GMSIH, HL7 France H', HL7 Germany, IHE-J, JAHIS, SFIL, IHE Italy

Integrating the Healthcare Enterprise

IHE Laboratory Technical Framework
Supplement 2004-2005

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Laboratory Device Automation
(LDA)

Public Comment Version

June 15, 2005

Comments due July 15, 2005

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Foreword

20   Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems which support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather

30   to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. IHE maintain formal relationships with several standards bodies including HL7, DICOM and refers recommendations to them when clarifications or extensions to existing standards are necessary.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the

40   European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Francaise de Radiologie (SFR), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), and the European Society of Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan

50   Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly

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through the identification and correction of errata. The current version for these Technical Frameworks may be found at www.rsna.org/IHE or http://www.gmsih.fr/IHE.

60   The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles which highlight their capacity to address specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This supplement to the IHE Laboratory Technical Framework V1.2.1 is submitted for Public Comment between June 15, 2005 and July 15, 2005, per the schedule announced in February 2005.

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> **Comments shall be submitted before July 15, 2005 on the "Public Comment Lab Supplement" sheet, addressed by email to:**
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The IHE Laboratory Technical Committee will address these comments and publish the Trial Implementation version in November 2005.

Document production

80   Principal editor: Yoshimitsu Takagi – Hitachi
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Introduction

Version 1 of Laboratory Technical Framework considered the automation within the laboratory as a grouped actor named Automation Manager, receiving Work Orders from the Order Filler, using various automated devices to fulfill the observations for these orders, and sending back the

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results. Laboratory Technical Framework version 1 did not describe the workflow between the automation manager and the automated device involved in this process.

90   This new Integration Profile, Laboratory Device Automation (LDA) adds the description of this workflow, involving three new actors and four new transactions. This new Integration Profile will be added to Volume I of the IHE Laboratory Technical Framework version 2. The four new transactions will be added to Volume II of the IHE Laboratory Technical Framework version 2.

Profile Abstract

The Laboratory Device Automation Integration Profile describes the workflow between the Automation Manager and two new actors (Pre/Post-processor and Analyzer) to support the processing of Work Orders and fulfill their embedded clinical tests on the related specimen. This processing includes the **pre-analytical process** of the specimen (sorting, centrifugation, aliquoting, transportation, decapping) the **analytical process** itself (run of the ordered clinical tests on the specimen) and the **post-analytical process** (recapping, transportation, rerun, dilution,

100   storage and retrieval).

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). This profile assumes that each LD performs at most one WOS for a 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

110   Steps related information, the status of these Work Order Steps, and the results obtained.

Glossary

AM	Automation Manager
LD	Laboratory Device : A category of actors in LDA profile. A LD actor is either an Analyzer actor or a Pre/Post processor actor.
LAS	Laboratory Automation System: A system which handles a set of Laboratory Devices (LD). This system implements the Automation Manager actor.
WOS	Work Order Step: A step of a Work Order performed on one specimen

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	by one LD.
AWOS	Analytical Work Order Step: A WOS performed by an Analyzer actor.
SWOS	Specimen Wok Order Step: A WOS performed by a Pre/Post Processor actor.
QC	Quality Control performed by Analyzer actor on a quality control specimen.
Analyzer	An actor which is an automated device which fulfills clinical tests on biologic specimen. An Analyzer performs analyzing for a specimen according to AWOS, and return the result to the AM.
Pre/Post-processor	An actor which provides some pre- and post- processes to the specimen. This actor is categorized to two sub categories, one is pre-processor and the other one is post-processor. A Pre/Post-processor processes a specimen according to SWOS, and return the result to the AM.
Pre-processor	An automated device which provides some preparation (decapping, aliquoting, centrifugation, transportation, …) of the specimen before the clinical testing.
Post-processor	An automated device which deals with the specimen after clinical tests have been performed on it, making it ready for rerun or for storage, or that conveys it to another automated device.
Centrifuge	An automated device which divides the blood into a serum ingredient and a blood cell ingredient by centrifugal separation.
Decapper	An automated device which takes off the cap of the specimen container.
Aliquoter	An automated device which aliquots a parent specimen into one or more child specimen.
Labeler	An automated device which affixes the bar code label to the specimen container.
Conveyor	An automated device which transports specimen to the appropriate devices.
Sorter	An automated device which sorts the specimen according to their process type.
Dilution System	An automated device which dilutes a specimen by mixing a diluent.
Recapper	An automated device which re-caps a specimen container.

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Specimen Storage System	An automated storage device which saves and manages processed specimen.

Volume I – Integration Profiles

X Laboratory Device Automation Integration Profile

X.1 Scope of LDA Integration Profile

120   The LDA Integration Profile supports the workflow for the automated technical section of the clinical laboratory. It provides the transactions between the actors of this section (Automation Managers, Pre/Post-processors, Analyzers) to fulfill the Work Orders sent by the Order Filler, and send back the results produced for these Work Orders.

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 input to the LDA workflow is a Work Order generated by the Order Filler. The Automation Manager splits this Wok Order into a sequence of one or more Work Order Steps (**WOS**), sending each one to a particular automated device.

130   Among this sequence, the particular WOS that instructs the Analyzer to fulfill the clinical tests is called the Analytical Work Order Step (AWOS). The transaction carrying this AWOS instructs 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 tests are performed on specimen collected from the patients. 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

140   and QC specimen AWOS. The LSWF 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.

For the purpose of messaging, the identification of specimen is essential.

The primary specimen ID is provided either by the Order Placer or by the Order Filler. In case a Specimen Work Order Step (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

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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.

The ability to automatically create modification of the work order at the AM may be constrained by regulatory requirement.

The exchange of code sets and associated rules is supported by another profile: LCSD.

Observation results tracking implies the ability of each actor (Analyzer, Automation Manager) to store the raw results, before refining or translating them, automatically or interactively (e.g. during the technical validation). This safe storage is out of the scope of this profile.

This LDA profile may enrich its specifications in order to integrate specific types of pre or post processing laboratory devices. The manufacturers of laboratory devices are invited by the IHE Laboratory Committee to bring their contributions to these specifications.

X.2 Use cases

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

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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.

X.2.1 WOS downloaded on the LD before specimen arrival

Initial part of the scenario:

190   a) The Automation Manager sends the scheduled WOS to the LD. For some LD, many WOS may be grouped into a single work list, which is downloaded within a single message sent to the LD. But still in that case, each WOS part of the work list, is related to a single specimen.

        b) The LD recognizes the specimen (though barcode ID scanning, position identification on the carrier, or manual entry) and selects the related WOS from its memory.

        c) Optionally, the LD may then send a "specimen arrived" notification to the Automation Manager.

Final part of the scenario:

        r) The LD performs the ordered step on that specimen.

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

Exceptions handling:

In the case where the WOS has not been downloaded yet by the time the specimen is recognized, then several events may occur depending upon the LD own capabilities and upon the operator's actions: Either the LD skips this specimen or it suspends its process, waiting for the download of the missing WOS, or the LD queries the Automation Manager with the specimen ID (shift to second use case) or the operator manually enters the WOS (shift to third use case).

210   In the time between the WOS first download and the specimen recognition by the LD, the content of the parent order and Work Order may be modified (suppressing some tests, adding some others, shifting the target LD with another LD) or even canceled. Such events will result into the cancellation or the modification of the WOS on the Automation Manager, and therefore, SHALL trigger a message from the Automation Manager to the LD carrying this modification or cancellation.

X.2.2 Query for the WOS after specimen arrival on the LD

Initial part of the scenario:

        a) The Automation Manager schedules the WOS but does not send it to the LD.

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b) In the case where the Automation Manager receives a Work Order update or cancellation, it updates or cancels the related WOS appropriately, and creates new ones if needed.

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c) The LD recognizes the specimen (barcode scanning, or manual entry), and queries the Automation Manager with the specimen ID.

d) The Automation Manager replies to the query with the WOS to perform.

Final part of the scenario: same as in use case X.2.1

Exceptions handling:

In this use case, the step to perform is sent by the Automation Manager just in time, when the LD is ready to perform it on the specimen. Thus there is no need for "update WOS" and "cancel WOS" messages.

The specimen may be placed on the LD, before the Order Filler has sent the Work Order to the Automation Manager, and before the WOS exist on the latter. In that case the query in step c) is unsuccessful. The answer sent in step d) will be "unknown specimen, no pending WOS for it". Then, either the LD skips this specimen and will try a new query later, or (especially in case of an urgent order) the operator manually enters the WOS on the LD(shift to third use case).

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X.2.3 Manual entry of the WOS on the LD

a) The Automation Manager schedules the WOS and prints it on a sheet of paper, with all related information which will be required by the LD.

b) The laboratory technical staff enter the WOS manually on the LD, from the paper sheet.

c) At specimen recognition, the LD picks up the related WOS.

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d) Optionally, the LD may then send a "specimen arrived" notification to the Automation Manager.

Final part of the scenario: same as in use case X.2.1

Exceptions handling:

In the case where the WOS has not been entered by the time the specimen is recognized, then several events may occur: Either the LD skips this specimen or it suspends its process, waiting for the manual entry of the WOS by the operator, or the LD performs a default WOS. If the LD is an Analyzer, the default AWOS may be a panel of emergency tests which can be performed and reported quickly.

In the time between the WOS printing by the Automation Manager and its fulfillment on the LD, the content of the parent order and Work Order may be modified (suppressing some tests, adding some others, shifting the target LD with another LD) or even canceled. Such events will result in the cancellation or the modification of the WOS on the

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Automation Manager, which must inform the operator of those changes (on its user interface or by printing a new corrected WOS sheet). The operator must then, manually correct the WOS on the LD.

X.2.4 Rerun on the Analyzer

An AWOS usually needs one analytic run on the Analyzer (see Data Model in section 3.4). In some circumstances the results obtained from this first run need to be controlled by a second run or "rerun".

260   The need for a rerun may be decided

- either immediately after the first run on the LD, before uploading the results to the Automation Manager

- or during the technical validation of the Work Order with the first run results, on the Automation Manager application.

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

Thus, three sub cases are to be considered:

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:

270   - 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.

This rerun happens before the results upload to the Automation Manager. The results of the first run either does not exist or are improper.

The Automation Manager should be notified of this status change of the AWOS ("First run failed, second run scheduled"), in order to track the LD operations, and to register the reagent consumption.

The common final part of the three preceding scenarios is presented in the following sub-case:

Final part of the scenario:

280   r) The LD (Analyzer) performs the ordered step on that specimen (first run).

s) Considering the results obtained, a second run is scheduled. The Analyzer notifies the AWOS status change to the Automation Manager: "First run failed, second run scheduled".

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t) After the appropriate fix (dilution, reagent refill, needle wash, calibration…) the Analyzer performs the second run.

u) The Analyzer notifies the Automation Manager, with the results and status of the second run.

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

The control (rerun) 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 such as drifting or out of range quality control detected. This decision is taken by the technical staff, or automatically by the Automation Manager application.

The common final part of the three preceding scenarios is presented in the following sub-case:

Final part of the scenario:

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

s) The Analyzer notifies the Automation Manager, with the results and status of the first run for this AWOS.

t) The technical validation of the results is performed on the Automation Manager, resulting in a new run requested with the same tests 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 download mode (at least for reruns) the Automation 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 Automation 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 Automation Manager prints out the scheduled rerun. This starts a new X.2.3. scenario (step a)

In addition, the rerun may generate new SWOS entrusted on LDs other than the targeted Analyzer. Here are some examples:

- The rerun is scheduled on a new aliquot that needs to be produced by an aliquoter (Pre-Analyzer LD), using a new container.

- The rerun needs the transportation of the specimen to a different Analyzer. This involves the Post-Analyzer robotic conveyer.

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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 Automation 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 first three scenarios.

X2.5 QC performed on an analyzer

In the following use cases, in all exchanged messages, the specimen is playing the role of a "QC specimen".

X2.5.1 QC downloaded by the Automation Manager

a)   The Automation Manager schedules (automatically or interactively by the technician) a new QC AWOS to be performed by an Analyzer, for a set of tests on a QC specimen. The AWOS (with the specimen/container ID or specific position, and the tests to perform) is downloaded to the analyzer

b)   The analyzer recognizes the specimen (scanning the bar-coded ID, or by position) finds the related AWOS and performs the tests.

c)   The analyzer sends the results obtained for the AWOS to the AM.

d)   The AM applies its evaluation rules to these QC results (result accepted or out of control, or warning of deviation trend) and stores them into its QC data base.

e)   Conditionally, the AM may forward the QC results to the Order Filler, using LAB-5 transaction and a reflex QC Work Order.

X2.5.2 QC scheduled by the Automation Manager, queried by the Analyzer

a)   The Automation Manager schedules (automatically or interactively by the technician) a new QC AWOS to be performed by an Analyzer, for a set of tests on a QC specimen. The AWOS (with the specimen/container ID and the tests to perform) is prepared for the analyzer

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350   b)   The analyzer recognizes the specimen (scanning the bar-coded ID) and queries the AM with the specimen/container ID. The AM replies with the appropriate AWOS for this "QC specimen".

        c)   The analyzer performs the tests and sends the results obtained for the AWOS to the AM.

        d)   The AM applies its evaluation rules to these QC results (result accepted or out of control, or warning of deviation trend) and stores them into its QC data base.

        e)   Conditionally, the AM may forward the QC results to the Order Filler, using LAB-5 transaction and a reflex QC Work Order.

X2.5.3 Unsolicited QC results uploaded to the Automation Manager

        a)   The analyzer recognizes a QC specimen (by position, and/or manual entry of the required
360   information) and performs a pre-configured or manually entered list of tests on this specimen.

        b)   The analyzer sends the results to the AM within a reflex AWOS.

        c)   The AM applies its evaluation rules to these unsolicited QC results (result accepted or out of control, or warning of deviation trend) and stores them into its QC data base.

        d)   Conditionally, the AM may forward the QC results to the Order Filler, using LAB-5 transaction and a reflex QC Work Order.

At the end of section X.6 of volume 1, add the following workflows, related to the three above use cases:


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X.3 Systems interconnection in the laboratory

As formerly stated, a clinical laboratory uses an Order Filler (OF) application to manage its orders. It handles its technical automation with the help of one or more Automation Managers (AM), each of which may manage one or more Laboratory Devices (LD). The systems: Laboratory Information System (LIS), Laboratory Automation System (LAS), Devices (Dev) that support the IHE actors, may be interconnected in various ways:

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One level of LAS   **Two levels of LAS and single path**   **Two levels of LAS and multi-path**
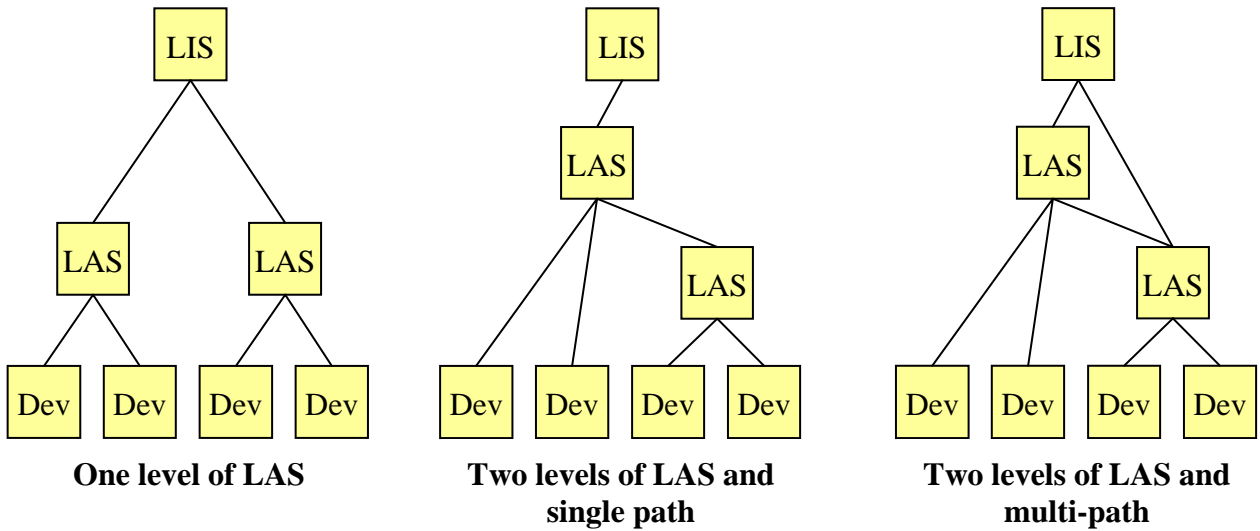
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Each of these architectures of interconnection is valid provided the systems implement the appropriate actors. That is:

One level of LAS   **Two levels of LAS and single path**   **Two levels of LAS and multi-path**
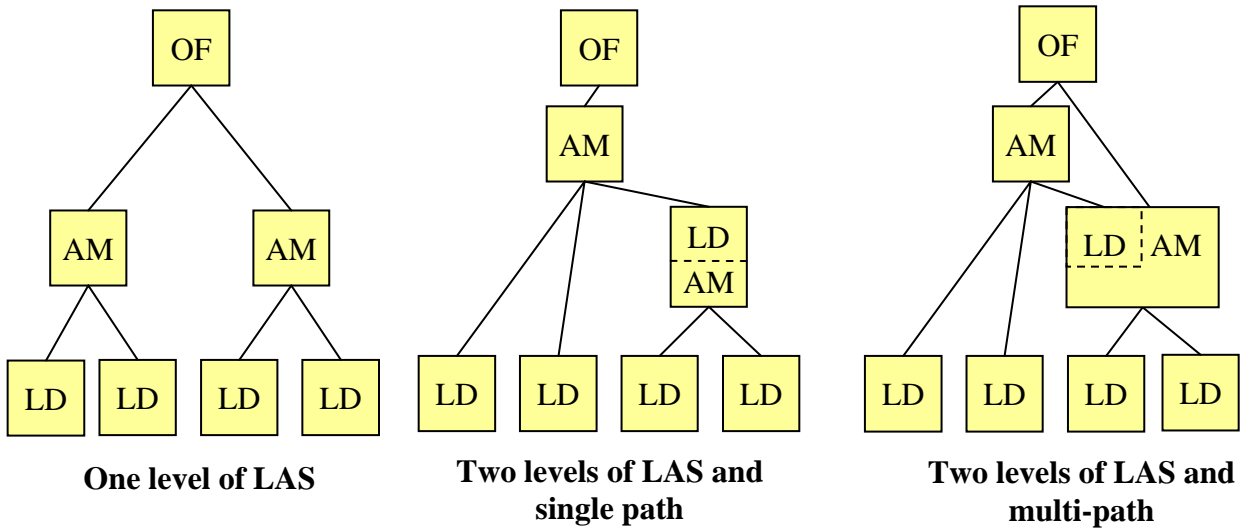
The management of multi-path Work Orders is an internal matter of the Order Filler application. These management rules are not part of the scope of IHE profiles.

X.4 Actors/ Transactions

X.4.1 Workflow Diagram
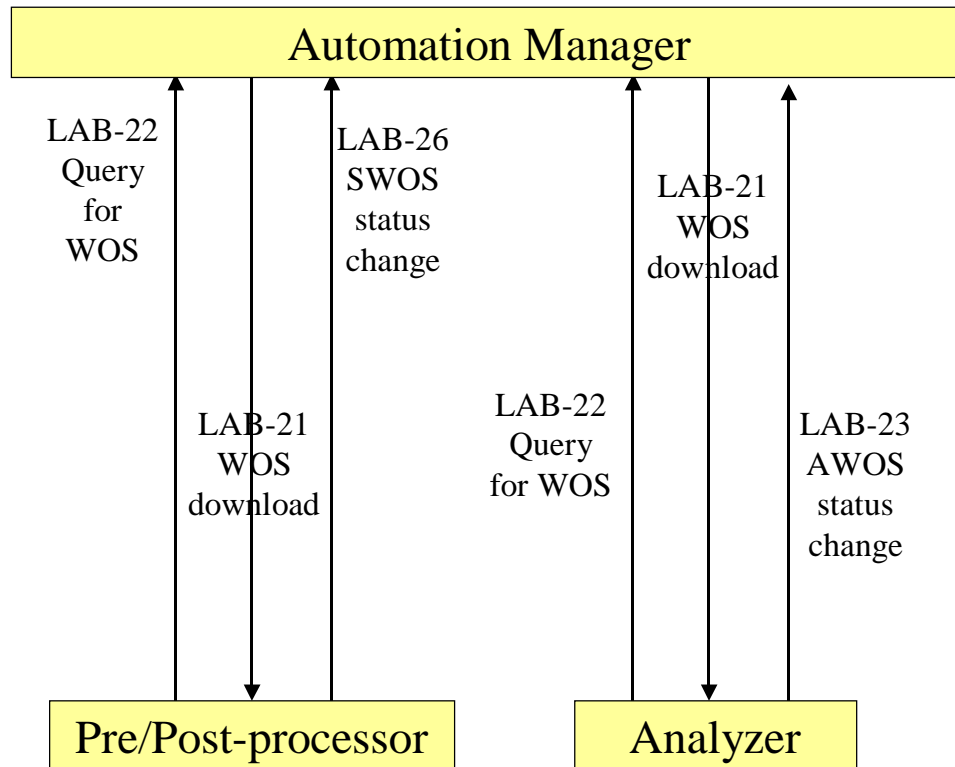
Figure X.4-1. Laboratory Device Automation Diagram

390 ### X.4.2 Transactions

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.

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400   **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-26: SWOS Status Change: This transaction contains the messages used by the Pre or Post-Processor to report all the status changes of the SWOS, and the related applicative acknowledgements. Status changes include: "specimen arrived", "SWOS complete", "SWOS failed"…

Table X.4-1 lists the transactions for each actor involved in the LDA Profile. To claim support of
410   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 the X.5 section below.

Table X.4-1. LDA Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Automation Manager	LAB-21 : WOS Download	R	
	LAB-22 : WOS Query	R	
	LAB-23 : AWOS Status Change	R	
	LAB-26 : SWOS Status Change	O	
Analyzer	LAB-21 : WOS Download	O	
	LAB-22 : WOS Query	O	
	LAB-23 : AWOS Status Change	R	
Pre/Post-processor	LAB-21 : WOS Download	O	
	LAB-22 : WOS Query	O	
	LAB-26 : SWOS Status Change	R	

X.5 LDA Integration Profile Options

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

Table X.5-1 Laboratory Device Automation - Actors and Options

Actor	Options	Vol & Section
Automation Manager	*Management of Pre/Post-processor*	
Analyzer	*Query mode WOS*	
	Download mode WOS	

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Actor	Options	Vol & Section
Pre/Post-processor	*Query mode WOS*	
	Download mode WOS	

420   **Management of Pre/Post-processor** : A product may implement an Automation Manager which manages only AWOS on Analyzers, and therefore supports only transactions LAB-21, LAB-22 and LAB-23. If a product supports the *Management of Pre/Post-processor* option, then it must also manages SWOS and it must support transactions LAB-26 with Pre/Post-processors.

Query mode WOS: An Analyzer implementing this option must support transaction LAB-22.

Download mode WOS: An Analyzer implementing this option must support transaction LAB-21.

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
430   LAB-21.

Note: A product implementing an Analyzer which supports neither transaction LAB-21 nor transaction LAB-22 can still claim for the LDA Integration Profile conformance: It is a one way Analyzer, only able to report its results using transaction LAB-23.

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

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X.6 LDA Integration Profile Process Flow

440 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 of a specimen with all LD working in downloLD mode

This process flow is based on use case X.2.1, with all LD working in download mode.
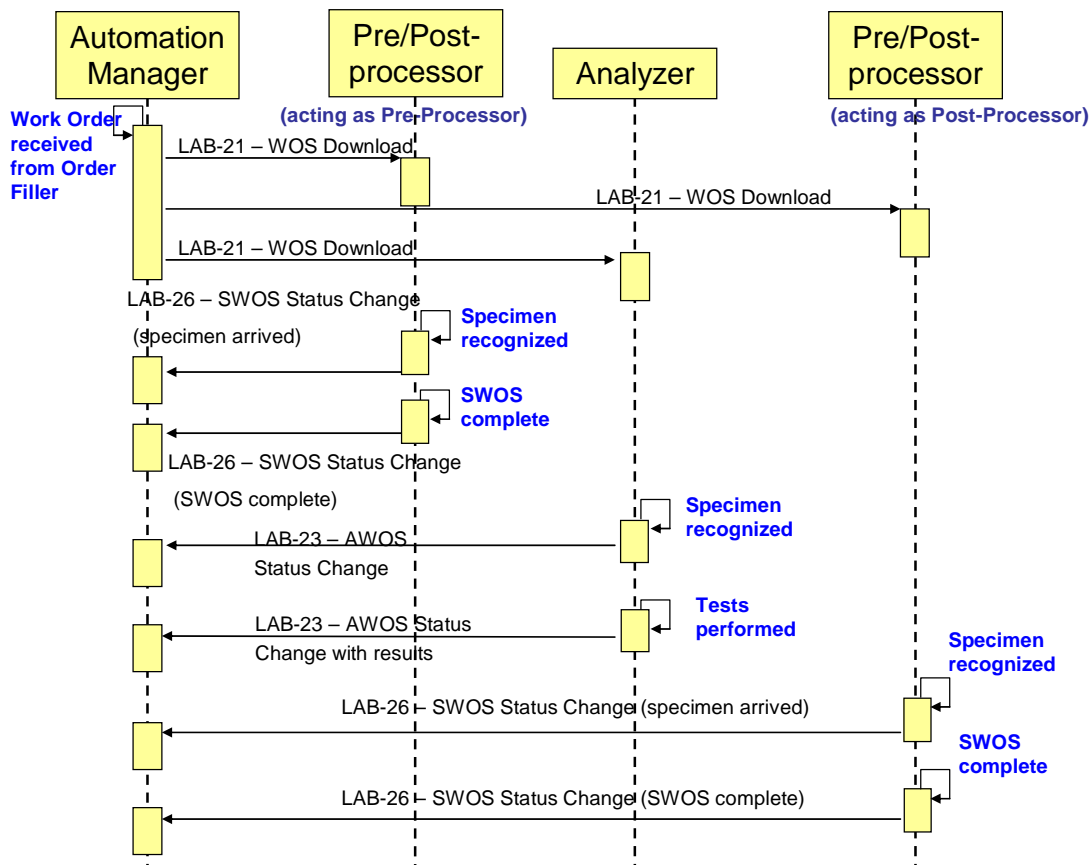
Figure X.6.1-1. Normal process in download mode

In this example, all LD support the optional message WOS Status Change triggered by the event "Specimen recognized on the LD carrier".

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450   This diagram shows a situation with one pre-processing device, one analyzer and one post-processing device. In the situation where the three LDs are combined in a single physical device, duplicate messages shall not be sent.

X.6.2 WOS Update with all LD working in download mode

This process flow based on use case X.2.1, shows the handling of the exception "Work Order updated" after download and before fulfillment of some of its WOS.
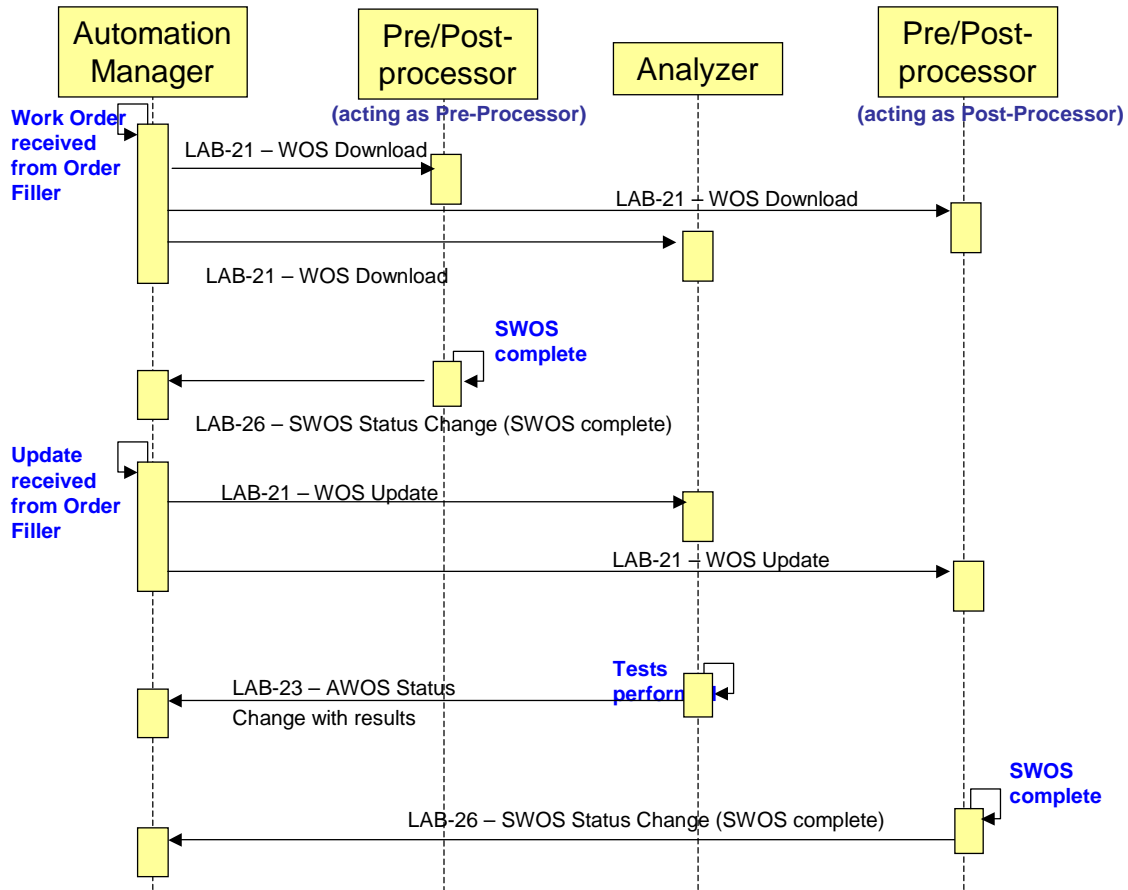

Figure X.6.2-1. WOS Update, in download mode

In this example, the LD do not use the optional message "WOS status change" triggered by the event "specimen recognized on the LD carrier".

460   When the Automation Manager receives the update from the Order Filler, it forwards this update only to those LDs which have not completed their Work Order Step yet, and which are concerned with this update.

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X.6.3 Normal process with AWOS manual entry and SWOS download

This process flow is based on use case X.2.1, for SWOS, and use case X.2.3 for AWOS: Pre/Post-processors are working in download mode, whilst the Analyzer, has a one-way interface supporting only transaction LAB-23 to report its results, and therefore needs the manual entry of its worklist of AWOS.

470
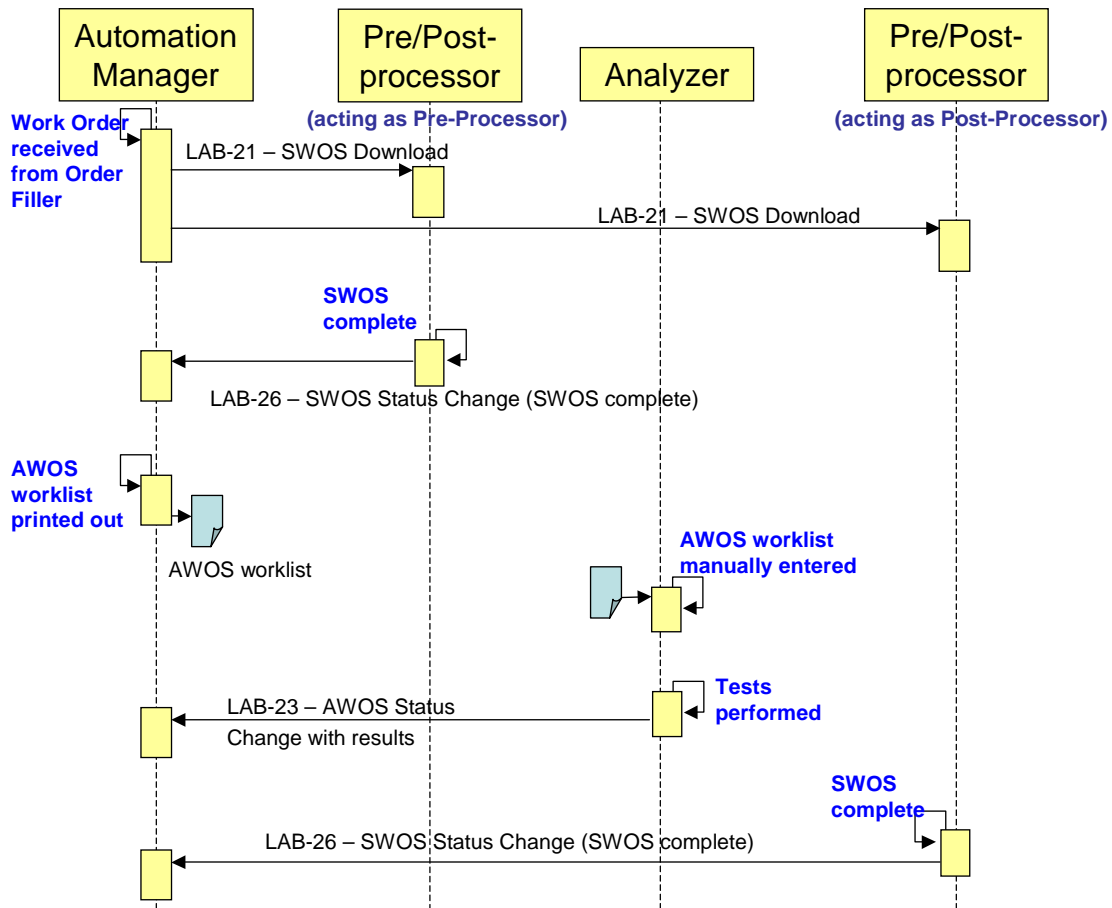
X.6.4 Normal process of a specimen with all LD working in query mode

This process flow is based on use case X.2.2, with all LD working in query mode.
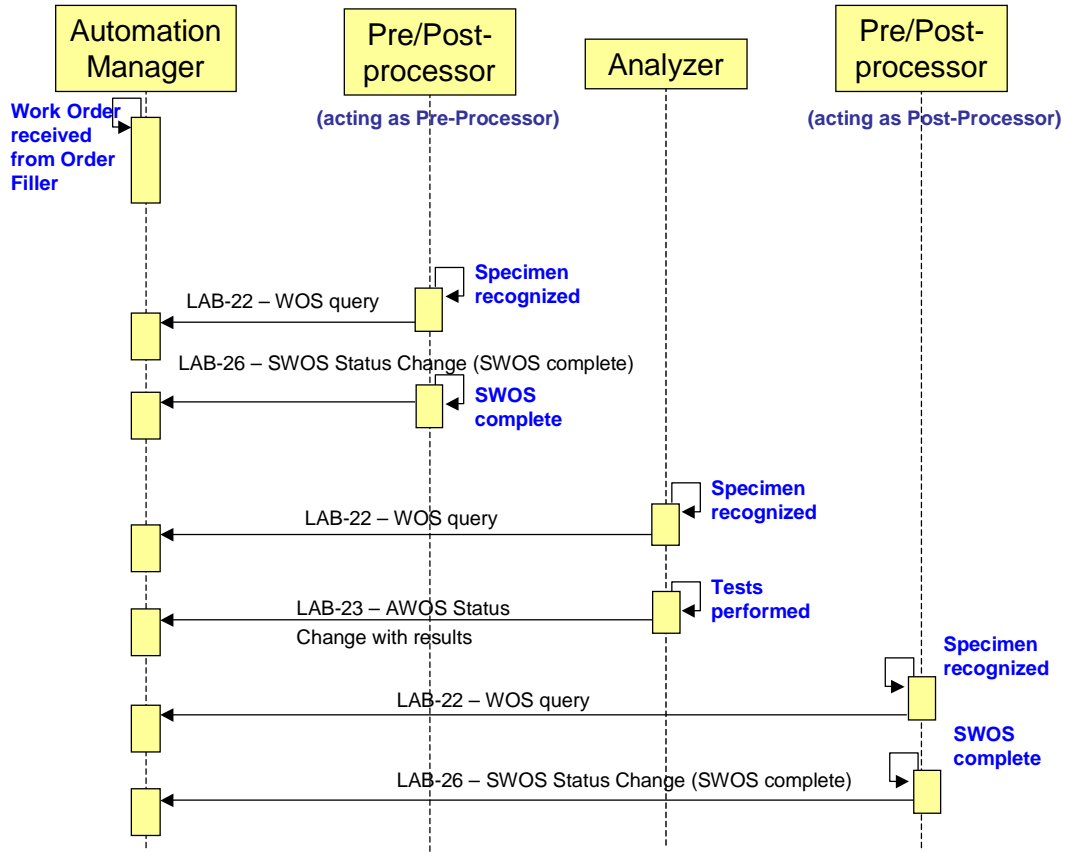
Figure X.6.4-1. Normal process in query mode

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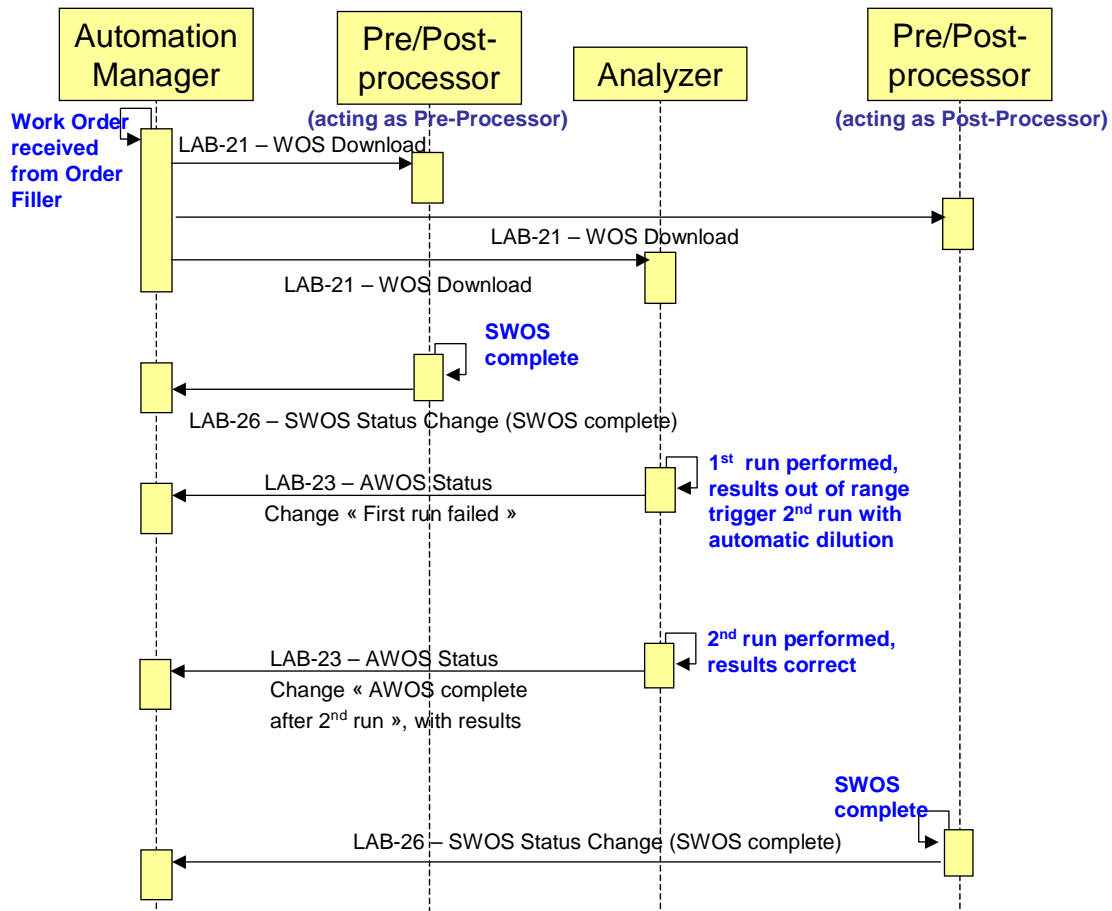
Figure X.6.5-1. Rerun decided on the Analyzer immediately after first run

480 **X.6.6 Rerun requested by the Automation Manager during technical validation**

This process flow is based on sub-use case X.2.4.2.
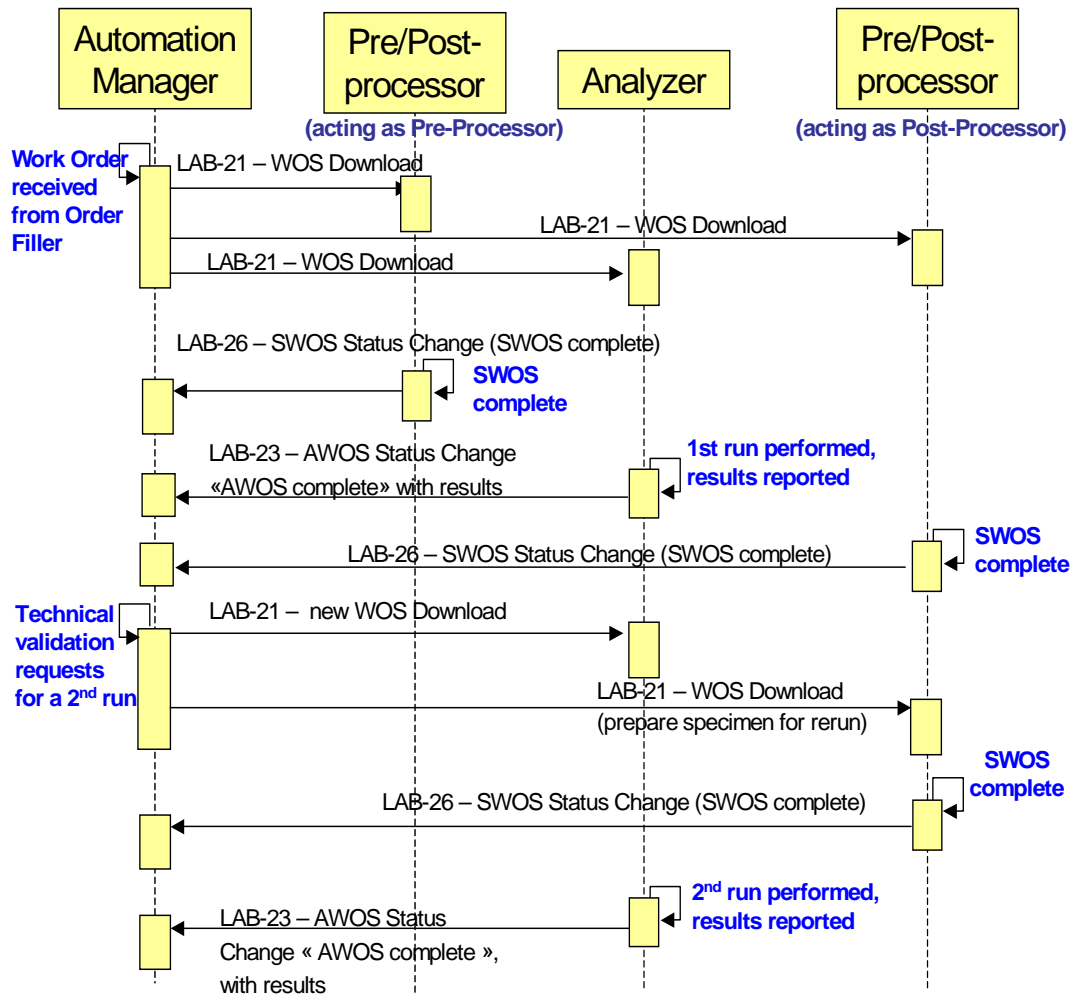
Figure X.6.6-1. Rerun decided on the Automation Manager at technical validation

The request for a second run generates a new AWOS for the same specimen on the Analyzer. In this example it also generates a new SWOS to the Post-processor, requesting it to prepare the specimen for the second run (aliquoting, retrieval, transportation to the analyzer…)

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

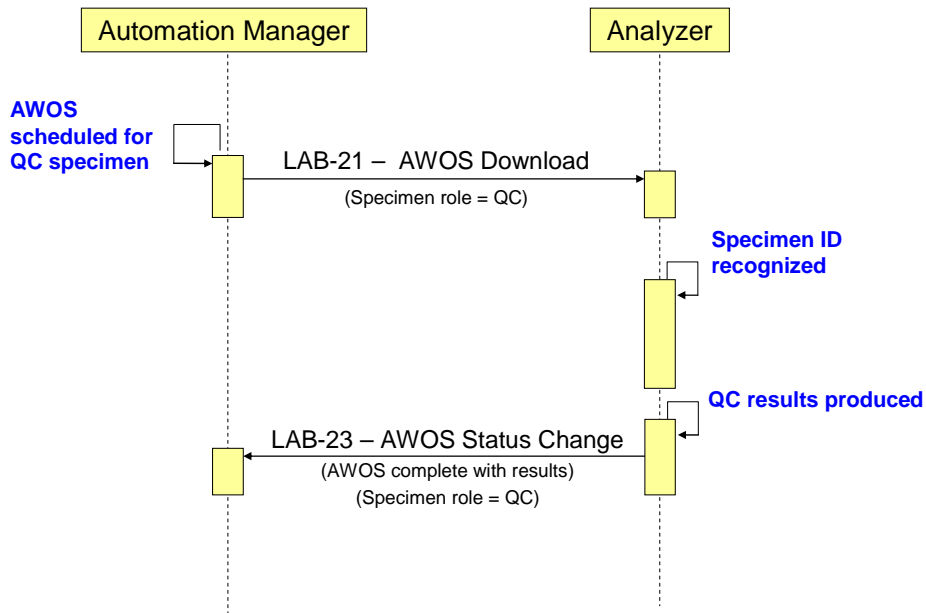This process flow is based on use case X.2.2 linked with use case X.2.3
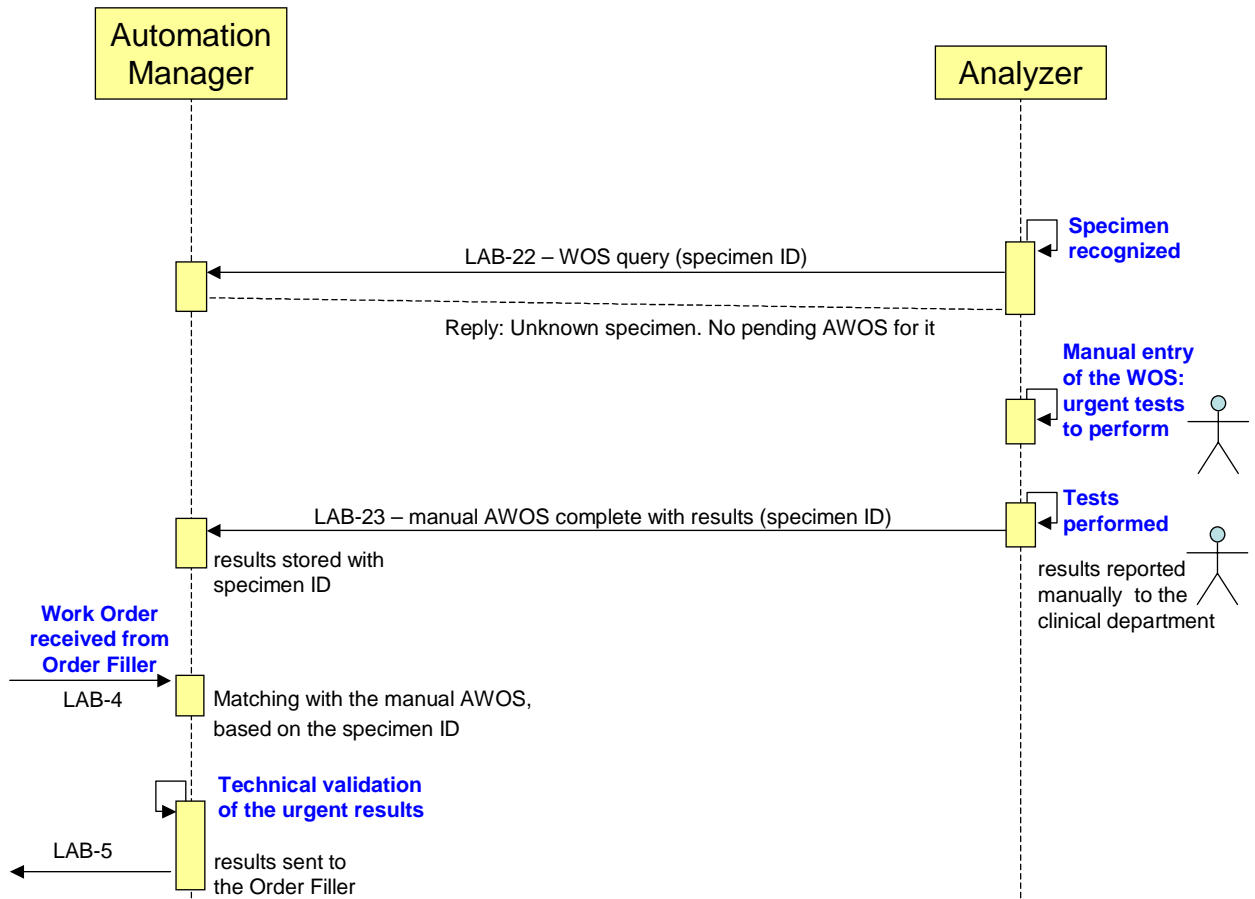
490

Figure X.6.7-1. Manual urgent AWOS performed and used before arrival of Work Order
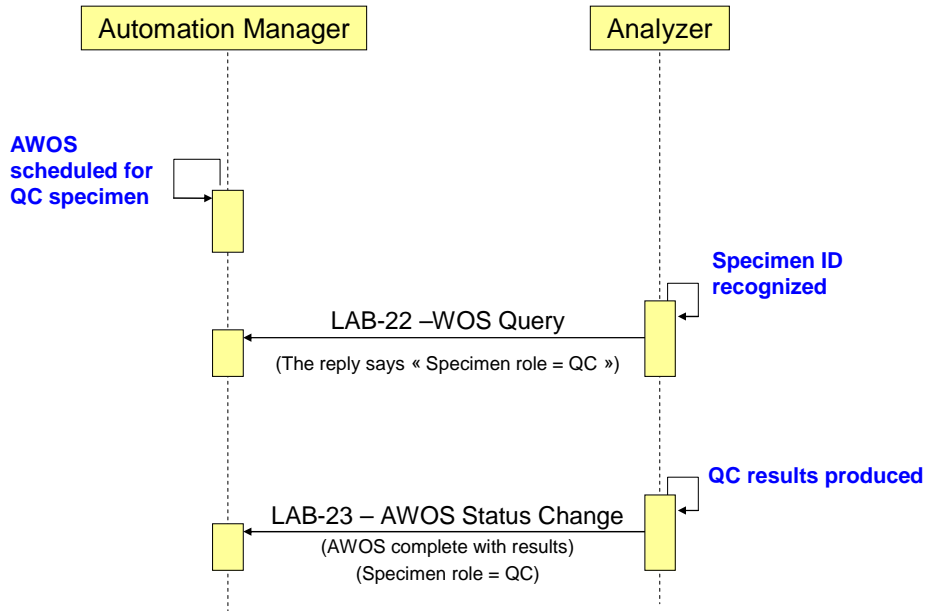
X6.8 QC downloaded by the Automation Manager

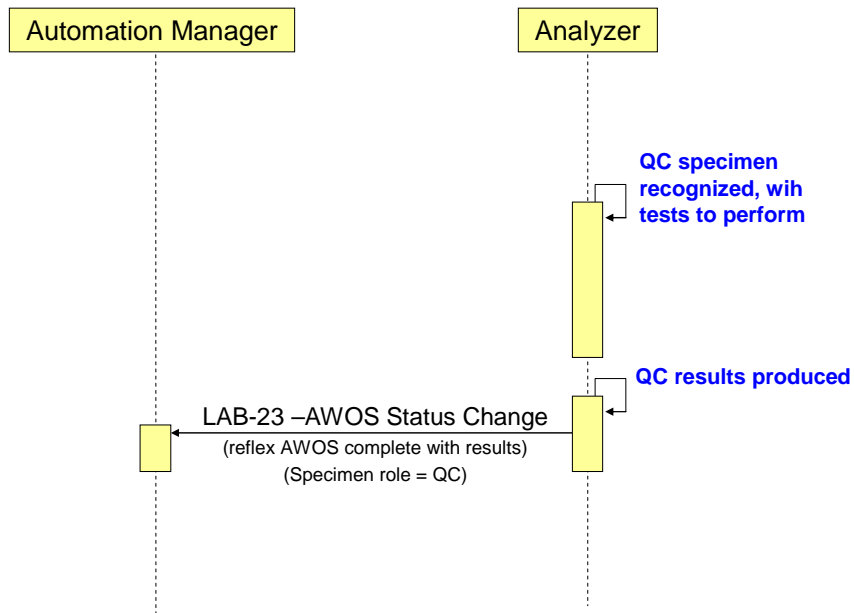The following diagram illustrates use case X.2.5.1

X6.9 QC scheduled by the Automation Manager, queried by the Analyzer

The following diagram illustrates use case X.2.5.2

X6.10 Unsolicited QC results uploaded to the Automation Manager

500   The following diagram illustrates use case X.2.5.3

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Volume 2 - Transactions

IHE Transactions

X.8 Transaction LAB-21: Work Order Step, Downloaded to LD

This section corresponds to Transaction LAB-21 of the IHE Technical Framework. Transaction LAB-21 is used by the Automation Manager and LD actors.
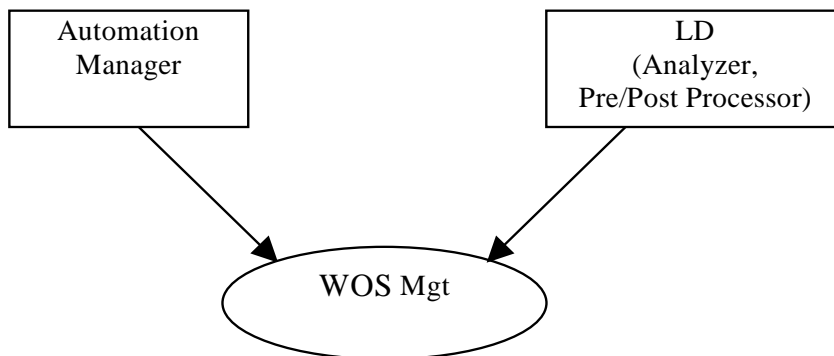
X.8.1 Scope

This transaction is used if the Automation Manager issues a new WOS to the LD.

In addition, this transaction is used to cancel and/or modify a WOS which was previously sent to 510   the LD.

It is also possible to cancel a previous WOS and send a new WOS to modify it.

X.Y.2 Use Case Roles

Actor: Automation Manager

Role: Manages the pre-processing, analysis, post-processing to fulfill the Work Order. Receives the Process Result from the Pre/Post Processor and (if necessary) performs the technical validation on it and (if necessary) sends the validated Process Result to the Order Filler.
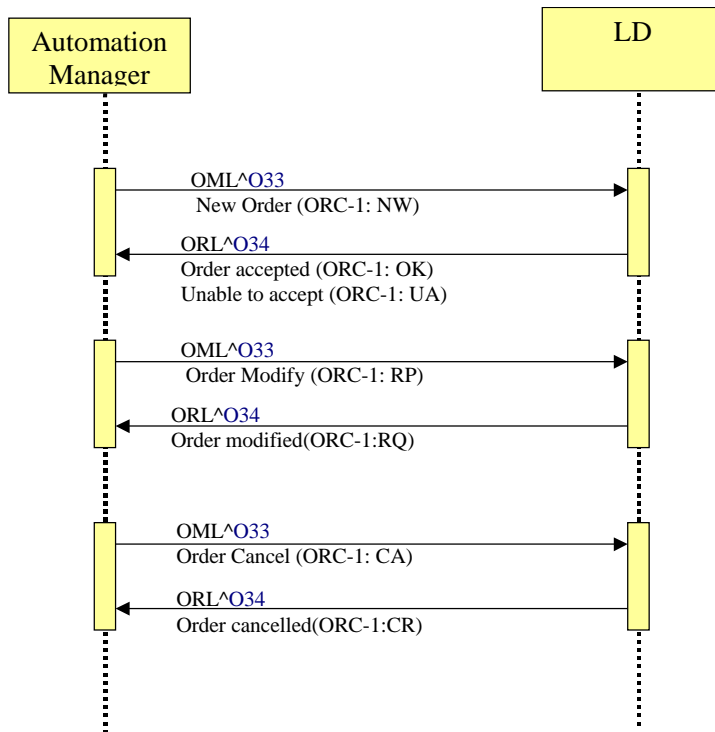
Actor: (LD) Pre/Post-processor, Analyzer

Role: Analyzes the specimen, perform the ordered tests and generates the test results, or 520   Manages the Pre/Post-process on the specimen and generates a Process Result.

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X.8.3 Referenced Standard

HL7 v2.5, Chapter 4

X.8.4 Interaction Diagram

X.8.4.1 Laboratory Order Message (OML^O33, ORL^O34)

This transaction contains the messages used to download a Work Order Step (WOS) from the Automation Manager to the Analyzer or Pre/Post-processor. It includes "new WOS", "update
530   WOS", "cancel WOS" and the related application acknowledgements.

X.8.4.1.1 Trigger Events

OML (O33): WOS sent by the Automation Manager.

ORL (O34): Acknowledgement of the WOS sent by the LD.

X.8.4.1.2 Message Semantics

Refer to the HL7 standard for the OML, ORL message of HL7 2.5 Chapter 4 and the general message semantics.

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

MSH-9 - Message Type (MSG) shall have its three components respectively valued to

540 "OML", "O33" and "OML_O33"

SPM-11 Specimen Role (CWE) in SPM segment shall be coded"Q"(Control specimen) in the case of a QC AWOS.

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Table : 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
[PID]	Patient Identification	O	[0..1]	3
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	O	[0..*]	13
[{	--- ORDER begin	O	[0..*]	
ORC	Common Order	R	[1..1]	4
[{TQ1}]	Timing/Quantity	RE	[0..1]	4
[OBR]	Observation Request	R	[1..1]	4
}]	--- ORDER end			
}	--- SPECIMEN end			

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

550

OBR segment

All fields are optional except those listed in table below.

Table : OBR Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
2	22	EI	R	[1..1]		00216	Placer Order Number
3	22	EI	RE	[0..1]		00217	Filler Order Number
4	250	CE	R	[1..1]		00238	Universal Service Identifier
5	2	ID	X	[0..0]		00239	Priority – OBR
6	26	TS	X	[0..0]		00240	Requested Date/Time
7	26	TS	X	[0..0]		00241	Observation Date/Time #
8	26	TS	X	[0..0]		00242	Observation End Date/Time #

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SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
9	20	CQ	X	[0..0]		00243	Collection Volume *
11	1	ID	RE	[0..1]	0065	00245	Specimen Action Code *
12	250	CE	X	[0..0]		00246	Danger Code
13	300	ST	X	[0..0]		00247	Relevant Clinical Information
14	26	TS	X	[0..0]		00248	Specimen Received Date/Time *
15	300	SPS	X	[0..0]		00249	Specimen Source
16	250	XCN	R	[1..1]		00226	Ordering Provider
17	250	XTN	RE	[0..2]		00250	Order Callback Phone Number
18	60	ST	X	[0..0]		00251	Placer Field 1
19	60	ST	X	[0..0]		00252	Placer Field 2
20	60	ST	X	[0..0]		00253	Filler Field 1 +
21	60	ST	X	[0..0]		00254	Filler Field 2 +
22	26	TS	X	[0..0]		00255	Results Rpt/Status Chng - Date/Time +
23	40	MOC	X	[0..0]		00256	Charge to Practice +
24	10	ID	C	[0..1]	0074	00257	Diagnostic Serv Sect ID
25	1	ID	X	[0..0]	0123	00258	Result Status +
26	400	PRL	X	[0..0]		00259	Parent Result +
27	200	TQ	X	[0..0]		00221	Quantity/Timing
29	200	EIP	X	[0..0]		00261	Parent
30	20	ID	X	[0..0]	0124	00262	Transportation Mode
40	250	CE	X	[0..0]		01031	Transport Arrangement Responsibility
41	30	ID	X	[0..0]	0224	01032	Transport Arranged
42	1	ID	X	[0..0]	0225	01033	Escort Required
43	250	CE	X	[0..0]		01034	Planned Patient Transport Comment
48	250	CWE	X	[0..0]	0476	01646	Medically Necessary Duplicate Procedure Reason.

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TCD segment

Table : TCD Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	250	CE	R	[1..1]		00238	Universal Service Identifier
2	20	SN	O	[0..1]		01420	Auto-Dilution Factor
3	20	SN	O	[0..1]		01421	Rerun Dilution Factor
4	20	SN	O	[0..1]		01422	Pre-Dilution Factor
5	20	SN	O	[0..1]		01413	Endogenous Content of Pre-Dilution Diluent
6	1	ID	O	[0..1]	0136	01416	Automatic Repeat Allowed
7	1	ID	O	[0..1]	0136	01424	Reflex Allowed
8	250	CE	O	[0..1]	0389	01425	Analyte Repeat Status

560

Note:

The usage of this segment needs to be considered between AM and LD.

Universal Service Identifier is a copy of OBR-4.

X.8.4.1.3 Expected Actions

If the OML message of the Order Control Code NW is received from Automation Manager, the LD will receive and register the order information, then it will transmit the result either "Accept" or "Reject" to Automation Manager by the ORL message.

## X.9 Transaction LAB-22: WOS Query

570 This section corresponds to Transaction LAB-22 of the IHE Technical Framework. Transaction LAB-22 is used by the Automation Manager and the Pre/Post-processor, Analyzer(LD) actors.

This transaction is used by the LD to get the WOS to perform for each specimen from the Automation Manager by querying after the specimen arrives. The transaction provides a query for multiple specimen and the reply will carry zero or one container and one WOS for each specimen. The Automation Manager and the LD preserve the conformity between the specimen and the WOS by checking the Specimen Information (Specimen ID and the like) within the message.

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X.9.1 Scope

580 This transaction is used by the general use case "Query for the WOS after specimen arrival on the LD" described in the Volume 1 of this LDA Technical Framework. It is used by the Automation Manager (Laboratory Automation System) and the LD which supports "Query Mode".

X.9.2 Use Case Roles
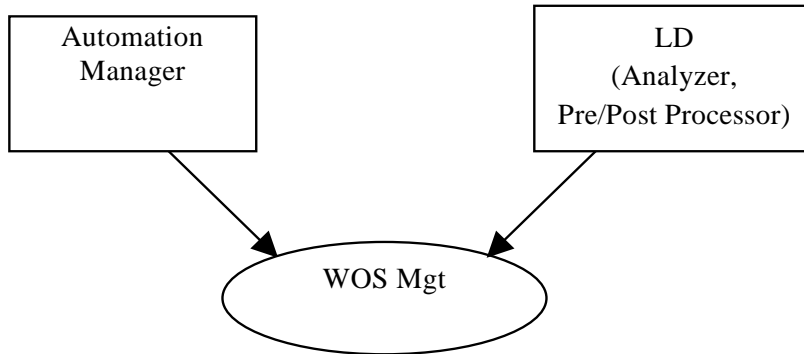
Actor: Automation Manager

Role: Manages the Work Orders and WOS. Returns the appropriate WOS to the query from the LD.

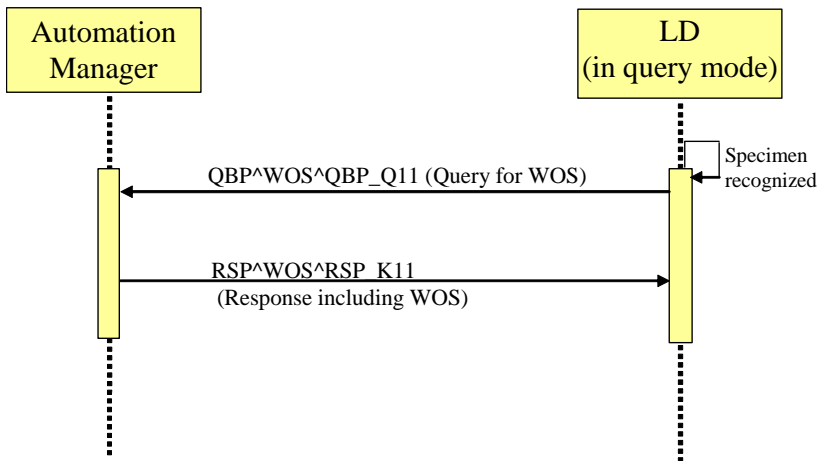**Actor:** (**LD) Pre/Post-processor, Analyzer**

Role: Queries the WOS to the Automation Manager when a specimen arrives, and receives the
590 WOS as the response.

X.9.3 Referenced Standard

HL7 version 2.5:

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

X.9.4 Interaction Diagram

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X.9.4.1 WOS Query Message (QBP^WOS^QBP_Q11, RSP^WOS^RSP_K11)

After the LD working in query mode recognizes one or more specimen arrival, the LD sends
600   "WOS Query Message"(QBP^WOS^QBP_Q11) with one or more Specimen IDs or other IDs to
the Automation Manager.

The Automation Manager replies with the response message (RSP^WOS^RSP_K11) containing
one or more WOS for each specimen identified in the query.

X.9.4.1.1 Trigger Events

QBP(Q11) : Query for the WOS sent by the LD.
RSP(K11) : Response including the WOS sent by the Automation Manager.

X.9.4.1.2 Message Semantics

Refer to the HL7 standard for the QBP message of HL7 2.5 Chapter 5 and the general message
semantics.

610   **Table : QBP^WOS^QBP_Q11**

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
[{SFT}]	Software Segment	O	[0..*]	2
QPD	Query Parameter Definition	R	[1..1]	5
RCP	Response Control Parameter	R	[1..1]	5
[DSC]	Continuation Pointer	O	[0..1]	2

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MSH-9 - Message Type (MSG) shall have its two first components respectively valued to "QBP" and "Q11".

Table : RSP^WOS^RSP_K11

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
[{SFT}]	Software Segment	O	[0..*]	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
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{OBX}]	Observation related to specimen	O	[0..*]	7
[{SAC}]	Specimen Container	RE	[0..1]	13
[	--- PATIENT begin	O	[0..1]	
PID	Patient Identification	R	[1..1]	3
[{OBX}]	Observation related to the patient	O	[0..*]	7
]	--- PATIENT end			
{	--- ORDER begin	R	[1..1]	
ORC	Common Order	R	[1..1]	4
[{TQ1}]	Timing/Quantity	RE	[0..1]	4
[	--- OBSERVATION REQUEST begin	O	[0..1]	
OBR	Observation Request	R	[1..1]	4
[TCD]	Test Code Details	O	[0..1]	13
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN end			

MSH-9 - Message Type (MSG) shall have its two first components respectively valued to "RSP" and "K11".

SPM-11 Specimen Role (CWE) in SPM segment shall be coded "Q" (Control specimen) in the case of a QC AWOS.

620   If the query was not based on the specimen ID, the response shall contain SAC.

QPD segment

Table : QPD segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	60	CE	R	[1..1]		01375	Message Query Name
2	32	ST	R	[1..1]		00696	Query Tag
3	80	EIP	C	[0..*]		01756	SPM-2:Specimen Identification
4	80	EI	C	[0..*]		01331	SAC-3:Container Identification
5	80	EI	C	[0..1]		01337	SAC-10:Carrier Identification
6	80	NA	C	[0..1]		01338	SAC-11:Position in Carrier
7	80	EI	C	[0..1]		01340	SAC-13:Tray Identification
8	80	NA	C	[0..1]		01341	SAC-14:Position in Tray
9	250	CE	C	[0..*]		01342	SAC-15:Location

QPD-1 Message Query Name (CE), required
Must be valued "**WOS^Work Order Step^IHE_LABTF''**

QPD-2 Query Tag (ST), required
Unique to each query message instance.

QPD-3 Specimen Identification (EIP), conditional
As for the 1st component "Placer Assigned Identifier"(EI), contains the placer assigned identifier
and its assigning authority.

630   As for the 2nd component "Filler Assigned Identifier"(EI), contains the filler assigned identifier
and its assigning authority.
If this field is valued all other query fields shall be empty.

QPD-4 Container Identification (EI), conditional
Contains the identification of the container.

QPD-5 Carrier Identification (EI), conditional
Contains the identification of the carrier (also known as Rack).
If this field is valued, then the field "QPD-6:Position in Carrier" shall also be valued.
If these 2 fields(QPD-5,6) are valued all other query fields shall be empty, with the possible
exception of the Location field(QPD-9).

640   **QPD-6 Position in Carrier (NA),** conditional
Contains the positions of the specimen/aliquot on the carrier (rack).
If this field is valued, then the field "QPD-5: Carrier Identification" shall also be valued.

QPD-7 Tray Identification (EI), conditional
Contains the identification of the Tray.

QPD-8 Position in Tray (NA), conditional
Contains the position of the carrier on the tray.

QPD-9 Location (CE), conditional
Contains the physical location of the specimen.

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650 This field cannot be valued in isolation, it must always be combined with the physical location/position of the specimen on either a carrier or a tray.
This field shall never be used in combination with either the specimen identification or the container identification fields.

RCP segment

Table : RCP segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	1	ID	O	[0..1]	0091	00027	Query Priority
2	10	CQ	O	[0..1]	0126	00031	Quantity Limited Request
		NM					
		CE					
3	60	CE	O	[0..1]	0394	01440	Response Modality
7	256	ID	O	[0..*]		01594	Segment group inclusion

RCP-1 Query Priority(ID), optional

Fixed to "I" (=Immediate). If no value is given, the default is "**I**".

RCP-2 Quantity Limited Request(CQ), optional

As for the 1st component "Quantity"(NM), Number of Records which will be returned in each increment of the response. If no value is given, the entire response will be returned in a single
660 increment.
As for the 2nd component "Units"(CE), "RD"(=Records) is always set. If no value is given, the default is RD.

RCP-3 Response Modality(CE), optional

Fixed to "R" (=Realtime). If no value is given, the default is "R".

RCP-7 Segment group inclusion(ID), optional

Specifies those optional segment groups which are to be included in the response. If this field is not valued, all segment groups will be included.

Note: The usage of this segment needs to be considered between AM and LD.

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X.9.4.1.3 Expected Actions

When specimen arrives on the LD which supports "Query Mode", the LD sends a QBP message to the Automation Manager to get WOS. This QBP message may have one or more Specimen IDs/Container IDs.

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The Automation Manager receives the QBP message and prepares the appropriate WOS by checking IDs contained in the QBP message. The Automation Manager returns the RSP message with WOS to the LD immediately. The LD receives WOS and performs processing for the specimen.

680 Even if the Automation Manager could not prepare WOS for one or more IDs, the RSP message must have SPM segments of the same number as IDs contained in the QBP message. OBR/TCD segments can be omitted.
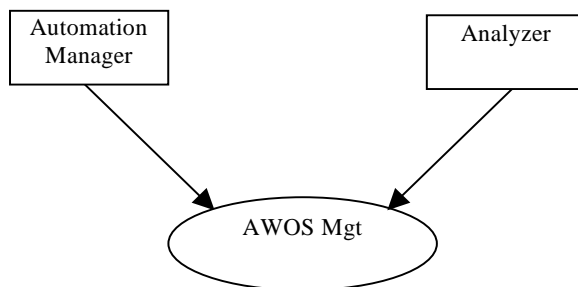
X.10 Transaction LAB-23: AWOS Performed, Analysis Results

This section corresponds to transaction LAB-23 of IHE Laboratory Technical Framework. The actors using this transaction are the Automation Manager and the Analyzer.

X.10.1 Scope

This transaction is used if the Analyzer sends test results to the Automation Manager.

X.Y.2 Use Case Roles

Actor: Automation Manager

690 **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
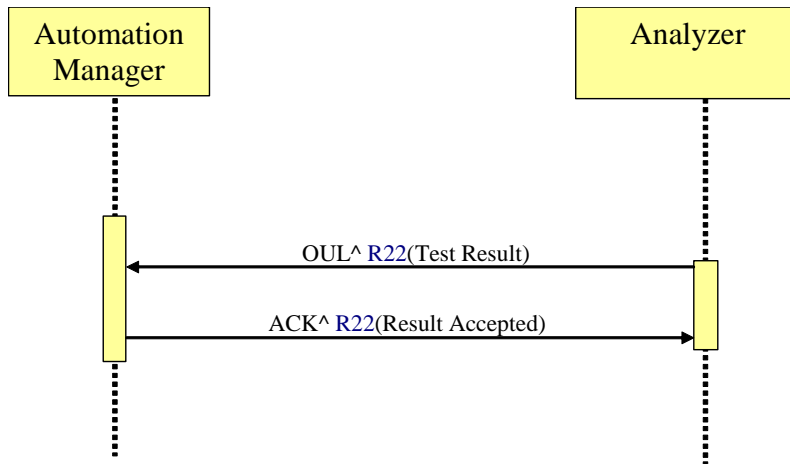
Actor: Analyzer

Role:

Analyzes the specimen and outputs the test results.

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X.10.3 Referenced Standard

HL7 Version 2.5--mainly referred to in Chapter 7.

700 ### X.10.4 Interaction Diagram

X.10.4.1 Analysis Results Upload (OUL^R22, ACK^R22)

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.

X.10.4.1.1 Trigger Events

Analyzer sends test results.

710 Automation Manager returns acknowledgement.

Notes HL7 V2.5 Chapter 7 has no description of ACK message. However, ACK message is necessary to exchange the messages on the HL7.

X.10.4.1.2 Message Semantics

Refer to the HL7 standard for the OUL message of HL7 2.5 Chapter 7 and the general message semantics.

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Table : OUL^R22

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
[PID]	Patient Identification	RE	[0..1]	3
[PV1]	Patient Visit	O	[0..1]	3
{	--- SPECIMEN begin	R	[1..1]	
SPM	Specimen information	R	[1..1]	7
[{ OBX }]	Observation Result (for Specimen)	O	[0..*]	7
[{	--- CONTAINER begin	0	[0..1]	
SAC	Container information	R	[1..1]	13
[INV]	Detailed Substance information (e.g., id, lot, manufacturer, … of QC specimen)	O	[0..1]	13
}]	--- CONTAINER end			
{	--- ORDER begin	R	[1..1]	
OBR	Observation Order	R	[1..1]	7
[ORC]	Common Order	O	[0..1]	4
[{	--- RESULT begin	O	[0..*]	
OBX	Observation Result	R	[1..1]	7
[TCD]	Test Code Detail	C[*1]	[0..1]	13
[{SID}]	Substance Identifier (e.g., reagents used for testing)	C[*1]	[0..*]	13
[{NTE}]	Notes and comments	O	[0..*]	
}]	--- RESULT end			
}	--- ORDER end			
}	--- SPECIMEN end			

Table 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

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[*1] If it is patient sample, this is Optional. If it is a QC sample it is Mandatory if it is available.

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

SPM-11 Specimen Role (CWE) in SPM segment shall be coded "Q" (Control specimen) in the case of a QC AWOS.

OBR segment

All fields are optional except those listed in table below.

730   **Table: OBR segment**

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
2	22	EI	RE	[0..1]		00216	Placer Order Number
3	22	EI	RE	[0..1]		00217	Filler Order Number
4	250	CE	R	[1..1]		00238	Universal Service Identifier
5	2	ID	X	[0..0]		00239	Priority – OBR
6	26	TS	X	[0..0]		00240	Requested Date/Time
7	26	TS	RE	[0..1]		00241	Observation Date/Time #
8	26	TS	RE	[0..1]		00242	Observation End Date/Time #
11	1	ID	RE	[0..1]	0065	00245	Specimen Action Code *
12	250	CE	X	[0..0]		00246	Danger Code
13	300	ST	X	[0..0]		00247	Relevant Clinical Information
14	26	TS	X	[0..0]		00248	Specimen Received Date/Time *
15	300	SPS	X	[0..0]		00249	Specimen Source
16	250	XCN	R	[1..1]		00226	Ordering Provider
17	250	XTN	RE	[0..2]		00250	Order Callback Phone Number
18	60	ST	X	[0..0]		00251	Placer Field 1
19	60	ST	X	[0..0]		00252	Placer Field 2
20	60	ST	X	[0..0]		00253	Filler Field 1 +
21	60	ST	X	[0..0]		00254	Filler Field 2 +
22	26	TS	C	[0..1]		00255	Results Rpt/Status Chng - Date/Time +
23	40	MOC	X	[0..0]		00256	Charge to Practice +
24	10	ID	C	[0..1]	0074	00257	Diagnostic Serv Sect ID
25	1	ID	R	[1..1]	0123	00258	Result Status +

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
27	200	TQ	X	[0..0]		00221	Quantity/Timing
30	20	ID	X	[0..0]	0124	00262	Transportation Mode
40	250	CE	X	[0..0]		01031	Transport Arrangement Responsibility
41	30	ID	X	[0..0]	0224	01032	Transport Arranged
42	1	ID	X	[0..0]	0225	01033	Escort Required
43	250	CE	X	[0..0]		01034	Planned Patient Transport Comment
48	250	CWE	X	[0..0]	0476	01646	Medically Necessary Duplicate Procedure Reason.

All field data should reflect LAB-21,22 transaction's OBR.

TCD segment

All fields are optional except those listed in table below.

Table : TCD segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	250	CE	R	[1..1]		00238	Universal Service Identifier

X.10.4.1.3 Expected Actions

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

X.11 Transaction LAB-26: Sending Process Result/Specimen Status Update Message

This section corresponds to Transaction LAB-26 of the IHE Laboratory Technical Framework. It
is used by the Automation Manager and the Pre/Post Processor.

X.11.1 Scope

This transaction is used when the Pre/Post Processor transmits a Process Results to the
Automation Manager.

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X.11.2 Use Case Roles
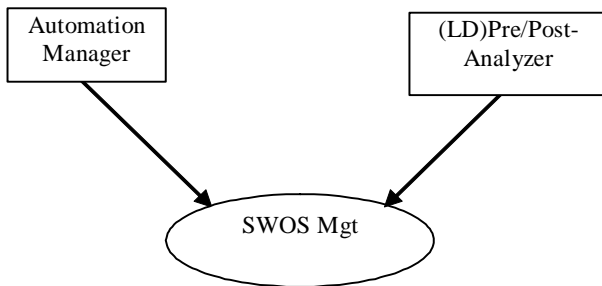
750

Actor: **Automation Manager**

Role: Manages the preprocessing, analysis, post-processing to fulfill the Work Order. Receives the Test Result from the Pre/Post Processor and (if necessary) performs the technical validation on it and (if necessary) sends the validated Result to the Order Filler.

Actor: (LD)**Pre/Post Processor**

Role: Manages the Pre/Post-analysis process on the specimen and generates a Process Result or Specimen Status Message.

X.11.3 Referenced Standard

760 HL7 Version 2.5--mainly referred to in Chapter 7 and Chapter13.
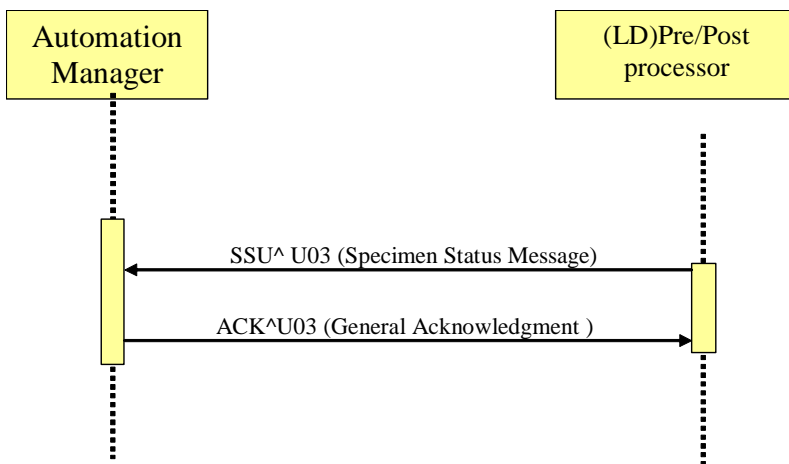
X.11.4 Interaction Diagram

Figure 2-2 : Unsolicited Specimen Status Update Message from Pre/Post Processor (SSU/ACK)

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X.11.4.1 Process Result Upload (SSU^U03, ACK^U03)

This transaction contains the messages used by the Pre or Post-Processor to report all the status changes of the SWOS, and the related application acknowledgements. Status changes include: "specimen arrived", "SWOS complete", "SWOS failed"…

770 **X.11.4.1.1 Trigger Events**

SSU (U03): Pre/Post Processor transmits a Specimen Status Update Message.

ACK (U03): Automation Manager sends the affirmative response.

X.11.4.1.2 Message Semantics

Refer to the HL7 standard for the SSU message in HL7 2.5 Chapter 13.

Table 2-5: SSU^U03

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
EQU	Equipment Detail	R	[1..1]	13
{	--- SPECIMEN_CONTAINER begin	R	[1..1]	
SAC	Specimen Container Detail	R	[1..1]	13
{ [OBX] }	Additional specimen characteristics	O	[0..*]	7
[{	--- SPECIMEN begin	R	[1..1]	
SPM	Specimen information	O	[1..1]	7
{ [OBX] }	Observation Result (for Specimen)	O	[0..*]	7
}]	--- SPECIMEN end			
}	--- SPECIMEN_CONTAINER end			

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Table 2-6: ACK^U03

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2

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MSA	Message Acknowledgement	R	[1..1]	2
[ERR]	Error	O	[0..1]	2

X.11.4.1.3 Expected Actions

The Pre/Post Processor sends a Process Result using the SSU message to the Automation
Manager. The Automation Manager accepts and registers the Process Result, and responds to the
Pre/Post Processor using the ACK message.

Note: The SSU message might appear too restrictive to meet future needs for carrying the output
data of a SWOS, brought along by specific pre or post processing devices. If such a use case
790 appears in the future for a specific device, alternative messages will be studied to extend this
profile.

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X.12 Real world use cases

X.12.1 Guideline

Each of the use cases in this section are to be considered as a template for handling a workflow of automated clinical laboratory through all the transactions of the LDA technical framework. Only major steps and interactions are described.

Each use case is described by a storyboard which describes the complete workflow in chronological order, completed by an interaction diagram, and illustrated by the most significant messages of the workflow. The message descriptions are abbreviated, to focus on the main points of interest.

800

OP : Order Placer

OF : Order Filler

AM : Automation Manager

ORT: Order Result Tracker

LD : Laboratory Device

WOS: Work Order Step

SWOS: Specimen Work Order Step

AWOS: Analytical Work Order Step

810   LIS: Laboratory Information System

X.12.2 Assumed in use case

This use case is in the context given where the following conditions are satisfied: The order is sent to the automation manager (AM) from the order entry system (OP) according to the workflow indicated in the LSWF technical framework. The patient ID is confirmed with the specimen container with appropriate label affixed according to the procedure specified by each facility, and then the sample is obtained appropriately. The filled specimen container is sent to the laboratory according to the procedure specified by the facility. The sample is processed in the Pre-processor immediately prior to or following the sample arrival checking

820   on the Order Filler (OF). The sample is transferred to the Pre-processor, the Analyzer, and then the Post-processor in this order. The measurement data is transmitted to ORT via OF after approval by AM.

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An example of use cases is described in this section, however a hybrid use case may be applicable in the field.

For instance, either of the Pre- or the Post-processor may be used or neither of them may be used. Therefore it is suggested that the uses case should be used to compare with real life scenarios evidenced in specific facilities.

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X.12.3 Typical specimen testing

X.12.3.1 Case Flow

This example corresponds to the use case described in Volume 1 as "Externally placed order with unidentified specimen or to be collected by the laboratory". AM schedules orders to be performed and transmits WOS for LDs (Analyzer, Pre/Post-processor) requiring WOS. Notifying AM of the sample arrival, LD processed the downloaded WOS whose result is transmitted to AM.

X.12.3.2 Storyboard

840

Dr. Smith orders five chemistry tests (TP, T-Bil, AST, ALT and LDH) on the patient (ID: 1111222) through the order entry system terminal. Ann Norman, technician sets the received sample onto the Laboratory Automation System (LAS) wherein the sample is treated by centrifugation, de-capping, aliquoting as well as labeling. However, if the sample process information has not arrived at the Pre-processor, it may have to wait for a while to receive the sample process information before processing..

The sample whose pre-processing is appropriately completed is measured in the analyzer. After measurement, the measurement result is transmitted to Laboratory Information System (LIS) where the approved sample is capped and unloaded.

850

Human actors and organizations participating to the process:

Assigning authority:	Marrione hospital
Placer:	Urology department
Filler:	Cytology laboratory
Ordering facility:	Urology
Patient:	Josie Macneal, Patient hospital identifier: 1111222, Patient visit number: 3333444, class = inpatient
Orderer:	Dr Smith. ID number 14789
Placer order enterer:	Tom Nurse. ID number 66623
Specimen collector:	Janet Kerry. ID number 48484
Technician:	Paul Stedt. ID number 99992

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Clinical expert: David Zhen 55565

ID numbers used by the workflow:

IDnumber	Value	Assigned by
Patient hospital ID	1111222	Admission office (ADT)
Patient visit number	3333444	Admission office (ADT)
Care unit order group	555	Enter-gastric department (OP)
Observation Order Code（TP）	1234561	Enter-gastric department (OP)
Observation Order Code（T-Bil）	1234562	Enter-gastric department (OP)
Observation Order Code（AST）	1234563	Enter-gastric department (OP)
Observation Order Code（ALT）	1234564	Enter-gastric department (OP)
Observation Order Code（LDH）	1234565	Enter-gastric department (OP)
Work Order Code (TP)	456	Bio-chemistry laboratory (OF)
Work Order Code (T-Bil)	457	Bio-chemistry laboratory (OF)
Work Order Code (AST)	458	Bio-chemistry laboratory (OF)
Work Order Code (ALT)	459	Bio-chemistry laboratory (OF)
Work Order Code (LDH)	460	Bio-chemistry laboratory (OF)
Work Order Step Code (TP)	456	Bio-chemistry laboratory (AM)
Work Order Step Code (T-Bil)	457	Bio-chemistry laboratory (AM)
Work Order Step Code (AST)	458	Bio-chemistry laboratory (AM)
Work Order Step Code (ALT)	459	Bio-chemistry laboratory (AM)
Work Order Step Code (LDH)	460	Bio-chemistry laboratory (AM)
Specimen ID	101_1	Bio-chemistry laboratory (AM)

LAB-21 interaction: AM transmits "new order" (NW) to LD (Analyzer, Pre/Post-processor).

LAB-23 interaction: The Analyzer transmits the sample arrival notice to AM by reading its ID label. After measurement completes, the measurement result is transmitted.

LAB-26 interaction: The Pre/Post-processor transmits the sample arrival notice and the process result to AM by reading its ID label.

X.12.3.3 Interaction diagram
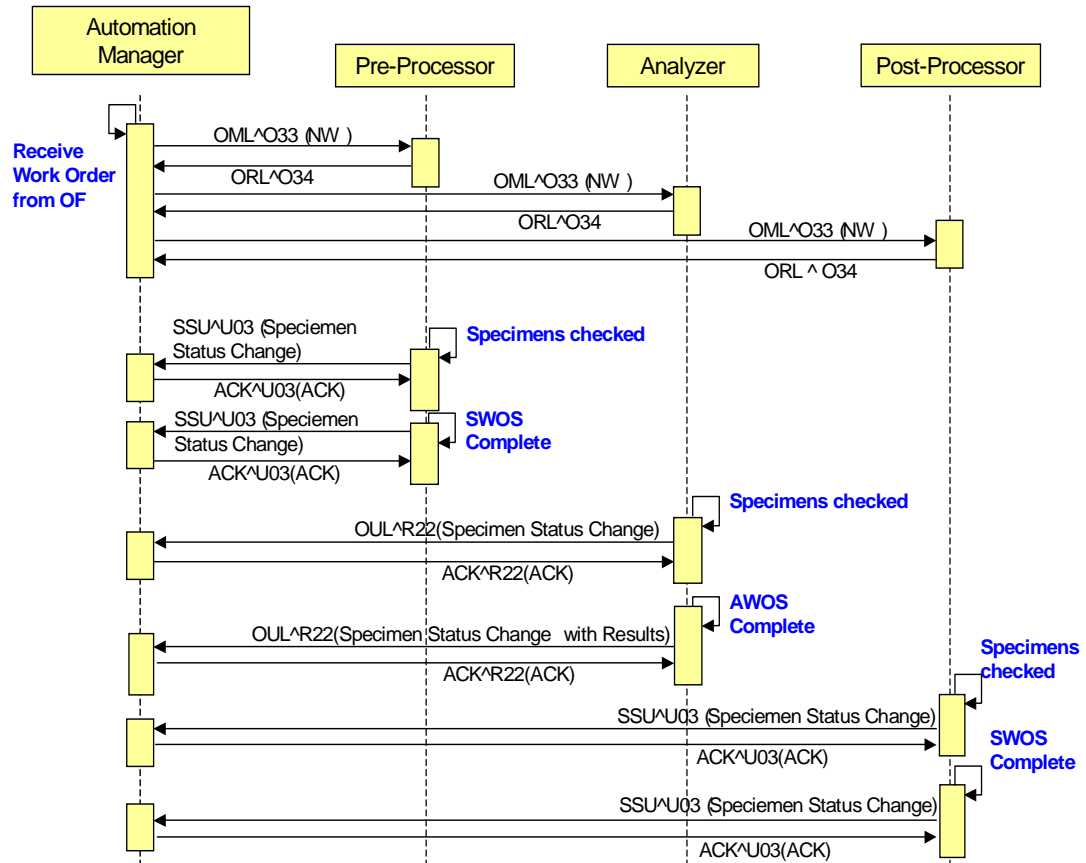
860

X.12.3.4 Message

LAB-21（AM→LD）： New WOS transmitted to LD

LAB-23（Analyzer→AM）： Performed AWOS transmitted to AM and measurement result

LAB-26（Pre/Post-processor→ AM）： Performed SWOS transmitted to AM

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X.12.4 Test with dedicated device for fixed items such as an urine qualitative device

870 **X.12.4.1 Case flow**

The Post-processor performs downloading of orders. Not receiving an order, the Analyzer transmits results of a predetermined item to AM. The sample ID is automatically (or manually) entered with the barcode label affixed to the sample container.

X.12.4.2 Storyboard

Dr. Thomas orders a battery of urine qualitative test on the patient (ID: 2222111) with a comment "urgent" through the order entry system terminal.

The battery consists of five urine qualitative tests (pH, protein, sugar, occult blood and ketone body).

880 Anne Norman, technician sets the sample arriving at the Emergency Laboratory onto the Analyzer, which automatically reads barcode info and sends measurement result to LIS after measurement completion. The measured sample is unloaded according to its sample processing info.

Urine qualitative tests are performed in an independent single analyzer.

Human actors and organizations participating to the process:

Assigning authority:	Marrione hospital
Placer:	Emergency Ward
Filler:	Emergency Laboratory
Ordering facility:	Emergency Ward
Patient:	Henry Schneider. account number 2222111 Patient visit number 050228011 class = outpatient.
Orderer:	Dr. Thomas, phone number 7999 ID number 99999
Placer order enterer:	Dr. Thomas, phone number 7999 ID number 99999
Specimen collector:	John nurse, ID number 99991
Technician:	Karen nurse, ID number 99992
Clinical expert:	Ema Scott, ID number 55565

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ID numbers used by the workflow

| ID number	Value	Assigned by
Patient hospital ID	2222111	Admission office (ADT)
Patient visit number	050228011	Admission office (ADT)
Care unit order group	999	Emergency ward (OP)
Care unit order comment (Stat)	Q	Emergency ward (OP)
Observation Order Code (Urine qualitative)	1234561	Emergency ward (OP)
Word Order Code (Urine qualitative)	45600	Emergency laboratory (OF)
Work Order Step Code (pH)	45601	Emergency laboratory (AM)
Work Order Step Code (Protein)	45602	Emergency laboratory (AM)
Work Order Step Code (Glucose)	45603	Emergency laboratory (AM)
Work Order Step Code (Occult Blood)	45604	Emergency laboratory (AM)
Work Order Step Code (Ketone Object)	45605	Emergency laboratory (AM)
Specimen ID	156	Emergency laboratory (AM)

890

LAB-21 interaction: As soon as AM receives Work order, it transmits NW to the Post-processor.

LAB-23 interaction: The Analyzer transmits the sample arrival notice to AM by reading its ID label. When measurement is completed, measurement result is transmitted.

LAB-26 interaction: The Post-processor transmits the sample arrival notice and sample processing results to AM by reading its ID label.

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X.12.4.3 Interaction diagram
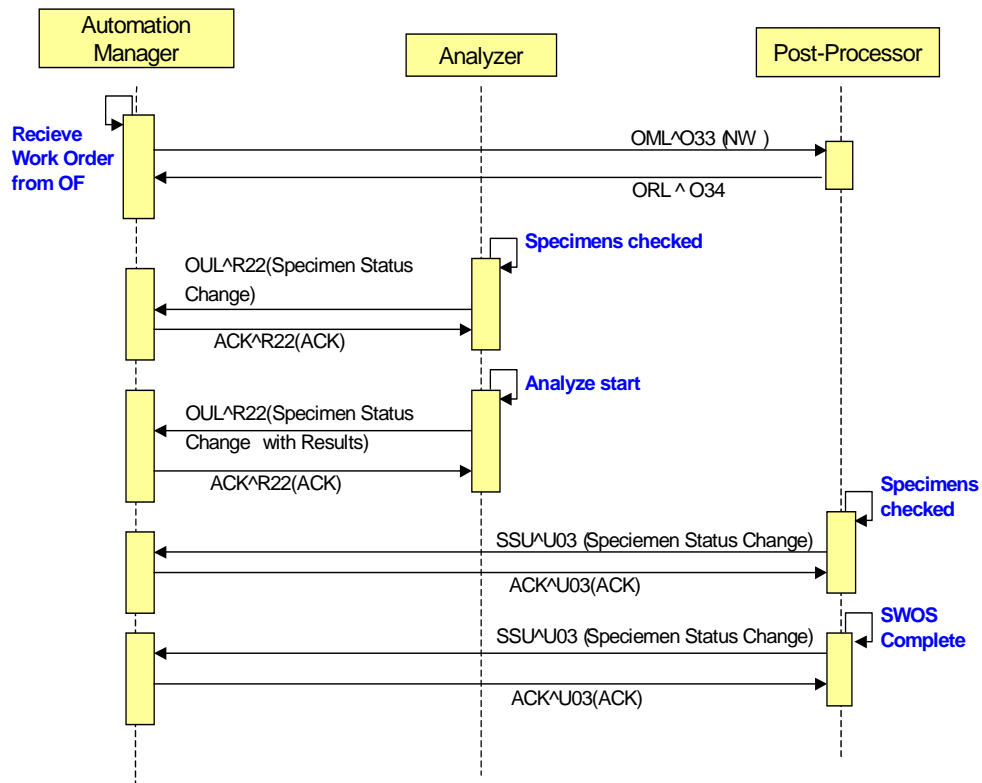
900

X.12.4.4 Message

LAB-21（AM→ Post-processor）: New SWOS transmitted to Post-processor

LAB-23（Analyzer→ AM）: Performed AWOS to be transmitted to AM and measurement result

LAB-26（Post-processor→ AM）: Performed SWOS transmitted to AM

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X.12.5 Setting of sample without pre-post processor

X.12.5.1 Case flow

910   A sample is set onto the Analyzer directly with no Pre/Post-processor. AM downloads AWOS to the Analyzer beforehand. The Analyzer identifies sample by reading its ID label and measures the sample according to AWOS, then transmits results to AM.

X.12.5.2 Storyboard

Dr. Smith orders an HbA1c test on the patient (ID: 2222333) from the order entry system terminal. The specimen, which arrived to the biochemistry laboratory, is placed to the analyzer by the technician Paul Stedt and analyzed.

After completing the measurement by the analyzer, the test result is transferred from analyzer to the LIS.

920   **Human actors and organizations participating to the process:**

|	
Assigning authority:	Marrione hospital
Placer:	Internal department
Filler:	Biochemistry laboratory
Ordering facility:	Internal secretion department
Patient:	Josie Macneal, Patient hospital identifier: 2222333, Patient visit number: 050228022, class = outpatient
Orderer:	Dr Smith. ID number 77777
Placer order enterer:	Dr Smith. ID number 77777
Specimen collector:	Janet Kerry. ID number 99991
Technician:	Paul Stedt. ID number 99992
Clinical expert:	David Zhen 55565

ID numbers used by the workflow

ID number	Value	Assigned by
Patient hospital ID	2222333	Admission office (ADT)
Patient visit number	050228022	Admission office (ADT)

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Care unit order group	333	Internal department (OP)
Observation Order Code (HbA1c)	1234567	Internal department (OP)
Work Order Code (HbA1c)	45678	Bio-chemistry laboratory (OF)
Work Order Step Code (HbA1c)	45678	Bio-chemistry laboratory (AM)
Specimen ID	147	Bio-chemistry laboratory (AM)

LAB-21 interaction: As soon as AM receives Work order, it transmits NW to the Post-processor.

LAB-23 interaction: The Analyzer transmits the sample arrival notice to AM by reading its ID label. When measurement is completed, measurement result is transmitted.

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X.12.5.3 Interaction diagram
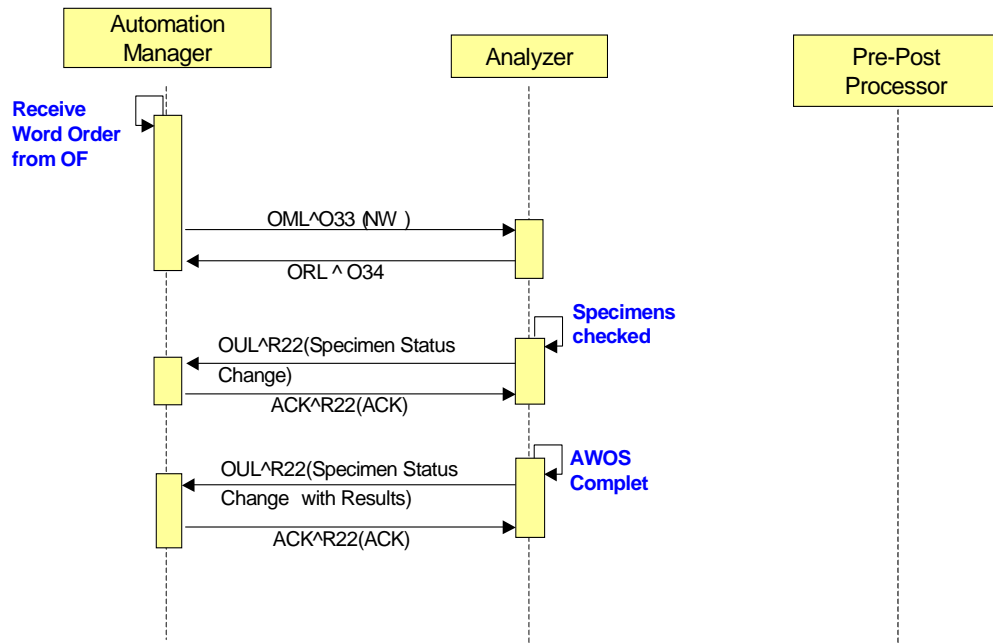
930

X.12.5.4 Message

LAB-21（AM→ Analyzer）：New AWOS transmitted to Analyzer

LAB-23（Analyzer→ AM）：Performed AWOS to be transmitted to AM and measurement result

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X.12.6 Manual ordering to the analyzer

X.12.6.1 Case flow

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This use case is the one example of Volume1 "X.2.3. Manual entry of the WOS on the LD". AM schedules the Work Order and transmit the WOS to the Pre-processor. A technician manually order test into the analyzer according to the worksheet, which is output from AM.

Pre-processor and Analyzer inform the sample arrival status to the AM, process WOS then transmit the result to AM.

X.12.6.2 Storyboard

Dr. Smith orders a Cyclosporin test on the patient (ID: 4444333) from the order entry system terminal. Technician Paul Stedt set a specimen onto the Laboratory automation system, then the specimen is treated by centrifugation, de-capping, aliquoting as well as labeling. After these pre-processes, Paul Stedt prints out the worksheet from LIS then input the test order manually to the analyzer.

950

Analyzer detects the specimen ID barcode and process measurement. After completing the measurement by the analyzer, the test result is transferred from analyzer to the LIS.

Human actors and organizations participating to the process:

Assigning authority:	Marrione hospital
Placer:	Urology department
Filler:	Biochemistry laboratory
Ordering facility:	Urology department
Patient:	Josie Macneal, Patient hospital identifier: 4444333, Patient visit number: 050228033, class = outpatient
Orderer:	Dr Smith. ID number 77777
Placer order enterer:	Dr Smith. ID number 77777
Specimen collector:	Janet Kerry. ID number 99991
Technician:	Paul Stedt. ID number 99992
Clinical expert:	David Zhen 55565

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ID numbers used by the workflow

| ID number	value	Assigned by
Patient hospital ID	4444333	Admission office (ADT)
Patient visit number	050228033	Admission office (ADT)
Care unit order group	555	Urology department (OP)
Observation Order Code (Cyclosporin)	234567	Urology department (OP)
Work Order Code (Cyclosporin)	54321	Bio-chemistry laboratory (OF)
Work Order Step Code (Cyclosporin)	54321	Bio-chemistry laboratory (AM)
Specimen ID	258	Bio-chemistry laboratory (AM)

LAB-21 interaction: As soon as AM receives Work order, it transmits NW to the Pre-processor.

960 **LAB-23 interaction:** The Analyzer transmits the sample arrival notice to AM by reading its ID label. When measurement is completed, measurement result is transmitted.

LAB-26 interaction: The Pre-processor transmits the sample arrival notice and sample processing results to AM by reading its ID label.

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X.12.6.3 Interaction diagram
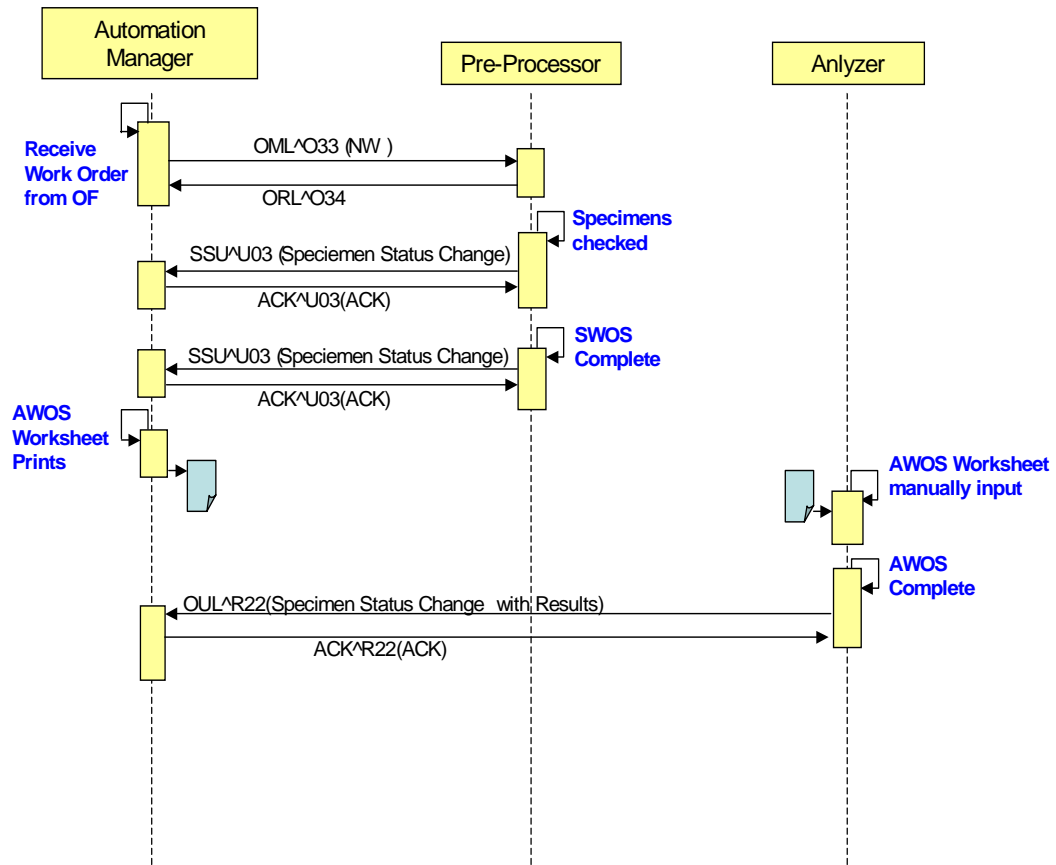
X.12.6.4 Message

970   LAB-21（AM→ Pre-processor）：New SWOS transmitted to Pre-processor

LAB-26（Preprocessor→ AM）：Perform SWOS transmitted to AM

LAB-23（Analyzer→ AM）：Perform AWOS to be transmitted to AM and measurement result

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X.12.7 Analyzer queries the test order

X.12.7.1 Case flow

This use case is one example of Volume 1 "X.2.2.Query for the WOS after specimen arrival on the LD".

AM schedules the Work Order and creates WOS. All LDs inform the sample arrival status to the AM, then query WOS. AM replies to the query from LD. LD processes WOS then
980 transmit the result to AM.

X.12.7.2 Storyboard

Dr. Smith orders three tests (Uric acid, BUN and Creatinine) on the Plasma specimen of the patient (ID: 4444555) from the order entry system terminal. Technician Paul Stedt set a specimen onto the Laboratory automation system. Pre/Post-processor detects the specimen ID barcode and queries sample processing info to the LIS.

The specimen is treated by centrifugation, de-capping, aliquoting as well as labeling according to the reply of the query. The specimen, which is successfully processed by Pre-processor, transferred to the analyzer and measured.

990 The measurement result is transferred from analyzer to the LIS, then the specimen is transferred to the Post-processor. At the Post-processor, the specimen is re-capped and stored to the storage unit.

Human actors and organizations participating to the process:

Assigning authority:	Marrione hospital
Placer:	Urology department
Filler:	Biochemistry laboratory
Ordering facility:	Urology department
Patient:	Josie Macneal, Patient hospital identifier: 4444555, Patient visit number: 050228066, class = outpatient
Orderer:	Dr Smith. ID number 77777
Placer order enterer:	Dr Smith. ID number 77777
Specimen collector:	Janet Kerry. ID number 99991
Technician:	Paul Stedt. ID number 99992

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Clinical expert: David Zhen 55565

ID numbers used by the workflow

| ID number	Value	Assigned by
Care unit order group	333	Internal department (OP)
Observation Order Code (Uric acid)	1234567	Internal department (OP)
Observation Order Code (BUN)	2345678	Internal department (OP)
Observation Order Code (Creatinine)	3456789	Internal department (OP)
Work Order Code (Uric acid)	34567	Bio-chemistry laboratory (OF)
Work Order Code (BUN)	45678	Bio-chemistry laboratory (OF)
Work Order Code (Creatinine)	56789	Bio-chemistry laboratory (OF)
Work Order Step Code (Urine acid)	34567	Bio-chemistry laboratory (AM)
Work Order Step Code (BUN)	45678	Bio-chemistry laboratory (AM)
Work Order Step Code (Creatinine)	56789	Bio-chemistry laboratory (AM)
Specimen ID	151	Bio-chemistry laboratory (AM)

LAB-22 interaction: LD queries WOS to AM. AM replies WOS to the LD.

LAB-23 interaction: The Analyzer transmits AWOS result to AM.

1000   **LAB-26 interaction:** The Pre/Post-processor transmits SWOS results to AM.

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X.12.7.3 Interaction diagram
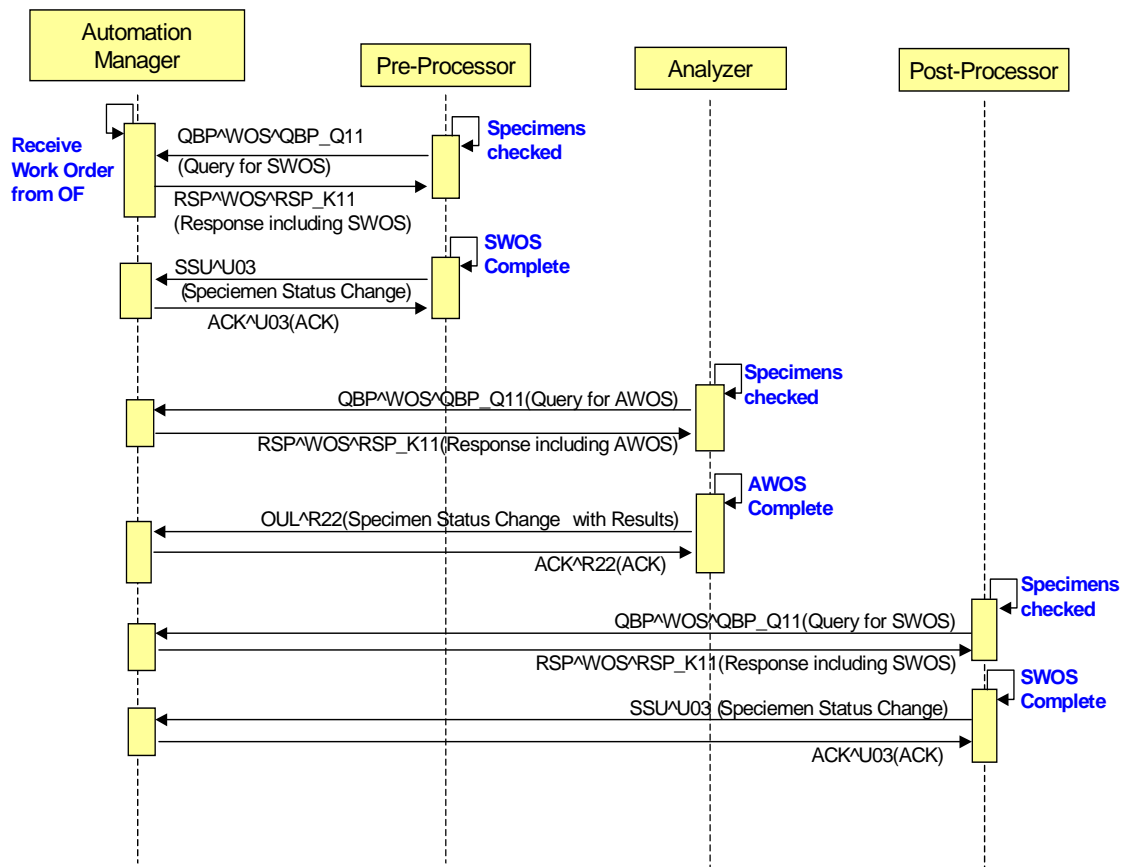
X.12.7.4 Message

LAB-22（LD→ AM→ LD）： Query of test order. WOS transferred from AM to LD

LAB-23（Analyzer→ AM）： Performed AWOS and measurement result transmitted to AM

LAB-26（Pre/Post-processor→ AM）： Performed SWOS transmitted to AM

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X.12.8 Two Hematology batteries on a blood specimen

This use case is the continuation in LDA profile, of the "real world example" presented in section 9.2 of the Laboratory Technical Framework.

X.12.8.1 Case Flow

This example corresponds to the use case described in Volume 1 as "Externally placed order with unidentified specimen or to be collected by the laboratory". This example continues the first real word use case described in Volume 2 of the Laboratory Scheduled Workflow profile. The Automation Manager schedules orders to be performed and transmits WOS for the Laboratory Device specialized in blood analysis. The LD combines the three functions (pre-processor, analyzer and post-processor) in one device. Notifying AM of the sample arrival, LD processed the downloaded WOS whose result is transmitted to AM.

1020

X.12.8.2 Storyboard

Dr. Physician orders two batteries of tests on the same specimen: blood count and differential blood count. Technician Ann Norman sets the received sample onto the Laboratory Automation System (LAS). The sample is pre-processed and analyzed by the same device. After measurement, results are transmitted to Laboratory Information System (LIS).

Human actors and organizations participating to the process:

|	
Assigning authority:	Abbeville hospital
Placer:	Urology department
Filler:	Cytology laboratory
Ordering facility:	Urology
Patient:	John Ill, Patient hospital identifier: 6543210, Patient visit number: 9998888, class = inpatient
Orderer:	Dr Uro, ID number 14788
Placer order enterer:	Janet Nurse, ID number 66622
Specimen collector:	John Collect, ID number 48483
Technician:	Marc Techos, ID number 99991
Clinical expert:	Jane Cyto, ID number 55564

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ID numbers used by the workflow:

ID number	Value	Assigned by
Patient hospital ID	6543210	Admission office (ADT)
Patient visit number	9998888	Admission office (ADT)
Care unit order group	555	Urology department (OP)
Observation Order Code（1st battery）	9876543	Urology department (OP)
Observation Order Code（2nd battery）	9876544	Urology department (OP)
Work Order Code (1st battery)	456	Cytology laboratory (OF)
Work Order Code (2nd battery)	457	Cytology laboratory (OF)
Work Order Step Code (1st battery)	456	Cytology laboratory (AM)
Work Order Step Code (2nd battery)	457	Cytology laboratory (AM)
Specimen ID	456_1	Cytology laboratory (AM)

LAB-21 interaction: AM transmits "new order" (NW) to LD. An identifier is already assigned to the specimen by the Order Filler.

LAB-23 interaction: the Analyzer transmits the sample arrival notice to AM by reading its ID label. After measurement completes, result are transmitted.

X.12.8.3 Interaction diagram
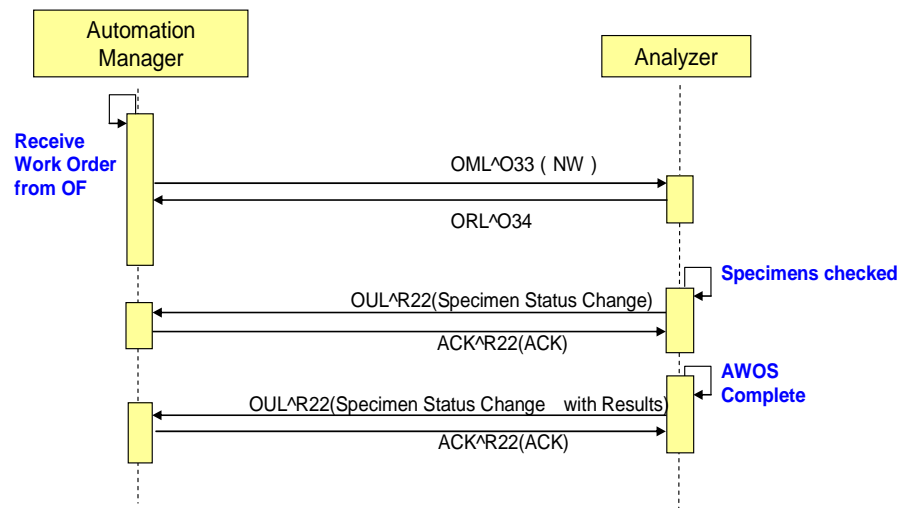
1040 **X.12.8.4 Message**

LAB-21（AM→LD : New WOS transmitted to the LD

```
MSH|^~\&|AM|Cytology|LD|Cytology|200506121348||OML^O33^OML_O33|001|T|2.5|||||USA||EN
PID|1||6543210^^^Abbeville Hospital^PI||ILL^JOHN^^^^^L|19810101|M
PV1|1|I|||||||||||||||||||9998888
SPM|1|456_1||BLD|||||||P||||||200506121330||||||||||1
ORC|NW|9876543^Urology|||||||200506121315|66622^NURSE^JANET|||||||||||Urology
TQ1|||||||||R
OBR||9876543||85027^Hemogram and platelet count, automated^CPT4||||||||||||||14788^URO
ORC|NW|9876544^Urology|||||||200506121315|66622^NURSE^JANET|||||||||||Urology
TQ1|||||||||R
OBR||9876544||85009^Differential WBC count, buffy coat^CPT4||||||||||||||14788^URO
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Acknowledgement sent by the LD:

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MSH|^~\&|LD|Cytology|AM|Cytology|200506121349||OML^O34^OML_O34|101|T|2.5|||||USA||EN
MSA|AA|001
1060  PID|1||6543210^^^Abbeville Hospital^PI||ILL^JOHN^^^^^L|19810101|M
PV1|1|I|||||||||||||||||9998888
SPM|1|456_1||BLD
ORC|OK|9876543^Urology|||||||200506121349
OBR||9876543||85027^Hemogram and platelet count, automated^CPT4
ORC|OK|9876544^Urology|||||||200506121349
OBR||9876544||85009^Differential WBC count, buffy coat^CPT4
```

LAB-23（LD→AM）：Specimen arrived on the LD

```
MSH|^~\&|LD|Cytology|AM|Cytology|200506121400||OUL^R22^OUL_R22|102|T|2.5|||||USA||EN
1070  PID|1||6543210^^^Abbeville Hospital^PI||ILL^JOHN^^^^^L|19810101|M
PV1|1|I|||||||||||||||||9998888
SPM|1|456_1||BLD
ORC|SC|9876543^Urology|||||||200506121400
OBR||9876543||85027^Hemogram and platelet count, automated^CPT4|||||||||||||||||||||||I
ORC|SC|9876544^Urology|||||||200506121400
OBR||9876544||85009^Differential WBC count, buffy coat^CPT4|||||||||||||||||||||||I
```

Acknowledgement sent by the AM: ACK (not described in this example)

LAB-23（LD→AM）：Performed AWOS transmitted to AM and measurement result

```
1080  MSH|^~\&|LD|Cytology|AM|Cytology|200506121410||OUL^R22^OUL_R22|102|T|2.5|||||USA||EN
PID|1||6543210^^^Abbeville Hospital^PI||ILL^JOHN^^^^^L|19810101|M
PV1|1|I|||||||||||||||||9998888
SPM|1|456_1||BLD
ORC|SC|9876543^Urology|||||||200506121410
OBR||9876543||85027^Hemogram and platelet count, automated^CPT4|||||||||||||||||||||||R
OBX|1|NM|11156-7^LEUKOCYTES^LN||8.2|10*3/mm3|||||R|||200506121410
OBX|2|NM|11273-0^ERYTHROCYTES^LN||4.08|10*3/mm3|||||R|||200506121410
OBX|3|NM|20509-6^HEMOGLOBIN^LN||13.4|10*3/mm3|||||R|||200506121410
OBX|4|NM|20570-8^HEMATOCRIT^LN||39.7|10*3/mm3|||||R|||200506121410
1090  OBX|5|NM|30428-7^MVC^LN||97|10*3/mm3|||||R|||200506121410
OBX|6|NM|28539-5^MCH^LN||33.0|10*3/mm3|||||R|||200506121410
OBX|7|NM|28540-3^MCHC^LN||33.8|10*3/mm3|||||R|||200506121410
OBX|8|NM|11125-2^PLATELETS^LN||220|10*3/mm3|||||R|||200506121410
ORC|SC|9876544^Urology|||||||200506121410
OBR||9876544||85009^Differential WBC count, buffy coat^CPT4|||||||||||||||||||||||R
OBX|1|NM|23761-0^NEUTROPHILS/100 LEUKOCYTES^LN||72|%|||||R|||200506121410
OBX|2|NM|26450-7^EOSINOPHILS/100 LEUKOCYTES ^LN||2|%|||||R|||200506121410
OBX|3|NM|26478-8^LYMPHOCYTES/100 LEUKOCYTES ^LN||20|%|||||R|||200506121410
OBX|4|NM|26485-3^MONOCYTES/100 LEUKOCYTES ^LN||6|%|||||R|||200506121410
1100  OBX|5|NM|30180-4^BASOPHILS/100 LEUKOCYTES ^LN||0|%|||||R|||200506121410
```

Acknowledgement sent by the AM: ACK (not described in this example)

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Note: Some Considerations for Pre/Post-processor

Since some arguments arose while this document is being made, we describe these here as future issues.

As the Pre-processors we are assuming these followings:

1110
- Centrifuge
- Decapper
- Aliquoter
- Sorter

and as the Post-processors, we are assuming these followings:

- Recapper
- Specimen storage system

However, it seems among these devices, the Aliquoter is the only device that can implement
1120 HL7. Since other devices will be under control of the Automation Manager as a precondition, otherwise standalone without the need for communicating, we may have to discuss the significance of defining their transactions.

On a practical basis, it may be more realistic that the AM spontaneously transmits the Process Result to the Order Filler or the other by using a message such as SSU.

In addition, if HL7 is implemented in these preprocessing devices, the installation of EAC messages may be required to conduct the specimen handling and execute Start/Stop.

On the Centrifuge:

One of our members commented "it would be useful if it could receive centrifugal conditions
1130 (time, acceleration and the like)". However it seems the existing HL7 has no appropriate message/segment/field to contain those centrifugal conditions.

Moreover, it has no data area to indicate that centrifugation is needed/unneeded, completed, successful/unsuccessful.

On the Decapper:

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It has no data area to indicate decapping is needed/not needed, completed, successful/unsuccessful.

However, because SAC-26 for example is Cap-type, it can contain values such as SCR (screw cap), PSH (push cap), FOIL (foil). Therefore, we think it is possible for the segment to contain 1140 indications such as "Decapped", "Fail" or the like.

On the Aliquoter:

Generally the Aliquoter set multiple items "to be dispensed in a specified area". Therefore it will be necessary to devise a way to define a work order when using OML messages.

In addition, HL7 has no data area to indicate explicitly the Label Printing Information of "the Aliquoter with label-issuing capability".

Moreover, an aliquoter/analyzer expert pointed out that the container information SAC-16-21 in the current SAC segment is inadequate. He insisted especially the need for a more detailed description of its bottom surface form.

1150

16	20	NM	O			01343	Container Height
17	20	NM	O			01344	Container Diameter
18	20	NM	O			01345	Barrier Delta
19	20	NM	O			01346	Bottom Delta
20	250	CE	O			01347	Container Height/Diameter/Delta Units
21	20	NM	O			00644	Container Volume

On the Recapper:

As same as Decapper, it has no data area to indicate recapping is needed/not needed, completed, successful/unsuccessful.

However, because SAC-26 for example is Cap-type, it can contain values such as SCR (screw cap), PSH (push cap), FOIL (foil). Therefore, we think it is possible for the segment to contain indications such as "Recapped", "Fail" or the like.

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1160   MEMO (2004/09/23)

- For QC result upload, "Specimen Role (SPM-11)" is used to distinguish QC sample or Patient sample. So it is "mandatory" if this is QC sample.

- OUL message for status change (specimen arrival) will be added in LAB-5. (CP is required)

- Need to add Use Cases for unsolicited analyzed results like QC.