13.4|10*3/mm3|||||P|||20120530182101
OBX|2|NM|20570-8^HEMATOCRIT^LN|1|39.7|10*3/mm3|||||P|||20120530182101
OBX|3|NM|20509-6^HEMOGLOBIN^LN|2|13.9|10*3/mm3|||||P|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|2|39.9|10*3/mm3|||||P|||20120530184001
```

Subsequent message carrying the correction to a previously reported observation:

```
MSH|...
PID|...
OBR|1|432156|123|85027^Hemogram and platelet count|...
ORC|OK||||CM||||20120530184001
OBX|1|NM|11156-7^LEUKOCYTES^LN|3|8.5|10*3/mm3|||||C|||20120530184001
OBX|2|NM|11273-0^ERYTHROCYTES^LN|3|4.5|10*3/mm3|||||C|||20120530184001
OBX|3|NM|20509-6^HEMOGLOBIN^LN|3|13.5|10*3/mm3|||||C|||20120530184001
OBX|4|NM|20570-8^HEMATOCRIT^LN|3|39.5|10*3/mm3|||||C|||20120530184001
```

W.2.5.3 Transmitting Alternate Representations

The Analyzer can also transmit alternate representations of an observation result, like images, scattergrams, X-Y plots, etc. An Analyzer Manager identifies groups of alternate representations for the same observation by identifying OBX segments that have the same value for OBX-3 and the same Run ID in OBX-4. A Representation ID will be appended to the Run_ID in the following manner <Run_ID.Representation_ID> to associate the representation with the run and uniquely identify the alternate representation.

The following describes how to transmit an observation along with additional graphical images and graphical points:

- After the OBR and ORC segment, use a series of OBX segments each representing a different observation result.
    - The first OBX segment contains the usual observation result, e.g., numeric value, code, run ID, etc.
    - The next OBX segment is optional, but if present it contains the graphical image as 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. OBX-3 contains the same value as the observation result. OBX-4 contains <Run_ID.Representation_ID>.
    - The next OBX segment is also optional, but if present it contains the pointer to the graphic as 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 has only a read access and the sender is responsible for the file management (e.g., deletion after 24 hours or any other defined retention time). OBX-3 contains the same value as the observation result. OBX-4 contains <Run_ID.Representation_ID>.
    - Finally, another optional OBX segment may follow that contains the series of values representing coordinates of individual points of the graphic as the HL7 "Numeric Array (NA)" data type for OBX-2. The NA data type may represent multidimensional arrays, e.g., X-Y or X-Y-Z plots. OBX-3 contains the same value as the observation result. OBX-4 contains <Run_ID.Representation_ID>.

- The major characteristics of the OBX segments used in the transfer of alternate representations of an observation result described above are as follows:
  - The OBX segments will have a different OBX-2 Value Type, e.g., NM, ED, RP and NA as described above.
  - Each OBX segment has the same OBX-3 Observation Identifier.
  - The OBX segments are grouped by OBX-3 and the Run_ID in OBX-4.
  - The alternate representations are uniquely identified by the numerical Representation_ID in the OBX-4, which contains values such as "1.1", "1.2", and so on.

W.2.5.4 Transmitting Raw Values

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.

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 same AWOS as the cooked values, so the OBX segments have the same values for OBX-3, OBX-8, OBX-11, OBX-16, OBX-18, and OBX-19.

The raw values differ from the cooked value in the OBX-2 Value Type and the use of a numerical dot suffix for the Representation_ID added to the Run_ID in OBX-4 Observation Sub-ID using the following format <Run_ID.Representation_ID>. This is the same approach used to identify multiple observation representations, as discussed above in section W.2.5.3. The OBX segments are grouped by OBX-3 and OBX-4, and the raw value representation uniquely identified by the Reperesentation_ID in the OBX-4, which contains values such as "1.1", "1.2", and so on.

The raw values are either structured or a series of values / series of vectors of values with similar semantics.

- The structured raw value will have the OBX-2 = ST (String) and the structure will be represented in XML notation (see examples below). The XML notation instead of delimiters permits explicit description of the structure and avoids the "hidden / uncontrolled" introduction of new data types potentially leading to conformance problems.
- The series of values / series of vectors of values will have the OBX-2 = NA (Numeric array) so that the values can be transmitted using multidimensional arrays.

Examples:

Raw value example	XML notation (OBX-2 = ST)	Delimiter notation (OBX-2 = NA)
Structure raw value:	<DataTable Description="Linear CurveParameters"> <tr pos="1" Description="Absorbance 1">	0.3456^1.6543

Raw value example	XML notation (OBX-2 = ST)	Delimiter notation (OBX-2 = NA)
Calibrator – Linear Curve Parameters	<td pos="1">0.3456</td> </tr> <tr pos="2" Description="K Factor"> <td pos="1">1.6543</td> </tr> </DataTable>	
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> <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 -	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&0.2&0.3&0.4&0.1&0.1&0.1&0.1

Raw value example	XML notation (OBX-2 = ST)	Delimiter notation (OBX-2 = NA)
	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> <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>	

W.2.6 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. If the Analyzer Manager decides a reflex is necessary, then a new AWOS for that test is sent to the selected Analyzer. The observation results of this test fulfill the new AWOS. The Analyzer Manager knows that this AWOS represents a reflex of a previous AWOS(s). The

observation message does not need to carry any specific information to enable the processing of the reflex observation.

However, for a reflex ordered at the Analyzer, details about the reflex must be transmitted. The following segment fields are used to identify 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 does not have an AWOS_ID.
- 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). In the situation where the parent AWOS(s) and the reflex are initiated at the Analyzer, the parent AWOS ID(s) are not available. The Analyzer Manager shall treat both the parent and reflex as unsolicited observations by setting OBR-2 to null ("") and leaving ORC-8 empty.

W.2.7 Enhanced Acknowledgement Mode

The enhanced acknowledgement mode shall be required for the LAW profile.

The sending application shall populate field MSH-15 with value "ER" and field MSH-16 with value "AL", thus instructing the receiving application to send an "accept acknowledgement" only in case of error (e.g. communication error, unavailability of the safe storage in to which the message cannot be saved) and to send an applicative acknowledgement in all other cases. Thus there shall be always one and only one acknowledgement message coming back to the sending application.

As stated for all IHE domain, within the ITI TF-2x: Section C.2.3 “Acknowledgement Modes”, a receiving application will 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. The message contains errors. It SHALL not be sent again without correcting the error.
- AR: Application rejection. The message has been rejected by the receiving application. If the rejection is not related to an invalid value in the MSH segment, the sender may try again to send the message later.

For example, if an Analyzer Manager identifies a sample by sending SAC-13 and SAC-14, but the Analyzer does not process trays, the Analyzer will send back an “application error” with MSA-1 = AE, ERR-2 referencing SAC-13, and ERR-3 valued with an appropriate code (e.g.; 204 “Unknown key identifier”).

Implementers of this profile SHALL read ITI TF-2x: Section C.2 "HL7 Implementation Notes", and particularly sub-section C.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 all situations of errors.

W.2.8 MLLP Connections

This profile requires the use of the network connections defined in section 2.4.5 IHE Laboratory Technical Framework Acknowledgement Policies. 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 LAB TF-1: Sections X.4 Actors/Transactions and X.5 LAW Integration Profile Options for more details about the transactions and option). One network connection will support the *LAB-27 Query for AWOS* and *Lab-29 AWOS Status Change* transactions from the Analyzer, while the other network connection will support the *LAB-28 AWOS Broadcast* 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 the ITI TF-2x: Section C.2.1.

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.

W.3 LAW Segments

The following segment definitions supersede the common segment definitions from section 3. Cardinality and usages are defined to clarify differences when segments are sent by the Analyzer Manager versus the Analyzer.

W.3.1 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'. See section **C.2.3.2 in Appendix C of ITI TF volume 2** for additional information.

Table W.3.1-1: ERR Segment

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
2	18	ERL	C (M/X)	[1..*]		01812	Error Location
3	705	CWE	M	[1..1]	0357	01813	HL7 Error Code
4	2	ID	M	[1..1]	0516	01814	Severity

ERR-2 Error Location (ERL), conditional.

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

Predicate: Usage is Mandatory when the error is within an HL7 field, component, or sub-component. Otherwise, usage is Not Supported.

Table W.3.1-2: Element ERR-2 Error Location

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

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

Identifies the HL7 (communications) error code. Only the first component (Identifier) is supported using codes from the following subset of codes in HL7 Table 0357.

Table W.3.1-3: 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.

Value	Description	Comment
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 W.3.1-4: Element ERR-3 HL7 Error Code

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	

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 W.3.1-5: Subset of HL7 Table 0516 – Error severity

Value	Description	Comment
E	Error	Transaction was unsuccessful

W.3.2 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.

Table W.3.2-1: INV Segment

SEQ	LEN	DT	Usage Analyzer	Card.	TBL#	ITEM#	Element name
1	250	CE	M	[1..1]	0451	01372	Substance Identifier
2	250	CE	M	[1..1]	0383	01373	Substance Status
3	250	CE	M	[0..1]	0384	01374	Substance Type

SEQ	LEN	DT	Usage Analyzer	Card.	TBL#	ITEM#	Element name
12	26	TS	O	[0..1]		01383	Expiration Date/Time
16	200	ST	O	[0..1]		01387	Manufacturer Lot Number

INV-1 Substance Identifier (CE), mandatory.

This is a manufacturer-specific unique identifier for the control material. If the control material is in a bar-coded tube, this is also what is encoded in the bar-code to identify the material.

Table W.3.2-2: INV-1 Substance Identifier

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Identifier of substance

INV-2 Substance Status (CE), mandatory.

This field contains a subset of values taken from HL7 Table 0383 as described below to identify the current status of the substance.

Table W.3.2-3: Element INV-2 Substance Status

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	2	Substance status

Table W.3.2-4: Subset of HL7 Table 0383 - Substance Status (Control material)

Value	Description	Comment
OK	OK Status	

INV-3 Substance Type (CE), mandatory.

This field contains a subset of values taken from HL7 Table 0384 to identify the material as control material.

Table W.3.2-5: Element INV-3 Substance Type

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	2	Type of substance (e.g., Control, Reagent, Bulk Supply, Waste)

Table W.3.2-6: Subset of HL7 Table 0384 – Substance Type

Value	Description	Comment
CO	Control	Quality Control Specimen

INV-12 Expiration Date/Time (TS), optional.

This is the expiration date of the material. Precision supported is to the day.

Table W.3.2-7: Element INV-12 Expiration Date/Time

Component/Sub-Component	Usage	Comment
YYYYMMDD	R	

INV-16 Manufacturer Lot Number (ST), optional.

This is a manufacturer-specific lot number of the control material.

W.3.3 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 W.3.3-1: 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 W.3.3-2: 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 due to and error in either content of format
AR	Original mode: Application Reject	Message rejected due to MSH error(s)

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.

W.3.4 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 W.3.4-1: 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	M	[1..1]		00003	Sending Application
4	227	HD	M	[1..1]		00004	Sending Facility
5	227	HD	M	[1..1]		00005	Receiving Application
6	227	HD	M	[1..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)	[1..1]	0155	00015	Accept Acknowledgement Type
16	2	ID	C (M,X)	[1..1]	0155	00016	Application Acknowledgement Type
18	16	ID	M	[1..1]	0211	00692	Character Set
21	427	EI	M	[1..1]	01598	01598	Message Profile Identifier

MSH-1 Field Separator (SI), mandatory.

This profile supports the HL7-recommended value; that is | (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 supports the HL7-recommended values ^~\& (ASCII 94, 126, 92, and 38, respectively).

MSH-3 Sending Application (HD), mandatory.

This field contains the name of the sending application.

Table W.3.4-2: Element MSH-3 Sending Application (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	R	Vendor specified value

MSH-4 Sending Facility (HD), mandatory.

This field contains the name of the sending facility.

Table W.3.4-3 Element MSH-4 Sending Facility (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	R	Laboratory specified value

MSH-5 Receiving Application (HD), mandatory.

This field contains the name of the receiving application.

Table W.3.4-4: Element MSH-5 Receiving Application (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	R	Laboratory specified value

MSH-6 Receiving Facility (HD), mandatory.

This field contains the name of the receiving facility.

Table W.3.4-5: Element MSH-6 Receiving Facility (HD)

Component/Sub-Component	LEN	Usage	Contents
namespace ID (IS)	20	RE	Laboratory specified value

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 W.3.4-6: Element MSH-7 Date/Time of Message

Component/Sub-Component	LEN	Usage	Comment
YYYYMMDDHHMMSS+/-ZZZZ	19	R	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 W.3.4-7: 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.

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 W.3.4-8: Element MSH-11 Processing ID

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

Table W.3.4-9: 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 W.3.4-10: 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. The LAW profile uses Enhanced Acknowledgement mode to have the accept acknowledgement report errors. MSH-15 will contain the value "ER".

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

Table W.3.4-11: Subset of HL7 Table 0155 – Accept/application acknowledgment type

Value	Description	Comment
ER	Error/reject conditionals always	Only send accept acknowledgment for an error

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 W.3.4-12: Subset of HL7 Table 0155 – Accept/application acknowledgment type

Value	Description	Comment
AL	Always	Application acknowledgments are always required

MSH-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 W.3.4-13: 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.

From the ITI Technical Framework Volume 2x, the field contains one repetition with a value representing the IHE transaction identifier, in the form <domain>-<transaction number>^IHE" (e.g., "LAB-27^IHE"), as shown below.

Table W.3.4-14: Element MSH-21 Message Profile Identifier (EI)

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

W.3.5 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 W.3.5-1: OBR Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card	TBL#	ITEM#	Element name
2	50	EI	M	M	[1..1]		00216	Placer Order Number (AWOS ID)
3	50	EI	X	O	[0..1]		00217	Filler Order Number
4	250	CE	M	M	[1..1]		00238	Universal Service Identifier
16	250	XCN	RE	O	[0..1]		00226	Ordering Provider

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card	TBL#	ITEM#	Element name
17	250	XTN	RE	O	[0..2]		00250	Order Callback Phone Number

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 actor and should be unique across all OBR segments across all messages. For the Analyzer, if the AWOS ID is unknown, then the value should be "", which is the NULL value. 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.

Note on Element Length**:** The maximum element length for OBR-2 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) for AWOS IDs.

Table W.3.5-2: Element OBR-2 Placer Order Number

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

OBR-3 Filler Order Number (EI), optional (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 extended to 50 characters from the HL7 defined length of 22. This extension allows sending systems to use globally unique identifiers (such as GUIDs).

Table W.3.5-3: Element OBR-3 Filler Order Number

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. The usage of LOINC(r) test codes for the identification of tests is strongly recommended. The value of the "Name of Coding System" in the case of LOINC is "LN".

Table W.3.5-4: Element OBR-4 Universal Service Identifier

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	20	Name of coding system

OBR-16 Ordering Provider (XCN), required if available (Analyzer Manager), optional (Analyzer).

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

Table W.3.5-5: Element OBR-16 Ordering Provider (XCN)

Component/Sub-Component	LEN	Usage	Comment
ID number (ST)	20	R	Locally defined identifier

OBR-17 Order Callback Phone Number (XTN), required if available (Analyzer Manager), optional (Analyzer).

This field is the telephone number or Internet address for reporting an AWOS status.

XTN-3 is required, and the profile supports the following subset of values from HL7 Table 0202.

Table W.3.5-6: Subset of HL7 Table 00202 – Telecommunication Equipment Type

Value	Description	Comment
PH	Telephone	
FX	Fax	
MD	Modem	
CP	Cellular or Mobile Phone	
SAT	Satellite Phone	
BP	Beeper	
Internet	Internet Address	

Component predicates: This field carries either an email address or a phone number.

- Email address: XTN-4 is populated when XTN-3 is valued to “Internet”. In that case the only other components that can be populated are XTN-2 and XTN-9. All other components are left empty.

- Phone number: When XTN-3 is populated with a value other than "Internet", then either component XTN-7 or XTN-12 must be populated. If XTN-7 is populated then XTN-12 must be empty. If XTN-12 is populated then XTN-7 must be empty. Other components that may be populated are XTN-2, XTN-5, XTN-6, and XTN-8 through XTN-11.

Table W.3.5-7: Element OBR-17 Ordering Callback Phone Number (XTN)

Component/Sub-Component	LEN	Usage	Comment
Telephone Number (ST)	20	X	Deprecated as of HL7 v2.3
Telecommunication Use Code (ID)	3	O	See HL7 Table 0201 – Telecommunication Use Code for valid values
Telecommunication Equipment Type (ID)	8	R	Subset of values from HL7 Table 0202 – Telecommunication Equipment Type
Email Address (ST)	199	C (R/X)	Required when equipment type is *Internet*
Country Code (NM)	3	C (O/X)	
Area/City Code (NM)	4	C (O/X)	
Local Number (NM)	5	C (R/X)	
Extension (NM)	5	C (O/X)	
Any Text (ST)	199	C (O/X)	Comments about the telephone number or email address
Extension Prefix (ST)	4	C (O/X)	Locally defined
Speed Dial Code (ST)	6	C (O/X)	Locally defined
Unformatted Telephone Number (ST)	199	C (R/X)	Phone number as unparsable string

W.3.6 OBX Segment

HL7 v2.5.1: chapter 7 (7.4.2 OBX – Observation/Result Segment).

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

Table W.3.6-1: 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)	[1..1]	0125	00570	Value Type
3	250	CE	M	M	[1..1]		00571	Observation Identifier
4	20	ST	X	M	[1..1]		00572	Observation Sub-ID
5	99999	Varies	C (M/X)	C (M/X)	[1..1]		00573	Observation Value
6	250	CE	C (M/X)	C (M/X)	[1..1]		00574	Units
7	70	ST	RE	O	[0..1]		00575	References Range

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
8	5	IS	M	M	[1..*]	0078	00576	Abnormal Flags
11	1	ID	M	M	[1..1]	0085	00579	Observation Result Status
14	26	TS	RE	X	[0..1]		00582	Date/Time of the Observation
16	250	XCN	M	M	[1..1]		00584	Responsible Observer
18	427	EI	M	M	[2..*]		01479	Equipment Instance Identifier
19	26	TS	M	M	[1..1]		01480	Date/Time of the Analysis

OBX-1 Set ID (SI), mandatory.

If the segment occurs only one time within a message structure, then its value will be '1'. If the message structure (e.g., segment group) repeats, then the first occurrence of the segment in each segment group will be '1'.

OBX-2 Value Type (ID), conditional.

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

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

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

Table W.3.6-2: Subset of HL7 Table 0125 – Value Type

Value	Description	Comment
CE	Coded Entry	Used to report exception code (reason test failed to produce a final result yet.
ED	Encapsulated Data	Used to report graphs, plots, etc.
NM	Numeric	Numeric result value only
NA	Numerical Array	n-dimensional set of plot values
RP	Reference Pointer	Reference to a location of the observation
SN	Structured Numeric	Used when result is above or below dynamic range of assay. (> or <).
ST	String	Interpretation string result

OBX-3 Observation Identifier (CE), mandatory.

This field contains a unique identifier for the observation. The usage of LOINC(r) test codes for the identification of tests is strongly recommended. The value of the "Name of Coding System" in the case of LOINC is "LN".

Table W.3.6-3: Element OBX-3 Observation Identifier

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	20	Name of coding system

OBX-4 Observation Sub-ID (ST), conditional.

This field is used to distinguish between multiple OBX segments with the same Observation ID organized under one OBR. This field is required so that each OBX segment has a unique combination of OBX-3 and OBX-4 when multiple runs are performed and their observation results reported by the Analyzer. Each run is uniquely identified by a numerical value, or Run_ID, starting from "1".

In addition, OBX-4 is populated with a Representation_ID when there are alternate representations or raw values for an observation result. The Representation_ID is a numerical value starting from "1" that is added as a dot suffix to the Run_ID in the format "Run_ID.Representation_ID". The Representation_ID ensures that each OBX-3 and OBX-4 combination is unique.

See section W.2.5 Observation Identification for more details about the use of this field to identify runs, alternate representations, and raw values.

OBX-5 Observation Value (varies), conditional.

The observation value shall be reported using one of the allowed value types as specified in OBX-2; contains the result value for the test result part identified in OBX-3 Observation Identifier.

Predicate: Usage is Mandatory when the value of OBX-11 Observation Result Status is not "D. Otherwise usage is Not Supported.

If the result type is for an exception result, then the CE data type is used to report the exception code as the reason the test failed to run. The following table defines how to use the CE components to report exception.

Table W.3.6-4: Element OBX-5 Observation Value (when CE data type)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	4	R	4 digit exception/error code
Text (ST)	260	R	Text message associated with

Component/Sub-Component	LEN	Usage	Comment
			exception
Name of Coding System (ID)	20	R	Analyzer Model

OBX-6 Units (CE), conditional.

This field is populated with the unit of measure for the result. UCUM shall be used to define the unit of measure.

Predicate: Usage is Mandatory if OBX-2 is valued with either with “NM” or “SN”. Otherwise usage is Not Supported.

Table W.3.6-5: Element OBX-6 Units (CE)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Unit of measure
Text (ST)	199	R	
Name of Coding System (ID)	4	R	UCUM

OBX-7 Reference Range (ST), required if available (Analyzer Manager), optional (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 Abnormal Flags (IS), mandatory.

The field contains analyzer defined result flags (if any) assigned to the result. The field is set to NONE if no flags apply. Multiple flags 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.

The required flags defined in HL7 User-defined Table 0078 that shall be semantically processed by the Analyzer Manager are defined in the table below. However, an Analyzer may extend the set with additional flags.

Table W.3.6-6: Subset of HL7 User-defined Table 0078 – Abnormal Flags

Value	Description	Comment
<	Below assay dynamic range	
>	Above assay dynamic range	

Value	Description	Comment
L	Below low normal	
H	Above high normal	
LL	Below assay panic range	
HH	Above assay panic range	
N	Normal	Non-numeric results
A	Abnormal	Non-numeric results
POS	Positive	
NEG	Negative	
IND	Indeterminate	
QCF	Quality Control Failure	
NONE	No flags	

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

This field supports a subset of values taken from HL7 Table 0085 as described below:

Table W.3.6-7: Subset of HL7 Table 0085 – Observation Result Status

Value	Description	Comment
C	Record coming over is a correction and thus replaces a final result	The current result (C) is a correction of a result previously transmitted as final (F)
D	Deletes the OBX record	Delete previously reported result
F	Final results	Final result of a unique run or selected result of multiple runs
I	Specimen in lab, results pending	Testing is in progress on the Analyzer
P	Preliminary instrument response	The result is preliminary
X	Results cannot be obtained	Test Exception. The reason for failure is being reported. This test will not produce any result

When the Analyzer has selected a run among multiple runs of the same AWOS, it marks the results of this selected run by populating OBX-11 with value:

- "F" if all the results from the other runs have been reported with status "P" ;
- "C" if one of the results of the other runs was reported with status "F".

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. Degree of precision component is not supported.

Table W.3.6-8: Element OBX-14 Date/Time of the Observation (TS)

Component/Sub-Component	Usage	Comment
YYYYMMDDHHMMSS	R	

OBX-16 Responsible Observer (XCN), mandatory.

This field contains the identity of the observer that causes the change of the observation result status. Only the first component (ID number) of this field is necessary. If the value is unknown, then a NULL value will be used for the ID number.

Table W.3.6-9: Element OBX-16 Responsible Observer (XCN)

Component/Sub-Component	Usage	Len	Comment
ID number (ST)	R	20	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 manufacturer or site specific identifiers. See section W.2.2 Device Identification for more details.

Table W.3.6-10: 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 defined
Namespace ID (IS) 	R R O	20	First Repeat: Manufacturer Second Repeat: Manufacturer Subsequent repeats: Vendor 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. Degree of precision component is not supported.

Table W.3.6-11: Element OBX-19 Date/Time of Analysis (TS)

Component/Sub-Component	Usage	Comment
YYYYMMDDHHMMSS	R	

W.3.7 ORC Segment

HL7 v2.5: 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 W.3.7-1: 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	EI	X	C (M/X)	[0..1]		00216	Placer Order Number
4	22	EIP	RE	O	[0..1]		00218	Placer Group Number
5	2	ID	X	M	[1..1]		00219	Order Status
8	200	EIP	X	C (RE/X)	[0..*]		00222	Parent
9	26	TS	M	M	[1..1]	0038	00223	Date/Time of Transaction
21	250	XON	RE	O	[0..1]		01311	Ordering Facility Name
27	26	TS	X	O	[0..1]		01642	Filler Expected Availability Date/Time

ORC-1 Order Control (ID), mandatory.

This field may be considered the "trigger event" identifier for orders. The IHE Laboratory Technical Framework allows only the following subset for the LAW profile:

Table W.3.7-2: 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) Event acknowledgement sent by Analyzer in OUL message of LAB-29
UA	Unable to accept order/service	Event acknowledgement sent by Analyzer in ORL message of

Value	Description	Comment
		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

ORC-2 Placer Order Number (EI), not supported (Analyzer Manager), conditional (Analyzer).

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.

Predicate: Usage is Mandatory if MSH-9.1 (Message type) is populated with "ORL" and MSH-9.2 (Event type) is populated with "O34". Otherwise, usage is Not Supported because the placer order number is only carried by field OBR-2 Placer Order Number.

Note on Element Length**:** The maximum element length for ORC-2 and OBR-2 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) for AWOS IDs.

ORC-4 Placer Group Number (EIP), required if available (Analyzer Manager), optional (Analyzer).

The data type of ORC-4 is upgraded from EI to EIP, in pre-adoption of HL7 2.8.

The Placer Group Number represents an identification of a set of closely related orders, i.e., a list of batteries and tests ordered together by the placer to the laboratory for one subject, known as an **Order Group**. This field carries the Order Group identification, which is a pair of identifiers. The first identifier, if present, is assigned by the Order Placer application. The second identifier, if present, is assigned by the Order Filler application.

An Order Group may be identified by the Order Placer application or by the Order Filler or by both applications. The Order Group consists of all the ORCs and order detail segments sharing the same Order Group identification.

In cases laboratory orders are not grouped under a common Order Group this field is empty.

Table W.3.7-3: Element ORC-4 placer Group Number (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	

ORC-5 Order Status (ID), mandatory (Analyzer).

The allowed values for this field within IHE Laboratory Technical Framework are a subset of HL7 table 0038 - Order Status as shown below:

Table W.3.7-4: Subset of HL7 Table 0038 – Order Status

Value	Description	Comment
A	Some, but not all, results available	
CA	AWOS was canceled	
CM	AWOS is completed	All observations for the AWOS have been reported
IP	AWOS in process, unspecified	Additional observations are in process
SC	AWOS in process, scheduled	Additional observations have been scheduled

ORC-8 Parent (EIP), not supported (Analyzer Manager), conditional (Analyzer).

The field is used by the Analyzer to associate an AWOS to its parent AWOS(s) in OUL^R22 messages when the AWOS has one or more parents. 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 LAB TF by pre-adoption of this repeatability stated in HL7 V2.9.

Predicate: Usage is Required when Available if MSH-9.1 Message Type is populated with “OUL”, MSH-9.2 Event Type is populated with “O22”, and OBR-2 is populated with null (""). Otherwise usage is Not Supported.

ORC-9 Date/Time of Transaction (TS), mandatory.

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.

In OML messages "Status changed", this field contains the date/time of the last status change of the unit of work (ORC-5).

Table W.3.7-5: Element ORC-9 Date/Time of Transaction (TS)

Component/Sub-Component	Usage	Comment
YYYYMMDDHHMMSS	R	

ORC-21 Ordering Facility Name (XON), required if available (Analyzer Manager), optional (Analyzer).

This field contains the name of the facility placing the order.

Table W.3.7-6: Element ORC-21 Ordering Facility Name (XON)

Component/Sub-Component	Usage	Comment
Organization Name (ST)	R	

ORC-27 Filler's Expected Availability Date/Time (TS), optional (Analyzer).

This field specifies the date/time the filler expects the services to be available. This element shall be reported to a precision of seconds. Indication of the time zone is not supported. The degree of precision component is not supported.

Table W.3.7-7: Element ORC-27 Filler's Expected Availability Start Date/Time (TS)

Component/Sub-Component	Usage	Comment
YYYYMMDDHHMMSS	R	

W.3.8 PID Segment

HL7 v2.5: chapter 3 (3.4.2 PID – Patient Identification Segment).

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. Only a minimal set of identifying data is specified, as it is the responsibility of the Analyzer Manager to maintain patient demographic information.

Table W.3.8-1: PID Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
3	250	CX	M	C (M/O)	[0..*]		00106	Patient Identifier List
5	250	XPN	RE	O	[0..1]		00108	Patient Name
6	250	XPN	RE	O	[0..1]		00109	Mother's Maiden Name
7	26	TS	RE	O	[0..1]		00110	Date/Time of Birth
8	1	IS	RE	O	[0..1]	0001	00111	Administrative Sex
10	250	CE	RE	O	[0..1]	0005	00113	Race

PID-3 Patient Identifier List (CX), mandatory (Analyzer Manager), conditional (Analyzer).

This element supports the list of identifiers (one or more) used by the healthcare facility to uniquely identify a patient (e.g., medical record number, billing number, birth registry, national unique individual identifier, etc.). Additional characteristics of the identifier are not necessary because only the identifier value is required for the Analyzer to identify the patient. The Analyzer should not receive multiple identifiers for the same patient.

Predicate: For Analyzer, usage is Mandatory in all messages where field OBR-2 is not carrying a null value represented by two double quotes, (meaning that the AWOS ID is not known). Otherwise, usage is Optional.

Table W.3.8-2: Element PID-3 Patient Identifier List (CX)

Component/Sub-Component	Usage	Comment
ID (ST)	R	Locally defined

PID-5 Patient Name (XPN), required if available (Analyzer Manager), optional (Analyzer).

This element contains the primary or legal name of the patient.

Table W.3.8-3: Element PID-5 Patient Name (XPN)

Component/Sub-Component	Usage	LEN	Comment
family name (FN)	RE		
Surname (ST) (a.k.a. last name)	RE	50	
given name (ST) (a.k.a. first name)	RE	30	
second and further given names or initials thereof (ST) (a.k.a. middle name)	RE	30	
suffix (e.g., JR or III) (ST)	X		
prefix (e.g., DR) (ST)	X		
degree (e.g., MD) (IS)	X		
name type code (ID)	R	1	Always "L"

PID-6 Mother's Maiden Name (XPN), required if available (Analyzer Manager), optional (Analyzer).

This element contains the primary or legal maiden name of the patient's mother.

Table W.3.8-4: Element PID Mother's Maiden Name (XPN)

Component/Sub-Component	Usage	LEN	Comment
family name (FN)	RE		
Surname (ST) (a.k.a. last name)	RE	50	maiden family name
given name (ST) (a.k.a. first name)	RE	30	
second and further given names or initials thereof (ST) (aka middle name)	RE	30	
suffix (e.g., JR or III) (ST)	X		
prefix (e.g., DR) (ST)	X		
degree (e.g., MD) (IS)	X		
name type code (ID)	R	1	Always "L"

PID-7 Date/Time of Birth (TS), required if available (Analyzer Manager), optional (Analyzer).

This field contains the patient's date and time of birth. Only the birth date is supported. Time of birth and time zone indicator are not supported. Degree of precision component is not supported.

Table W.3.8-5: Element PID-7 Date/Time of Birth (TS)

Component/Sub-Component	Usage	Comment
YYYYMMDD	R	

PID-8 Administrative Sex (IS), required if available (Analyzer Manager), optional (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 W.3.8-6: 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), optional (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 Analyzer will define the set of HL7 User-defined Table 0005 – Race values that are supported.

Table W.3.8-7: Element PID-10 Race (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Value from HL7 User-defined Table 0005
Text (ST)	R	199	Description from HL7 User-defined Table 0005
Name of Coding System (ID)	R	20	Analyzer defined

W.3.9 PV1 Segment

HL7 v2.5: chapter 3 (3.4.3 PV1 – Patient Visit Segment).

The PV1 segment is to communicate patient location information.

Table W.3.9-1: PV1 Segment

SEQ	LEN	DT	Usage AM	Usage Analyzer	Card.	TBL#	ITEM#	Element name
2	1	IS	M	M	[1..1]	0004	00132	Patient Class
3	80	PL	M	O	[0..1]		00133	Assigned Patient Location

PV1-2 Patient Class (IS), mandatory.

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.

PV1-3 Assigned Patient Location (PL), required if available (Analyzer Manager), optional (Analyzer).

This field contains the patient's initial assigned location or the location to which the patient is being moved. Only a single patient location element is supported.

Table W.3.9-2: Element PV1-3 Assigned Patient Location (PL)

Component/Sub-Component	Usage	LEN	Comment
Point of Care (IS)	X		
Room (IS)	RE	20	

W.3.10 SAC Segment

HL7 2.5.1: chapter 13 (13.4.5 SAC – Specimen Container Detail Segment).

The SAC segment is used to describe the specimen container.

Table W.3.10-1: 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	RE	X	[0..1]		0378	Carrier Type
10	80	EI	C (M/X)	O	[0..1]		01337	Carrier Identifier
11	80	NA	C (M/X)	O	[0..1]		01338	Position in Carrier
13	80	EI	C (M/X)	O	[0..1]		01340	Tray Identifier
14	80	NA	C (M/X)	O	[0..1]		01341	Position in Tray
15	250	CE	C (RE/X)	O	[0..1]			Location
21	20	NM	RE	O	[0..1]		00644	Container Volume
22	20	NM	RE	O	[0..1]		01349	Available Specimen Volume
24	250	CWE	RE	O	[0..1]		01351	Volume Units
29	20	SN	RE	O	[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. A container may contain the primary (original) specimen or an aliquot (secondary sample) of that specimen. For primary sample this field contains Primary Container ID; for bar-coded aliquot samples this field contains Aliquot Container ID; for non-bar-coded aliquot samples (e.g., microtiter plate) this field is empty.

It is expected that the Container ID here is normally encoded as the ID (barcode, RFID) on the sample container.

See section W.2.1 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 W.3.10-2: Element SAC-3 Container Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	20	

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 W.2.1 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 W.3.10-3: Element SAC-4 Primary (Parent) Container Identifier

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	C	20	

SAC-9 Carrier Type (CE), required if available (Analyzer Manager), not supported (Analyzer).

This field specifies the type of carrier. It can be used when the same sample container ID is used for various sample types and the carrier is used to differentiate between the samples. The Analyzer will define the set of HL7 User-defined Table 0378 – Carrier Type values that are supported.

Table W.3.10-4: Element SAC-9 Carrier Type

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Value from HL7 User-defined Table 0378
Text (ST)	O	199	Description from HL7 User-defined Table 0378
Name of Coding System (ID)	O	20	Analyzer defined

SAC-10 Carrier Identifier (EI), conditional (Analyzer Manager), optional (Analyzer).

This field specifies the rack identifier.

See section W.2.1 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 W.3.10-5: Element SAC-10 Carrier Identifier

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	20	Rack ID

SAC-11 Position in Carrier (NA), conditional (Analyzer Manager), optional (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 W.3.10-6: Element SAC-11 Position in Carrier

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), optional (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 W.2.1 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 W.3.10-7: Element SAC-13 Tray Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	20	Tray ID

SAC-14 Position in Tray (NA), conditional (Analyzer Manager), optional (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 W.3.10-8: 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), optional (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 W.3.10-9: Element SAC-15 Location (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	80	Additional location information

SAC-21 Container Volume (NM), required if available (Analyzer Manager), optional (Analyzer).

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), optional (Analyzer).

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), optional (Analyzer).

This field is the unit identifier that is being used to describe the volume of the container. The units shall be described using UCUM.

Table W.3.10-10: Element SAC-24 Volume Units

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Unit of measure
Text (ST)	199	O	Recommended when identifier is insufficient
Name of Coding System (ID)	4	R	UCUM

SAC-29 Dilution Factor (SN), required if available (Analyzer Manager), optional (Analyzer).

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 W.3.10-11: 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	3	Integer between 2 - 999

W.3.11 SID Segment

HL7 v2.5.1: chapter 13 (13.4.11 SID – Substance Identifier Segment).

The Substance Identifier segment contains data necessary to identify the substance (e.g., reagents) used in the production of analytical test results. The combination of these fields must uniquely identify the substance, i.e., depending on the manufacturer all or some fields are required. If the analysis requires multiple substances, this segment is repeated for each substance.

Table W.3.11-1: SID Segment

SEQ	LEN	DT	Usage Analyzer	Card	TBL#	ITEM#	Element name
1	250	CE	M	[1..1]		01426	Application / Method Identifier
2	20	ST	C (M/X)	[0..1]		01129	Substance Lot Number
3	200	ST	C (M/X)	[0..1]		01428	Substance Container Identifier
4	250	CE	O	[0..1]	0385	01429	Substance Manufacturer Identifier

SID-1 Application / Method Identifier (CE), mandatory.

The SID segment can be used to identify substances that were used in the production of the result. Examples include:

- assay specific reagents
- multi-test bulk liquid reagents (e.g., Trigger solution)

To fully identify a substance, both an identifier and a substance type are needed. In the INV segment, these are INV-1 and INV-3 elements. Since the SID segment does not have a substance type field, the HL7 standard is extended by defining these elements and a substance version as components in SID-1.

Table W.3.11-2: Element SID-1 Application/Method Identifier (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R		Extended with the three components below
Substance Identifier (ST)	R	20	Identifier of substance
Substance Version (NM)	RE	1	Version of substance (if applicable)
Substance Type (ST)	R	2	Type of substance (e.g., Reagent, Bulk Supply)

Each of the sub-components can vary based on the type of substance. See below for explanation.

The Substance Type sub-component will contain one of the following values, taken from HL7 Table 0384.

Table W.3.11-3: Subset of HL7 Table 0384 – Substance Type

Value	Description	Comment
SR	Single Test Reagent	Assay Specific Reagent Pack
LI	Measurable Liquid Item	e.g., Pre-Trigger, Trigger, Wash Buffer
SC	Countable Solid Item	e.g., Reaction Vessels

Assay reagent sent with results message:

Substance Identifier: Reagent Configuration ID.

Substance Version: reagent configuration version

Substance Type: SR

Bulk supplies/waste sent with results message:

Substance Identifier: manufacturer defined

Substance Type: LI or SC

SID-2 Substance Lot Number (ST), conditional.

This field identifies the master lot number of the reagent assigned by the manufacturer.

Predicate: Either SID-2 Substance Lot Number or SID-3 Substance Container Identifier must be provided.

SID-3 Substance Container Identifier (ST), conditional.

This field specifies the container assigned by the manufacturer during production of the substance. This identifier should be unique within specific lot of specific application / method.

For assay specific reagents, this is the reagent serial number. Bulk reagent containers are not serialized, thus this field may be empty.

Predicate: Either SID-2 Substance Lot Number of SID-3 Substance Container Identifier must be provided.

SID-4 Substance Manufacturer Identifier (CE), optional.

This field identifies the manufacturer of this substance.

Table W.3.11-4: Element SID-4 Substance manufacturer Identifier (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R		Manufacturer
Text (ST)	O		
Name of Coding System (ID)	O		

W.3.12 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.).

Table W.3.12-1: 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	RE	O	[0..1]		01755	Specimen ID
3	80	EIP	RE	O	[0..*]		01756	Specimen Parent IDs
4	250	CWE	M	O	[1..1]	0487	01900	Specimen Type
7	250	CWE	RE	O	[0..1]	0488	01759	Specimen Collection Method
8	250	CWE	RE	O	[0..1]		01901	Specimen Source Site
9	250	CWE	RE	O	[0..1]	0542	01760	Specimen Source Site Modifier
11	250	CWE	M	M	[1..1]	0369	01762	Specimen Role
13	6	NM	C (M/X)	C	[0..1]		01763	Grouped Specimen Count
16	1	ID	RE	O	[0..1]	0489	01903	Specimen Risk Code
17	26	DR	C (RE/X)	C (RE/X)	[0..1]		01765	Specimen Collection Date/Time
18	26	TS	C (RE/X)	C (O/X)	[0..1]		00248	Specimen Received Date/Time
27	250	CWE	RE	O	[0..1]		01773	Container Type

SPM-1 Set ID (SI), mandatory.

This field contains the sequence number. This field is used to identify segment instances in message structures (e.g., segment group) where the segment repeats within that structure. For the first occurrence of the segment, the sequence number shall be one, for the second occurrence, the sequence number shall be two, etc.

If the segment occurs only one time within a message structure (e.g., segment group), then its value will be '1'. If the message structure (e.g., segment group) repeats, then the first occurrence of the segment in each segment group will be '1'.

SPM-2 Specimen ID (EIP), required if available (Analyzer Manager), optional (Analyzer).

This field contains the specimen identifier. It may be the enterprise-wide unique specimen identifier.

Table W.3.12-2: Element SPM-2 Specimen ID (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/X)	20	
Universal ID (ST)	C (R/X)	20	
Universal ID Type (ID)	C (R/X)	6	

Sub-component Placer Assigned Identifier.1 (Entity Identifier) is required. 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 if available (Analyzer Manager), optional (Analyzer).

This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance. For pooled patient samples indicated by SPM-11 equal to "L", this field will contain the specimen identifiers of the specimens that were pooled.

Table W.3.12-3: Element SPM-3 Specimen Parent IDs (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/X)	20	
Universal ID (ST)	C (R/X)	20	
Universal ID Type (ID)	C (R/X)	6	

Sub-component Placer Assigned Identifier.1 (Entity Identifier) is required. 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 (Analyzer Manager), optional (Analyzer)**.**

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). It will be NULL if

the SPM-11 Specimen Role is "Q" (Control specimen) or "U" (Unknown specimen as part of a Negative Query Response).

Table W.3.12-4: Element SPM-4 Specimen Type (CWE)

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	Code from HL7 Table 0487 – Specimen Type or NULL

SPM-7 Specimen Collection Method (CWE), required if available (Analyzer Manager), optional (Analyzer).

This field describes the procedure or process by which the specimen was collected.

Table W.3.12-5: Element SPM-7 Specimen Collection Method

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	No suggested value

SPM-8 Specimen Source Site (CWE), required if available (Analyzer Manager), optional (Analyzer).

This field specifies the source from which the specimen was obtained.

Table W.3.12-6: Element SPM-8 Specimen Source Site

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	No suggested value

SPM-9 Specimen Source Site Modifier (CWE), required if available (Analyzer Manager), optional (Analyzer), repeatable.

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 Laboratory Technical Framework leaves the usage of this field optional, with no pre-specified vocabulary. HL7 User-defined Table 0453 does not suggest any values.

Table W.3.12-7: Element SPM-9 Specimen Source Site Modifier

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	No suggested value

SPM-11 Specimen Role (CWE), mandatory.

This identifies the role of the specimen to be a Patient, Pooled Patient, or QC specimen. Only the first component (i.e. Identifier) is supported.

Table W.3.12-8: Subset of HL7 User-defined Table 0369 – Specimen Role

Value	Description	Comment
P	Patient specimen	
Q	Control specimen	
L	Pooled patient specimens	Specimens from multiple patients, number of pooled specimens is provided in SPM-13
U	Unknown	Unknown specimen role; used for negative query response in LAB-28

Table W.3.12-9: Element SPM-11 Specimen Role

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	Code from above table

SPM-13 Grouped Specimen Count (NM), conditional.

This field identifies the number patient specimens that were pooled.

Predicate: Usage is Mandatory if SPM-11 Specimen Role is “L”. Otherwise usage is Not Supported.

SPM-16 Specimen Risk Code (CWE), required if available (Analyzer Manager), optional (Analyzer).

This field contains any known or suspected specimen hazards, e.g., exceptionally infectious agent or blood from a hepatitis patient.

Table W.3.12-10: Element SPM-16 Specimen Risk Code

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	3	Risk code. No suggested value

Component/Sub-Component	Usage	LEN	Comment
Text (ST)	RE	200	Free text

SPM-17 Specimen Collection Date/Time (DR), conditional.

The date and time when the specimen was acquired from the source. Only the start date/time component is supported (i.e. first component).

Predicate: Usage is Required if Available when SPM-11 is "P". Otherwise usage is Not Supported.

This element shall be reported to a precision of seconds. Indication of the time zone is not supported. The degree of precision component is not supported.

Table W.3.12-11: Element SPM-17 Specimen Collection Start Date/Time

Component/Sub-Component	Usage	Comment
YYYYMMDDHHMMSS[+/-ZZZZ]	R	

SPM-18 Specimen Received Date/Time (DR), conditional.

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. Only the start date/time component is supported (i.e. first component).

Analyzer Manager Predicate: Usage is Required if Available when SPM-11 is "P". Otherwise usage is Not Supported.

Analyzer Predicate: Usage is Optional when SPM-11 is "O". Otherwise usage is Not Supported.

This element shall be reported to a precision of seconds. Indication of the time zone is not supported. The degree of precision component is not supported.

Table W.3.12-12: Element SPM-17 Specimen Collection Start Date/Time

Component/Sub-Component	Usage	Comment
YYYYMMDDHHMMSS	R	
Degree of precision	X	

SPM-27 Container Type (CWE), required if available (Analyzer Manager), optional (Analyzer).

The container type in or on which a specimen is transported.

Table W.3.12-13: Element SPM-27 Container Type

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	No suggested value

W.3.13 TCD Segment

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 W.3.13-1: TCD Segment

SEQ	LEN	DT	Usage AM	Card.	TBL#	ITEM#	Element name
1	250	CE	M	[1..1]		00238	Universal Service Identifier
2	20	SN	RE	[0..1]		01420	Auto-Dilution Factor
3	20	SN	RE	[0..1]		01421	Rerun Dilution Factor
4	20	SN	RE	[0..1]		01422	Pre-Dilution Factor
5	20	SN	RE	[0..1]		01413	Endogenous Content of Pre-Dilution Diluent
6	1	ID	RE	[0..1]	0136	01416	Automatic Repeat Allowed
7	1	ID	RE	[0..1]	0136	01424	Reflex Allowed
8	250	CE	RE	[0..1]	0389	01525	Analyte Repeat Status

TCD-1 Universal Service Identifier (CE), mandatory.

This field contains a unique identifier for the service identifier. The usage of LOINC(r) test codes for the identification of tests is strongly recommended. The value of the "Name of Coding System" in the case of LOINC is "LN".

Table W.3.13-2: 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	20	Name of coding system

TCD-2 Auto-Dilution Factor (SN), required if available.

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. (See examples in definition of SAC-29 "Dilution factor" in the "Specimen Container Detail Segment".)

Table W.3.13-3: Element TCD-2 Auto-Dilution Factor (SN)

Component/Sub-Component	Usage	Comment
Comparator (ST)	R	
Num1 (NM)	R	
Separator/Suffix (ST)	R	
Num2 (NM)	R	

TCD-3 Rerun Dilution Factor (SN) required if available.

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 W.3.13-4: Element TCD-3 Rerun Dilution Factor (SN)

Component/Sub-Component	Usage	Comment
Comparator (ST)	R	
Num1 (NM)	R	
Separator/Suffix (ST)	R	
Num2 (NM)	R	

TCD-4 Pre-Dilution Factor (SN) required if available.

This field is the value that is to be used as the factor for a particular specimen that is delivered to the automated system as pre-diluted for this particular test code.

Table W.3.13-5: Element TCD-4 Pre-Dilution Factor (SN)

Component/Sub-Component	Usage	Comment
Comparator (ST)	R	
Num1 (NM)	R	
Separator/Suffix (ST)	R	
Num2 (NM)	R	

TCD-5 Endogenous Content of Pre-Dilution Diluent (SN) required if available.

This field represents the rest concentration of the measured test in the diluent. It is the value that is to be used for calculation of the concentration of pre-diluted specimens for this particular test code.

Table W.3.13-6: Element TCD-5 Endogenous Content of Pre-Dilution Diluent (SN)

Component/Sub-Component	Usage	Comment
Comparator (ST)	R	

Component/Sub-Component	Usage	Comment
Num1 (NM)	X	
Separator/Suffix (ST)	X	
Num2 (NM)	X	

TCD-6 Automatic Repeat Allowed (ID) required if available.

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 W.3.13-7: HL7 Table 0136 – Yes/no indicator

Value	Description	Comment
Y	Yes	
N	No	

TCD-7 Reflex Allowed (ID) required if available.

Definition: 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 W.3.13-8: HL7 Table 0136 – Yes/no indicator

Value	Description	Comment
Y	Yes	
N	No	

TCD-8 Analyte Repeat Status (CE) required if available.

Definition: 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 W.3.13-9: 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)
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 W.3.13-10: Element TCD-8 Analyte Repeat Status

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	

W.3.14 TQ1 Segment

HL7 v2.5: chapter 4 (4.5.4 TQ1 – Timing/Quantity Segment).

This segment is used to provide the priority of the service request.

Table W.3.14-1: TQ1 Segment

SEQ	LEN	DT	Usage AM	Card.	TBL#	ITEM#	Element name
9	250	CWE	M	[1..1]	0485	01635	Priority

TQ1-9 Priority (CWE), mandatory.

This field identifies the priority of the order. Only the first component (i.e. Identifier) is supported and it can contain only values taken from HL7 User-defined Table 0485 (see below).

Table W.3.14-2: Subset of HL7 User-defined Table 0485 – Extended Priority Codes

Value	Description	Comment
R	Routine	
S	Stat	

Table W.3.14-3: Element TQ1-9 Priority (CWE)

Component/Sub-Component	Usage	Comment
Identifier (ST)	R	Code from HL7 User-defined Table 0485

Q Transaction LAB-27: Query for AWOS

This transaction is used between an Analyzer Manager and an Analyzer working in query mode. It enables the Analyzer Manager to issue a new AWOS to the Analyzer. This is a two-part transaction that requires two message exchanges between the Analyzer Manager and Analyzer.

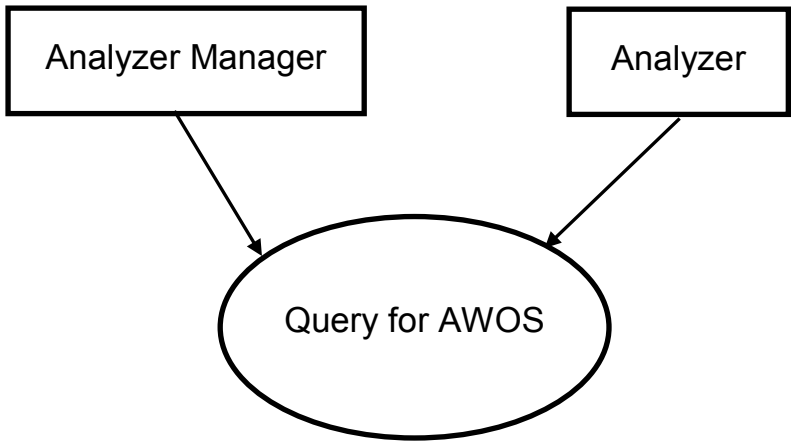
This transaction is used by the Analyzer to get the AWOS to perform for each specimen by querying the Analyzer Manager after specimen container recognition. The transaction provides an initial message exchange of a query for one specimen or all specimens and the reply will carry the acknowledgement status of the request. The Analyzer Manager will follow the query exchange with a second message exchange consisting of a LAB-28 AWOS Broadcast that provides the work to perform or an indication there is no work for that specimen.

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.

Q.1 Scope

This transaction supports the use case X.2.1.2 *AWOS Query by the Analyzer for ALL specimens before specimen arrival* and the use case X.2.2 *AWOS Query by the Analyzer at specimen arrival*. It is used by the Analyzer Manager and the Analyzer in "Query Mode".

Q.2 Use Case Roles



Actor: Analyzer Manager

Role: Manages the Work Orders and AWOS. Responds with LAB-28 AWOS Broadcast to the Analyzer.

Actor: Analyzer

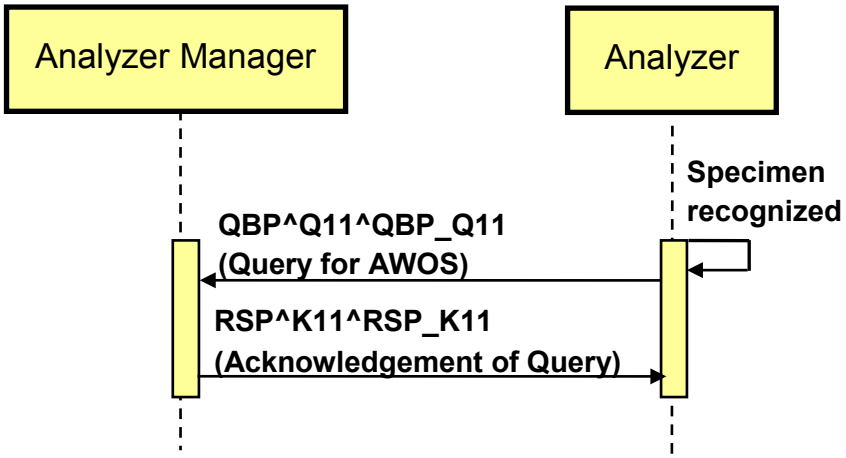
Role: Queries the Analyzer Manager for an AWOS related to the specimen, and receives the query acknowledgement. Waits for the LAB-28 AWOS Broadcast from the Analyzer Manager. If no LAB-28 AWOS Broadcast for the queried specimen is received by an Analyzer-specific period of time, the Analyzer may notify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

Q.3 Referenced Standard

HL7 version 2.5.1:

- Chapter5: "Query" → QBP and RSP messages
- Chapter5: "Query" → QPD, RCP and QAK segments

Q.4 Interaction Diagram



Q.5 Message Static Definitions

After the Analyzer working in query mode recognizes one or more specimens, the Analyzer sends a "WOS Query Message" (QBP^Q11^QBP_Q11) for each specimen to the Analyzer Manager.

The Analyzer Manager replies with the response message (RSP^K11^RSP_K11) containing the acknowledgement of specimen query. The Analyzer Manager will then respond with a LAB-28 AWOS Broadcast containing the work for the specimen.

Q.5.1 Trigger Events

QBP (Q11): Query for the AWOS sent by the Analyzer.
RSP (K11): Response indicating the query was received.

Q.5.2 Message Semantics

Table Q.5.2-1: QBP^Q11^QBP_Q11

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

Table Q.5.2-2: RSP^K11^RSP_K11

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[ERR]	Error	O	[0..1]	2
QAK	Query Acknowledgement	R	[1..1]	5
QPD	Query Parameter Definition	R	[1..1]	5

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.

Q.5.3 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 "Query Mode", the Analyzer sends a QBP message to the Analyzer Manager to get the AWOS. The Analyzer identifies the query is for a single specimen by using the query name "WOS" (see description for QPD-1).

The Analyzer can identify the specimen by providing:

- QPD-2 Container Identifier, or
- QPD-3 Carrier Identifier and QPD-4 Position in Carrier, or
- QPD-5 Tray Identifier and QPD-6 Position in Tray.

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

Table Q.5.3-1: Specimen Identification Examples

QPD Fields	Specimen container w/barcode	Specimen container w/o barcode in rack	Specimen in tray
QPD-1.1 Message Query Name. Identifier	WOS	WOS	WOS
QPD-3 Container Identifier	987654	-	-
QPD-4 Carrier Identifier	-	12345	-
QPD-5 Position in Carrier	-	3	-
QPD-6 Tray Identifier	-	-	8523
QPD-7 Position in Tray	-	-	1^8
QPD-8 Location	-	-	A-8

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 LAB-28 AWOS Broadcast. The Analyzer receives the AWOS(s) and performs processing for the specimen.

If the Analyzer Manager has no work for that specimen, it will send a Negative Query Response by setting ORC-1 to "DC" in a LAB-28 AWOS Broadcast message. See section R.5 for more details on the contents of a Negative Query Response.

Query for All Work

An analyzer may query for all work by using the query name "WOS_ALL" (see description for QPD-1). No container information is provided when an Analyzer queries for all work. 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 LAB-28 AWOS Broadcast. The Analyzer receives the AWOS(s) and performs processing for the specimen(s).

If the Analyzer Manager has no work for Analyzer, it will send a Negative Query Response by setting ORC-1 to "DC" in a LAB-28 AWOS Broadcast message. See section R.5 for more details on the contents of a Negative Query Response.

Q.5.4 QPD Segment

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

This segment provides the specimen information for the query.

Table Q.5.4-1: 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	[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

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.

Table Q.5.4-2 HL7 User-defined Table 0471 – Query Name

Value	Description	Comment
WOS	Work Order Step	Use to query for a single specimen
WOS_ALL	Work Order Step All	Use to query for all analytical work

Query for a Single Specimen

Table Q.5.4-3: Element QPD-1 Message Query Name (CE) for single specimen

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	3	WOS
Text (ST)	R	15	Work Order Step
Name of Coding System (ID)	R	9	IHE_LABTF

Query for All Work

Table Q.5.4-4: Element QPD-1 Message Query Name (CE) for all work

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	7	WOS_ALL
Text (ST)	R	19	Work Order Step All

Component/Sub-Component	Usage	LEN	Comment
Name of Coding System (ID)	R	9	IHE_LABTF

QPD-2 Query Tag (ST), mandatory.

A unique identifier assigned to each query message instance.

QPD-3 Container Identifier (EI), conditional.

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: When QPD-1.1 is "WOS", QPD-3 usage is Mandatory if QPD-4 and QPD-6 are not populated. Otherwise usage is Not Supported. When QPD-1.1 is "WOS_ALL", usage is Not Supported.

Table Q.5.4-5: Element QPD-3 Container Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	20	

QPD-4 Carrier Identifier (EI), conditional.

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: When QPD-1.1 is "WOS", QPD-4 usage is Mandatory if QPD-3 and QPD-6 are not populated. Otherwise usage is Not Supported. When QPD-1.1 is "WOS ALL", usage is not supported.

Table Q.5.4-6: Element QPD-4 Carrier Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	20	Rack ID

QPD-5 Position in Carrier (NA), conditional.

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: Usage is Mandatory if QPD-4 is populated. Otherwise usage is Not Supported.

Table Q.5.4-7: 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.

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

Predicate: When QPD-1.1 is "WOS", QPD-6 usage is Mandatory if QPD-3 and QPD-4 are not populated. Otherwise usage is Not Supported. When QPD-1.1 is "WOS_ALL", usage is Not Supported.

Table Q.5.4-8: Element QPD-6 Tray Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	20	Tray ID

QPD-7 Position in Tray (NA), conditional.

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: Usage is Mandatory if QPD-6 is populated. Otherwise usage is Not Supported.

Table Q.5.4-9: Element QPD-7 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	

QPD-8 Location (CE), conditional.

Used when the query is based on a location. This field contains additional information about the physical location of the specimen. This field must 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: Usage is Required if Available if QPD-4 or QPD-6 is populated. Otherwise usage is Not Supported.

Table Q.5.4-10: Element QPD-8 Location (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Provides additional location information

Q.5.5 RCP Segment

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

This segment provides additional information about the expected query response.

Table Q.5.5-1: 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.

This field is always set to the value of "R" (Realtime).

Table Q.5.5-2: Element RCP-3 Response Modality (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	1	Always set to "R"

Q.5.6 QAK Segment

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

This segment contains information about the query response.

Table Q.5.6-1: 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.

Table Q.5.6-2: 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 Q.5.6-3: Element QAK-3 Message Query name (CE)

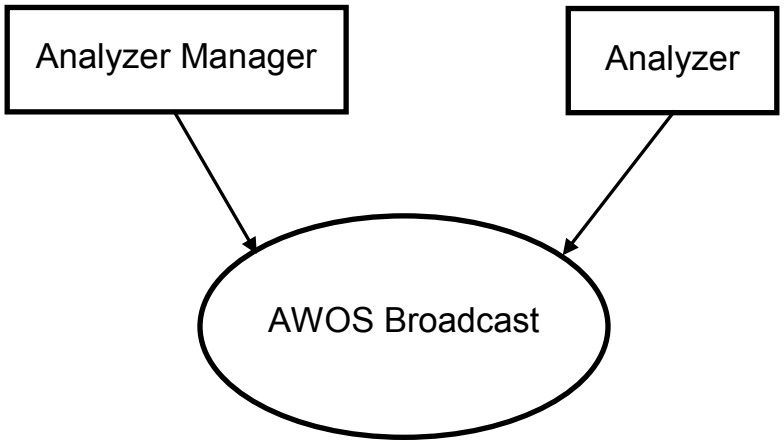
Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Contains value from QPD-1
Text (ST)	R	15	Contains value from QPD-1
Name of Coding System (ID)	R	9	Contains value from QPD-1

R Transaction LAB-28: Analytical Work Order Step Broadcast

R.1 Scope

This transaction is used between an Analyzer Manager and an Analyzer working in broadcast mode. It enables the Analyzer Manager to issue a new AWOS to the Analyzer or cancel an existing AWOS previously sent to the Analyzer. Modification is achieved by combining cancellation and sending of a new AWOS.

R.2 Use Case 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.

Actor: Analyzer

Role: Performs the AWOS on the specimen

R.3 Referenced Standard

HL7 v2.5.1, Chapter 4 and Chapter 13

- OML^O33 and ORL^R34 message and response
- PID, PV1, SPM, SAC, ORC, TQ1, OBR, TCD, and NTE segments

R.4 Interaction Diagram

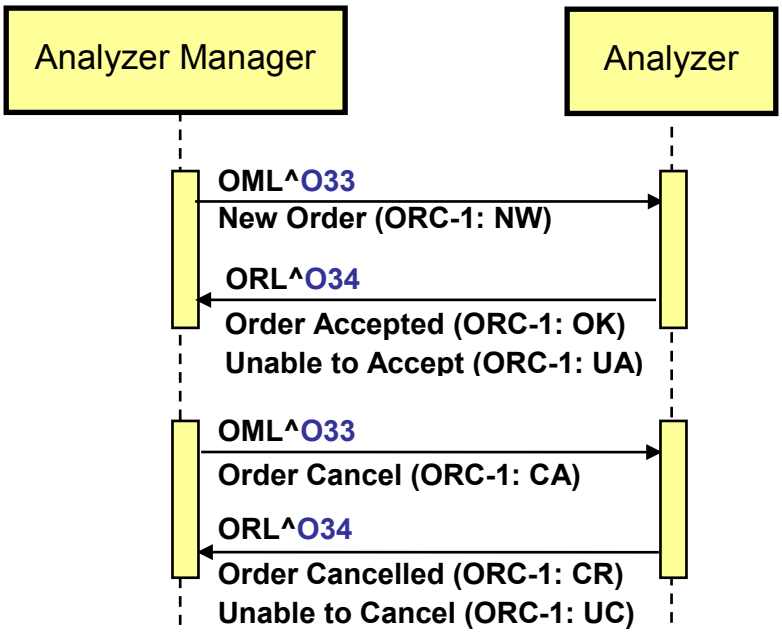


Figure R.4-1: AWOS management on Analyzer in broadcast mode

R.5 Message Static Definitions

This transaction contains the messages used to broadcast an Analytical Work Order Step (AWOS) from the Analyzer Manager to the Analyzer. It includes "new AWOS", "cancel AWOS" and the related application acknowledgements.

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

R.5.1Trigger Events

OML (O33): AWOS sent by the Analyzer Manager.

ORL (O34): Acknowledgement sent by the Analyzer.

R.5.2 Message Semantics

OML^O33

Table R.5.2-1: OML^O33

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[	--- PATIENT begin	O	[0..1]	
PID	Patient Identification	R	[1..1]	3

Segment	Meaning	Usage	Card.	HL7 chapter
[PV1]	Patient Visit	O	[0..1]	3
]	--- PATIENT end			
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	R	[1..1]	13
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
[{TQ1}]	Timing Quantity	RE	[0..1]	4
[	--- OBSERVATION REQUEST begin	RE	[0..1]	
OBR	Observation Request	R	[1..1]	4
[TCD]	Test Code Details	O	[0..1]	13
[{ NTE }]	Notes and comments	O	[0..*]	2
[{	--- OBSERVATION begin	O	[0..*]	
OBX	Observation/Result	R	[1..1]	7
[TCD]	Test Code Details	O	[0..1]	13
[{NTE}]	Notes and comments	O	[0..*]	2
}]	--- OBSERVATION end			
[{	--- PRIOR RESULT begin	O	[0..*]	
PV1	Patient Visit – previous result	R	[1..1]	3
{	--- ORDER PRIOR begin	R	[1..*]	
ORC	Common order – prior result	R	[1..1]	4
OBR	Order detail – prior result	R	[1..1]	4
{	--- OBSERVATION PRIOR begin	R	[1..*]	
OBX	Observation/Result – prior result	R	[1..*]	
[{NTE}]	Comment of the result	C	[0..*]	2
}	--- OBSERVATION PRIOR end			
}	--- ORDER PRIOR end			
}]	--- PRIOR RESULT end			
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN end			

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 “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 PRIOR RESULT segment group provides the prior results obtained for the same patient. Segment PID is not provided in this segment group because it is the same patient, and the laboratory is not concerned by the fact that this patient might have had a different identification when the prior results were produced.

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 W.3.9 PV1 Segment**)**. The sender of this message SHALL set the value the field PV1-2 to “U”, which stands for “patient class unknown”.

The ORC appearing in the PRIOR RESULT segment group is mandatory and SHALL have its first field “Order Control” populated with “PR” (Prior results).

The message supports an optional OBSERVATION segment group to provide the Analyzer with results related to the tests to be performed.

The OML^O33 message can be used to carry a Negative Query Response indicating there is no work to perform for a LAB-27 Query. Only the MSH, SPM, SAC, and ORC segments will be sent in this case. 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-8 values from the query, which were used to identify the specimen. SAC-3 will be set to QPD-3, 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.

ORL^O34

Table R.5.2-2: ORL^O34

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[{ERR}]	Error	O	[0..*]	2
[	--- RESPONSE begin	O	[0..1]	

Segment	Meaning	Usage	Card.	HL7 chapter
[	--- PATIENT begin	R	[1..1]	
PID	Patient Identification	O	[0..1]	3
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	R	[1..1]	13
[{	--- ORDER begin	R	[1..*]	
ORC	Common Order	R	[1..1]	4
}]	--- ORDER end			
}	--- SPECIMEN end			
]	--- PATIENT end			
]	--- RESPONSE end			

MSH-9 Message Type (MSG) shall have its three components respectively valued to "ORL", "O34" and “ORL_O34”.

MSH-21 Message Profile Identifier shall be “LAB-28^IHE”.

The RESPONSE segment group is not present when the acknowledgement is a response to a Negative Query Response.

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

The RESPONSE segment group may be used by the Analyzer to inform the Analyzer Manager about the 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 or IP.
  - 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 will 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 A, CM, IP or SC.

R.5.3 Expected Actions

The Analyzer receives the OML^O33 message from the Analyzer Manager.

If the OML message contains the Order Control Code "NW", the Analyzer will receive and register the new order information. As part of the ORL^O34 response, it may transmit either "Notification or request accepted" or "Unable to accept order/service" for each AWOS contained in the OML message. See the ORC-1/ORC-5 discussion above for further details. The Analyzer Manager will consider the absence of a response for an individual AWOS the same as receiving a "Notification or request accepted" for the AWOS from the Analyzer.

If the OML message contains the Order Control Code "CA", the Analyzer will evaluate the cancel request. As part of the ORL^O34 response, the Analyzer will transmit either "Cancel as requested" or "Unable to cancel" for each AWOS contained in the OML message. See the ORC-1/ORC-5 discussion above for further details.

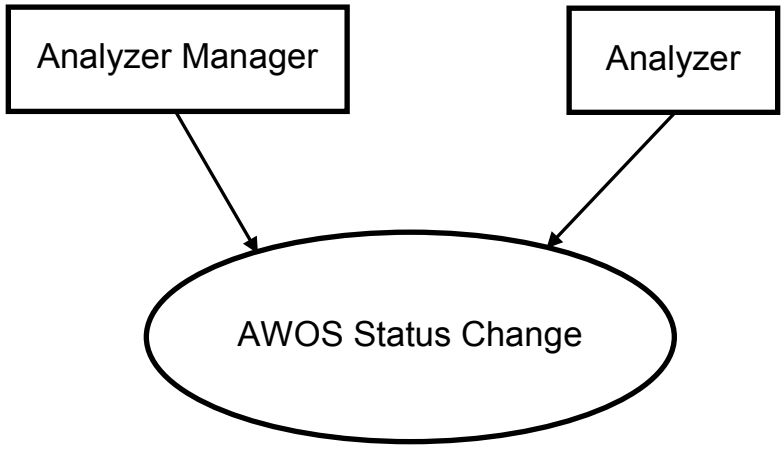
If the OML message contains the Order Control Code "DC", the Analyzer will respond only with the MSH and MSA segments to acknowledge receipt of the Negative Query Response.

Y Transaction LAB-29: AWOS Status Change

Y.1 Scope

This transaction is used by the Analyzer to send test results to the Analyzer Manager.

Y.2 Use Case Roles



Actor: Analyzer Manager

Role: Manages Analyzer in order to implement the AWOS. Receives the test results from Analyzer, performs technical validation, then sends the validated results to Order filler

Actor: Analyzer

Role: Analyzes the specimen and outputs the test results.

Y.3 Referenced Standard

HL7 Version 2.5 Chapter 7 and Chapter 13.

- OUL^R22 message
- PID, PV1, SPM, OBX, SAC, INV, OBR, ORD, TCD, SID, and NTE Segments

Y.4 Interaction Diagram

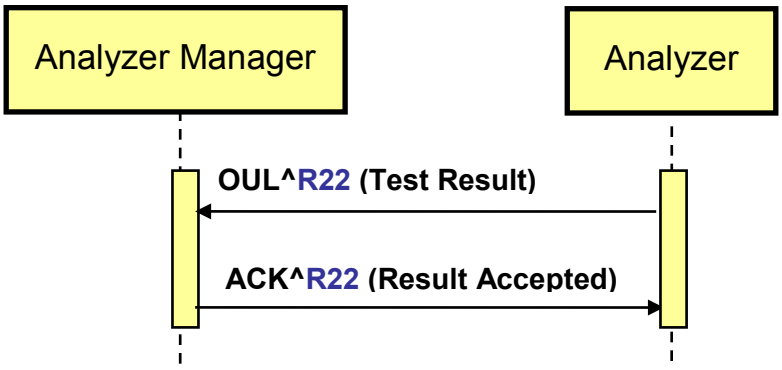


Figure Y.4-1: AWOS Status Change

Y.5 Message Static Definitions

This transaction contains the messages used by the Analyzer to send the tests results when the AWOS is complete. It also includes the related application acknowledgements from the Analyzer Manager.

The message contains zero or more observations for one or more AWOSs for one or more specimens. The observations are grouped by AWOS, and the AWOSs are grouped by specimen.

Y.5.1 Trigger Events

Analyzer sends test results. Analyzer Manager returns acknowledgement.

Y.5.2 Message Semantics

Table Y.5.2-1: OUL^R22

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
[	-- PATIENT begin	O	[0..1]	
[PID]	Patient Identification	R	[1..1]	3
]	-- PATIENT end			
[	-- VISIT begin	O	[0..1]	
[PV1]	Patient Visit	R	[1..1]	3
]	-- VISIT end			
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen information	R	[1..1]	7
[{ OBX }]	Observation Result (for Specimen)	O	[0..*]	7
[{	--- CONTAINER begin	R	[1..1]	
SAC	Container information	R	[1..1]	13

Segment	Meaning	Usage	Card.	HL7 chapter
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, … of QC specimen)	C (O/X)	[0..1]	13
}]	--- CONTAINER end			
{	--- ORDER begin	R	[1..*]	
OBR	Observation Order	R	[1..1]	7
[ORC]	Common Order	R	[1..1]	4
[{	--- RESULT begin	R	[1..*]	
OBX	Observation Result	R	[1..1]	7
[TCD]	Test Code Detail	O	[0..1]	13
[{SID}]	Substance Identifier (e.g., reagents used for testing)	O	[0..*]	13
[{NTE}]	Notes and comments	O	[0..*]	
}]	--- RESULT end			
}	--- ORDER end			
}	--- SPECIMEN end			

The message shall be used to send the observation results for one or more specimens of one patient. 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 “LAB-29^IHE”.

The PATIENT segment group is optional and may be supported by Analyzers that implement these enhanced data elements.

The optional OBX segment with the meaning Observation Result (for Specimen) may be used by Analyzers that implement these enhanced data elements to document the condition of the specimen.

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 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 neither the SAC-3 Container Identifier or the SAC-4 Primary Container Identifier are known, then SAC-3 shall be populated with a null value (""). The remaining fields of the SAC segment are optional for this message and may be populated by Analyzers that implement these enhanced data elements.

The INV segment usage is optional when SPM-11 is set to the value of "Q", and may be populated by Analyzers that implement these enhanced data elements for QC results. Otherwise the usage is not supported.

The OBR segment is mandatory and shall be used to transmit information about the requested observation.

- 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.
- All other fields are optional and may be populated by Analyzers that implement these enhanced data elements.

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 "OK".
- 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 W.2.6 Reflex Imitated at the Analyzer for more details.

The RESULT segment group is mandatory. It shall be used to report the observation results for the specimen container.

The OBX segment will be used to carry the observation results.

- OBX-4 will be used to uniquely identify each observation run and alternate representations. See section W.2.5 Observation Identification for more details.
- The other OBX fields are used to convey information about the observation result. See section W.3.6 OBX Segment for more details.

The optional TCD, SID, and NTE segments can be used to provide additional details about the observation result. These segments may be populated by Analyzers that support these enhanced data elements.

Table Y.5.2-2: ACK^R22

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[ERR]	Error	O	[0..1]	2

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 “LAB-29^IHE”.

Y.5.3 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 run, reruns, and alternate results. See section W.2.5 Observation Identification 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, ask the operator to manually link the observation to an AWOS, or notify the operator that the observation will be discarded.