Integrating the Healthcare Enterprise

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IHE Laboratory (LAB)
Technical Framework

10

Volume 1
(LAB TF-1)
Integration Profiles

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Revision 4.0 – Final Text

October 2, 2012

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1 Introduction

1.1 Overview of IHE

185 Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that 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 190 established interoperability standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework, organizes educational sessions, 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 to support the use of existing standards (e.g., 195 HL7, ASTM, DICOM, ISO, IETF, OASIS, CLSI and others as appropriate) rather than to define new standards. IHE profiles further constrain configuration choices where necessary in these standards to ensure that they can be used in their respective domains in an integrated manner between different actors. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

200 1.2 Overview of the Laboratory Technical Framework

1.2.1 Production

This document, the Laboratory Technical Framework (LAB TF), defines specific implementations of established standards to achieve integration goals of clinical laboratories with other components of a healthcare enterprise or with a broader community of healthcare 205 providers, hereafter called a healthcare community.

This document is updated annually, following a period of public review, and maintained regularly through the identification and correction of errata. The current version, rev. 4.0 Final Text, specifies the IHE transactions defined and implemented, as of September 2012. The latest version of the document is always available via the Internet at
210 http://www.ihe.net/Technical_Framework/index.cfm

It has been produced with the help of the following organizations:
- CAP (College of American Pathologists)
- ASIP Santé (Agence des Systèmes d'Information Partagés de Santé) formerly GMSIH (Groupement pour la Modernisation du Système d'Information Hospitalier)
215 - JAHIS (Japanese Association of Healthcare Information Systems Industry)
- IHE-J (IHE Japan)
- SFIL (Société Française d'Informatique de Laboratoire)
- HL7 and its affiliate organizations
- RSNA (Radiological Society of North America)

220   1.2.2 How the Laboratory Technical Framework is organized

The IHE Laboratory Technical Framework identifies a subset of the functional components of the healthcare enterprise or healthcare community, 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, and is organized in volumes:

225   • The present volume, **Volume 1** of the Laboratory Technical Framework (LAB TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called integration profiles that highlight their capacity to address specific integration requirements for clinical purposes.

• **Volumes 2a, 2b, and 2x** of the Laboratory Technical Framework (LAB TF-2a, Lab TF-2b,
230   LAB TF-2x) provide a detailed technical description of each message-based transaction and of its messages.

• **Volume 3** of the Laboratory Technical Framework (LAB TF-3) provides a detailed technical description of each document-based transaction, its persistent content and binding.

• **Volume 4** of the Laboratory Technical Framework (LAB TF-4) has been deprecated

235   1.3 Audience

The intended audience of this document is:

• Technical staff of vendors participating in the IHE initiative

• IT managers of healthcare institutions and healthcare communities

• Experts involved in standards development

240   • Anyone interested in the technical aspects of integrating healthcare information systems

1.4 Relationship to Standards

The IHE Laboratory Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a
245   coordinated set of transactions based on HL7, IETF, ISO, CLSI, OASIS and W3C standards. As the scope of the IHE initiative expands, transactions based on other international standards may be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these
250   standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have
255   implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration

Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them.

1.5 Relationship to Real-world architectures

The IHE Actors and transactions are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g., Hospital Information System, Electronic Patient Record, Clinical Information System, Laboratory Information System, Laboratory Automation System, analyzer, robotic transportation system and other pre and post-analytic process equipment), the IHE Laboratory Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Laboratory Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

1.6 Conventions

This document has adopted the following conventions for representing the framework concepts and requirements.

1.6.1 IHE Actor and Transaction Diagrams and Tables

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in healthcare. Transactions are interactions between actors that communicate the required information through standards-based messages.

The diagrams and tables of actors and transactions in subsequent sections indicate which transactions each actor in a given profile must support. The transactions shown on the diagrams are identified both by their name and the transaction number as defined in LAB TF-2.

The transaction numbers are shown on the diagrams as bracketed numbers prefixed with the specific Technical Framework domain.

In some cases, a profile is dependent on a prerequisite profile in order to function properly and be useful. For example, Sharing Laboratory Reports (XD-LAB) content profile depends on one of the three document sharing profiles XDS, XDM and XDR. These dependencies can be found by locating the desired profile in Table 3.3-1 to determine which profile(s) are listed as prerequisites. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

1.6.2 Process Flow Diagrams

The descriptions of integration profiles that follow include process flow diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

295   These diagrams are intended to provide an overview so the transactions can be seen in the context of a healthcare institution or community workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in italics to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

300   These diagrams are not intended to present the only possible scenario. Often, other actor groupings are possible, and transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations. Transactions are shown as arrows oriented according to the flow of the primary information handled by the transaction and not

305   necessarily the initiator.

1.6.3 Technical Framework Cross-references

When references are made to another section within a Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:

310   <domain designator> TF-<volume number>: <section number>, where

<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, PCC = Patient Care Coordination, LAB = Laboratory)

<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3),

<section number> is the applicable section number.

315   For example: ITI TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework.

When references are made to Transaction numbers in the Technical Framework, the following format is used: [<domain designator>-<transaction number>], where

<transaction number> is the transaction number within the specified domain. For example:

320   [LAB-1] refers to Transaction 1 from the IHE Laboratory Technical Framework, [ITI-30] refers to Transaction 30 from the IT Infrastructure Technical Framework.

1.7 History of Annual Changes

The IHE Technical Framework is updated annually to reflect new profiles, corrections and new transactions.

325   ### 1.7.1 Scope of Changes Introduced in the Current Year (2012)

This V4.0 of the Laboratory Technical Framework incorporates a number of change proposals resulting from the Connectathons of years 2008 - 2012. This release will be the basis for the 2013 Connectathon testing and exhibition processes.

The major enhancements brought by this V4.0 are:

Enhancement	Vol.
Division of LAB TF-2 into 3 separate documents, parts A, B, and X (Appendices).	2

Enhancement	Vol.
Clarification requests from Connectathons.	2
Corrections in XD-LAB.	3

330 1.7.2 Summary of changes introduced in 2011

This V3.0 of the Laboratory Technical Framework incorporates a number of change proposals resulting from the Connectathons of years 2008 - 2010. This release is the basis for the 2012 Connectathon testing and exhibition processes.

The major enhancements brought by this V3.0 are:

Enhancement	Vol.
Combined use of LBL and LTW profile for specimen identification performed in cooperation between OP and OF actors	1
More detailed specifications for LCSD	2
Corrections in XD-LAB	3
Deprecation of LOINC Subset in Technical Framework volume 4	4

335 1.7.3 Summary of changes introduced in 2008

This V2.1 Final Text finalizes V2.0 of the Laboratory Technical Framework by changing the status of each of its Profiles from "Trial Implementation" to "Final Text", suppressing the two deprecated profiles LWSF and LIR, and incorporating a number of Change Proposals that were addressed to the IHE Laboratory Committee as a result of the 2008 Connectathons.

340   The major enhancements brought by the change proposals integrated in this version V2.1 are:

Enhancement	Vol.
Extension of the general scope to non-human specimens, either isolated or paired with human in vitro specimens, in order to support some particular use cases of the sharing of public health laboratory reports	1, 3
Extension of XD-LAB profile to address Public Health Laboratory reports, including observations on non-human specimens, reportable conditions, case and outbreak identification	1, 3
Enhancement of microbiology workflow in transaction LAB-3, using child order mechanism and observation sub-id mechanism, in harmonization with the "HL7 Lab result message to EHR" implementation guide	2
Harmonization of XD-LAB with PCC TF Content Module specifications	3
Reducing the extensions from XD-LAB to the CDA R2 standard	3
Complementing the usage of specimen attributes in the messages of LAB-1 and LAB-3	2
Support of HL7 v2.5.1 with new OBX fields characterizing the subcontractor in LAB-3	2
Correcting the example messages	2

Enhancement	Vol.
Adding a new option "*Report Facsimile For Order Group*" to LTW Profile	1, 2
Glossary complemented	1

1.7.4 Summary of Changes Introduced in 2007

Version 2.0 Trial Implementation expanded V1.2 of the Laboratory Technical Framework by:
- Integrating the supplements LDA, LPOCT, LCSD, XD-LAB and LBL
- Deprecating LSWF and LIR profiles and replacing then by the new LTW profile
345
- Integrating Change Proposals for LDA and XD-LAB profiles
- Leveraging PAM and PDQ profiles from the IT Infrastructure Technical Framework, for obtaining up-to-date patient identification and movements data.
- Adding requirements to support the optional grouping of Order Result Tracker and Order Placer Actors in the LTW profile

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1.8 Comments

IHE International welcomes comments on this document and the IHE initiative. They should be directed to the co-chairs of the IHE Laboratory Committee, using the address lab@ihe.net

1.9 Copyright permissions

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1.10 IHE Technical Framework Development and Maintenance Process

365 The IHE Laboratory Technical Framework is being continuously extended and maintained by the IHE Laboratory Technical committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.

370 The first of these principles is that any extensions, clarifications and corrections to the Technical Framework must maintain backward compatibility with previous versions of the framework in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there.

1.11 Glossary

375   This glossary introduces all the acronyms, abbreviations and specific terms used in this Laboratory Technical Framework.

Aliquoter	An automated device which aliquots a parent specimen into one or more child specimen. Acts as a Pre/Post-processor in LDA integration profile.
AM	Automation Manager: An Actor involved in LTW and LDA integration profiles of the LAB-TF.
Analyzer	An Actor in LDA integration profile, played by a device producing measurements or findings on a specimen.
ATNA	Audit Trail & Node Authentication integration profile in ITI-TF
Authenticator	Role played by a laboratory "Clinical Expert" (see this term) when performing "Clinical Validation" (see this term) of a set of results issued in a CDA R2 laboratory report, by which this person authenticates and endorses the laboratory report or a subset of it.
AWOS	Analytical Work Order Step: A WOS performed by an Analyzer in LDA integration profile.
Battery	A set of one or more laboratory tests, identified by a single name and code that can be ordered to a laboratory. Synonym: Panel.
CDA	Clinical Document Architecture: An HL7 V3 standard for the electronic representation of clinical documents.
Centrifuge	An automated device which divides the blood into a serum ingredient and a blood cell ingredient by centrifugal separation. Acts as a Pre/Post-processor in LDA integration profile.
CIS	Clinical Information System
CLIA	Clinical Laboratory Improvement Amendments: Set of quality standards regulating activities related to in vitro testing for laboratories in the US, custodied by the Food and Drug Administration (FDA). See http://www.fda.gov/CDRH/clia/
Clinical expert	Also "Medical expert" or "Bio-medical scientist" or "Results principal interpreter": The person who assumes the overall responsibility for the clinical validation and reporting of an order or an order group. HL7 V2.5 speaks of "Result principal interpreter". In HL7 CDA R2 this actor is playing the role of "Authenticator" (AUTHEN) of the laboratory report or of a subset of this report. Synonym: "Validator"
Clinical Validation	Also "Medical validation": The process by which a clinical expert accepts and interprets the results of an order or an order group. Interpretation of the results considers the results together with the biological history, clinical and therapy information available for the patient. This step may sometimes be performed by an expert system that uses knowledge rules and emulates the reasoning of the bio-medical scientist, under its responsibility. In HL7 CDA R2 this process is recorded as "authentication" of the laboratory report or of a subset of this report.
CLSI	The Clinical and Laboratory Standards Institute
Code set	A code set is any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnosis codes, or medical procedure codes. An example of international code set is LOINC^{TM} (Logical Observation Identifier Names and Codes).

Conveyor	An automated device which transports specimen to other devices. Acts as a Pre/Post-processor in LDA integration profile.
CT	Consistent Time: Integration profile in ITI-TF.
Decapper	An automated device which takes off the cap of the specimen container. Acts as a Pre/Post-processor in LDA integration profile.
DML	Device Message Layer defined by the standard POCT1-A
EHR	Electronic Health Record
External Quality Control	Tests performed on an identified control specimen whose target values are hidden, in order to control the proficiency of the organization. External QC specimens are provided by an external institution that controls and compares the results obtained by multiple healthcare enterprises. This is also called proficiency testing.
Filler Order Number	The unique reference assigned to an Order by the Order Filler Actor on the laboratory side.
GBEA	Guide de Bonne Exécution des Analyses Médicales. Minimal regulatory set of quality standards regulating activities related to in vitro testing for laboratories in France
HIS	Hospital Information System
HL7	Health Level Seven: International Standards Development Organization in the domain of healthcare information exchange.
IHE	Integrating the Healthcare Enterprise
Internal Quality Control	Tests performed on an analyzer using an identified control specimen with usually known target values, in order to check the accuracy of the device.
ITI TF	IT Infrastructure Technical Framework
Label Broker	An Actor in the LBL integration profile, which receives label information, and delivers these labels in appropriate operations, and may notify the status of this process.
Label Information Provider	An Actor in the LBL integration profile, which labeling instructions and information to the Label Broker.
Labeler	An automated device which affixes the bar code label to the specimen container.
Laboratory Request	Synonym of "Order Group" (see below).
Laboratory Performer	A laboratory who performed (all or some of) the tests documented in a laboratory report or reported in a results message. It is described with the laboratory's name and address and the laboratory director's identification
LAB-TF	Laboratory Technical Framework
LAS	Laboratory Automation System
LB	Label Broker. Actor of LBL integration profile in LAB-TF.
LBL	Laboratory Specimen Barcode Labeling integration profile in LAB-TF.
LCSD	Laboratory Code Set Distribution integration profile in LAB-TF.
LD	Laboratory Device: A category of Actors in LDA profile. An LD is either an Analyzer

	or a Pre/Post processor.
LDA	Laboratory Device Automation integration profile
LIP	Label Information Provider. Actor of LBL integration profile in LAB-TF release 1. Retained for backward compatibility only in release 2.
LIR	Laboratory Information Reconciliation integration profile in LAB-TF release 1. Deprecated as of release 2.
	Described in ftp://ftp.ihe.net/Laboratory/Tech_Framework/V2/ihe_lab_TF_2.0_Vol1_FT_2006-12-04.doc
LIS	Laboratory Information System
LPOCT	Laboratory Point Of Care Testing integration profile in LAB-TF.
LSWF	Laboratory Scheduled Workflow integration profile in LAB-TF release 1. Deprecated as of release 2.
	Described in ftp://ftp.ihe.net/Laboratory/Tech_Framework/V2/ihe_lab_TF_2.0_Vol1_FT_2006-12-04.doc
LTW	Laboratory Testing Workflow integration profile. Created in n LAB-TF release 2, to replace the former profiles LSWF and LIR.
Master File	A common reference file used by one or more application systems. A code set can be considered as a master file.
MLLP	HL7 Minimal Lower Layer Protocol
Observation	A measurement of a single variable or a single value derived logically and/or algebraically from other measured or derived values. A test result is an observation.
OF	Order Filler. Actor in LPOCT and LTW integration profiles of the LAB-TF.
OP	Order Placer. Actor in and LTW integration profiles of the LAB-TF.
Order	A battery or test ordered by a ward and/or a physician to a laboratory, to be performed on one or more specimens collected from a patient.
Order Filler	The Actor played by the LIS, which manages Orders on the laboratory side.
Order Group	Also called the "Laboratory Request": A set of orders placed together by a ward and/or a physician to one or more laboratories for a patient, to be performed on one or more specimens collected from this patient.
Order Placer	The Actor played by the HIS or the CIS to generate, place and manage orders.
Order Result Tracker	The Actor tracking the results produced by laboratories.
ORI	Observation Reporting Interface defined by the standard POCT1-A from CLSI.
ORT	Order Result Tracker. Actor in LTW integration profile of the LAB TF.
PAM	Patient Administration & Movements integration profile in ITI TF.
PCC TF	Patient Care Coordination Technical Framework
PDQ	Patient Demographics Query integration profile in ITI-TF

PHR	Personal Health Record
Placer Group Number	The unique pair of identifiers assigned to an Order Group by the Order Placer Actor on the ward side and by the Order Filler Actor on the lab side. Either of the two identifiers may be present, or both may be present.
Placer Order Number	The unique reference assigned to an Order by the Order Placer Actor on the ward side.
POCDM	Point Of Care Data Manager Actor in LPOCT integration profile.
POCT1-A	Interoperability Standard supporting point of care testing, produced by CLSI
POCRG	Point Of Care Result Generator Actor in LPOCT integration profile.
Pre/Post-processor	An Actor in LDA integration profile, played by a device performing some steps (SWOS) on a specimen.
QC	Quality Control performed on an Analyzer in LDA integration profile, on a Point Of Care Results Generator in LPOCT integration profile.
QRPH TF	Quality Research Public Health Technical Framework
Recapper	An automated device which puts back the cap on a specimen container. Acts as a Pre/Post-processor in LDA integration profile.
Sorter	An automated device which sorts the specimen according to their process type. Acts as a Pre/Post-processor in LDA integration profile.
SWOS	Specimen Work Order Step: A WOS performed by Pre/Post-processor in LDA integration profile.
Technical Validation	The process by which a laboratory technician accepts a single observation or a set of observations that have been produced either with a manual technique or an automated one, generally under his control. Technical validation ensures that observations have been obtained in conformance with defined laboratory procedures and have satisfied quality control and other technical validation criteria.
Test	An operation performed in laboratory or on the point of care, manually or on an analyzer or with the help of a device, instrument or system, to produce one or more observations (aka results). The observations can be obtained by measurement of a quantity on an in-vitro specimen, finding on this specimen, calculation from other observations and data, or any other means.
Validator	Synonym of "Clinical Expert" (see this entry)
Verifier	This term is used in HL7 CDA R2 standard. A laboratory staff who performed "Technical Validation" (see this entry).
Work Order	The testing of a battery or a test requested by the Order Filler Actor to the Automation Manager Actor
Work Order Step	A battery or test requested by the Order Filler Actor to the Automation Manager Actor
XD-LAB	Sharing Laboratory Reports integration profile in LAB-TF
XDM	Cross Enterprise Document Media Interchange integration profile in ITI-TF
XDR	Cross Enterprise Document Reliable Interchange integration profile in ITI-TF
XDS	Cross Enterprise Document Sharing integration profile in ITI-TF

2 Scope of the Laboratory Technical Framework

2.1 Laboratory testing

380 The Laboratory Technical Framework provides a set of Workflow Integration Profiles involving clinical laboratories, clinical wards and other teams within healthcare institutions, to fully integrate diagnostic testing on in vitro specimens in the care workflows of the healthcare institution.

In addition the Laboratory Technical Framework provides a Content Integration Profile enabling clinical laboratories within healthcare institutions as well as private laboratories and public 385 health laboratories to share their results reports within a broad healthcare community (local, regional or national).

A laboratory receives test orders from clinical departments or from physicians.

The tests are performed on in vitro specimens. Depending upon the organization the specimen collection and identification may be performed by laboratory staff, ward staff, sample collection 390 room staff or third party.

The laboratory has the ability to accept, modify, or reject an order, with appropriate notification to the ordering organization.

The tests produce observations of various types: simple numeric value (e.g., a serum glucose level), rich textual observation (e.g., a bone marrow biopsy), simple coded result (e.g., a HIV 395 serology negative), graphical observation (e.g., a serum protein electrophoresis). Results are sent to the ordering ward and/or physician; copies may be sent to other physicians or departments, and/or stored in an electronic record.

Observation results may be generated for both ordered and unordered tests (i.e., reflex tests added by the laboratory).

400 Observation results progress through different steps of validation:

A **non-validated result** is acquired from the analyzer, without any human acceptance.

A **technically validated result** has been accepted by the laboratory technician who ensures that this result has been obtained through the correct analytic procedures, using operational and controlled equipment, taking into account quality control results, together with other 405 criteria.

A **clinically validated**[1] **result** (aka medically validated result) has been accepted and interpreted by a clinical expert (aka medical expert, bio-medical scientist, pathologist, validator, depending on the countries) who considered the consistency of the whole order group with the biological history of the patient, as well as the available clinical and therapy 410 information. The clinical expert may have been assisted in this step by an expert system that applied rules and reasoning to validate automatically the simplest cases.

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[1] See the precise definition of these terms in the glossary in this volume.

The laboratory usually delivers results after clinical validation. Under some conditions (e.g., emergency, permanent disposition with some wards), it may also deliver technically validated results, which will be confirmed or corrected later on, after clinical validation has occurred.

2.2 Point of care testing supervised by a laboratory

In some situations in vitro diagnostic tests can be performed straightforwardly on the point of care instrument or the patient's bedside by the ward staff. This organization allows the ward staff to obtain immediate access to observations for some common tests, whose specimens do not need pre-analytic preparation. The results are used immediately in clinical decisions by the care givers.

This Laboratory Technical Framework covers this situation under the condition this point of care testing process is supervised by a clinical laboratory of the healthcare enterprise. The point of care analyzers of several wards are connected to a central Point of Care Data Manager. This central system collects point of care tests and results related to patient specimens and QC specimens, enables the supervision of the point of care testing process, and forwards the results to the system of the supervising laboratory.

Core difference between laboratory testing and point of care testing:

When the workflow is initiated by the analytical testing producing a set of observations on the point of care, and when there is neither significant pre-analytical nor post-analytical process, then the analytical part of this workflow will be treated within the Laboratory Point Of Care Testing integration profile.

In all other cases the pre/post-analytical and analytical workflow is covered by the Laboratory Device Automation integration profile. This LDA profile supports the workflow initiated by an order, irrespective of whether this order is created at the Order Placer level or at the Order Filler level, and wherever the analyzers are located (on the point of care or in a laboratory).

2.3 Sharing laboratory reports

This Laboratory Technical Framework offers the content profile XD-LAB to enable clinical laboratories (in and out of healthcare institutions) as well as public health laboratories to share their results reports as electronic documents in a document sharing resource used by a community of healthcare settings and care providers.
These shared laboratory reports document orders related to human patient specimens, in some cases to non-human specimens, in other cases to a non-human specimen paired with a human patient specimen.

2.4 Sharing a common test codes set for further data exchanges.

The exchange of code sets and associated rules shared by multiple actors is taken care of by a dedicated integration profile called "Laboratory Code Set Distribution" (LCSD). The Laboratory Technical Framework recommends the use of LOINC codification for laboratory tests. Alternatively, other coding schemes, national or international (like SNOMED) may also be used with the integration profiles of this LAB-TF.

2.5 Laboratory specialties

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This Laboratory Technical Framework covers most specialties that perform tests on in-vitro specimens, including microbiology and blood bank testing (e.g., ABO group).

Anatomic pathology is excluded from the LAB TF. This discipline has its dedicated Technical Framework within IHE: the Anatomic Pathology Technical Framework.

455 The transfusion workflow performed by blood banks (blood product collection, storage, delivery, administration) is also excluded from the LAB-TF.

3 About the Laboratory Profiles

The Laboratory Technical Framework contains two kinds of profiles: Integration Profiles and Content Profiles.

460   Integration Profiles offer a common language that healthcare professionals and vendors can use to discuss integration needs of healthcare enterprises and the integration capabilities of information systems in precise terms. Integration Profiles specify implementations of standards that are designed to meet identified clinical needs. They enable users and vendors to state which IHE capabilities they require or provide, by reference to the detailed specifications of the IHE
465   Laboratory Technical Framework.

Integration profiles are defined in terms of IHE Actors, Transactions and their content. Actors (listed in LAB TF-1: Appendix A) are information systems or components of information systems that produce, manage, or act on information associated with clinical and operational activities. Transactions (listed in LAB TF-1: Appendix B) are interactions between actors that
470   communicate the required information through standards-based messages.

Content Profiles define how the content used in a transaction is structured. Each transaction is viewed as having two components, a payload, which is the bulk of the information being carried, and metadata that describes that payload. The binding of the Content to an IHE transaction specifies how this payload influences the metadata of the transaction. Content modules within
475   the Content Profile then define the payloads. Content modules are transaction neutral, in that what they describe is independent of the transaction in which they are used, whereas content bindings explain how the payload influences the transaction metadata.

3.1 Intra Institution Integration Profiles

The synopsis below shows the integration profiles from the Laboratory Technical Framework
480   usable intra healthcare institutions, their interdependencies as well as their dependencies towards integration profiles from the IT Infrastructure Technical Framework.
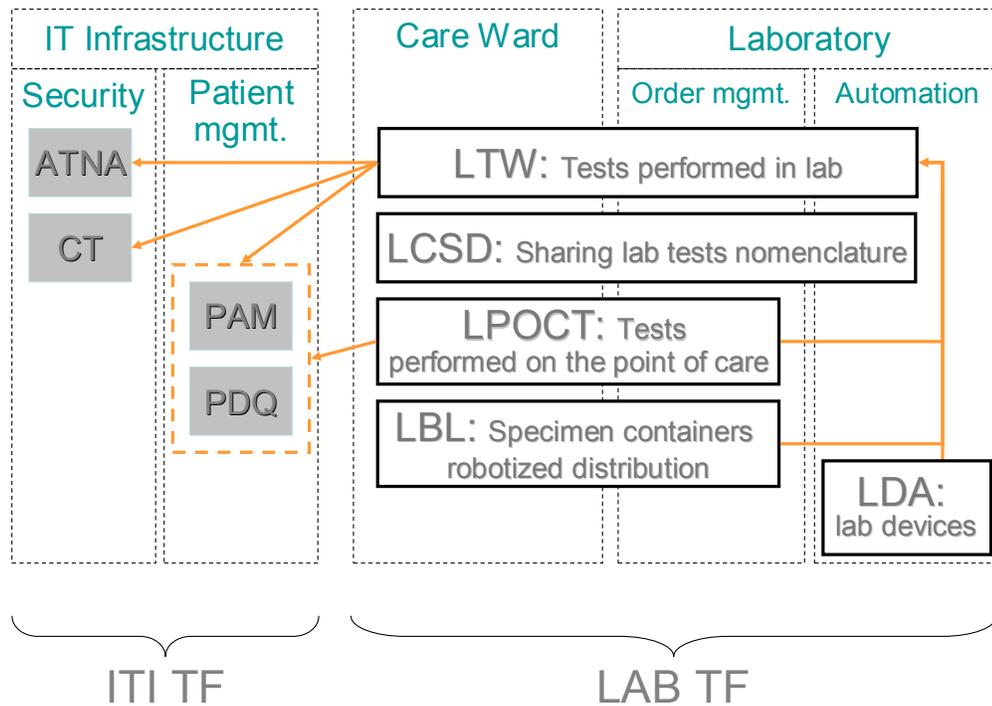
Figure 3.1-1: Intra institution integration profiles of LAB TF

LTW and LPOCT profiles leverage PAM or PDQ profiles from ITI TF to obtain up-to-date patient demographic and encounter data.

The LTW profile leverages ATNA and CT profiles from ITI TF, to secure its transactions.

LDA, LBL and LPOCT profiles are articulated on the LTW profile, which must be implemented first.

3.2 Content Profiles for a regional healthcare community

The synopsis below shows the Content Profiles of the Laboratory Technical Framework, and their dependencies.
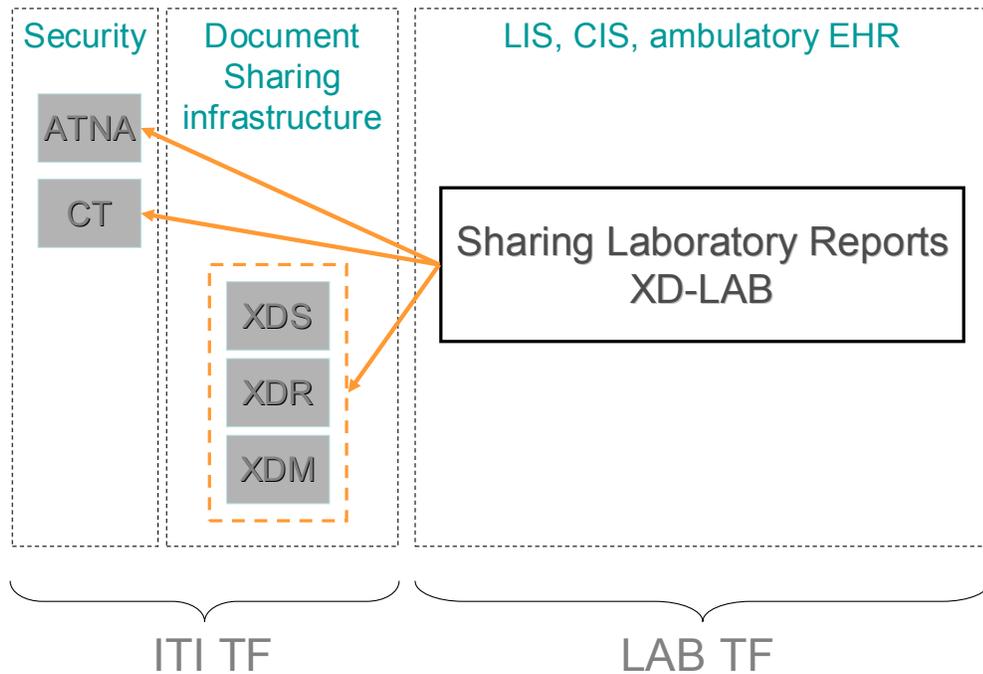
Figure 3.2-1: Content Profiles of LAB TF

495 The Laboratory Technical Framework offers one single content profile, "Sharing Laboratory Reports" (XD-LAB), which enables to share laboratory results reports in a document sharing resource. This profile defines the content of a laboratory report as an electronic document.

The document sharing resource is leveraging one of XDS, XDM or XDR profiles from the IT Infrastructure Technical Framework.

500 The security of the document sharing leverages ATNA and CT profiles from the IT Infrastructure Technical Framework.

3.3 Specification of Dependencies among Profiles

505   Dependencies among IHE profiles exist when implementation of one profile is a prerequisite for achieving the functionality defined in another profile.

The dependencies of the LAB-TF profiles are described in tabular form in the table below. Profiles deprecated as of release 2 of the LAB-TF appear in a grey background.

Table 3.3-1: Integration Profiles Dependencies

Integration Profile	Depends on	Dependency Type	Purpose
Laboratory Testing Workflow (LTW)	*PAM or PDQ in ITI-TF*	Each of OP, OF and ORT Actors of LTW shall be grouped with at least one of these combination of actors: Patient Demographics Supplier and Patient Encounter Supplier in PAM. Patient Demographics Consumer and Patient Encounter Supplier in PAM. Patient Demographics Consumer and Patient Encounter Consumer in PAM. Patient Demographics Consumer in PDQ.	The Actors OP, OF and ORT must be provided with up-to-date patient data as soon as they need it, provided this data is available in the healthcare institution
Laboratory Testing Workflow (LTW)	*Audit Trail and Node Authentication (ATNA) in ITI-TF*	Order Placer, Order Filler and Order Results Tracker Actors may be grouped with the ATNA Secured Node Actor.	Management of audit trail of exported PHI, node authentication, and transport encryption.
Laboratory Testing Workflow (LTW)	*Consistent Time (CT) in ITI-TF*	Order Placer, Order Filler and Order Results Tracker Actors shall be grouped with the CT Time Client Actor	Required to manage and resolve conflicts in multiple updates.
Laboratory Device Automation (LDA)	*LTW*	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 Point Of Care Testing (LPOCT)	*LTW*	The system implementing the Order Filler Actor in LPOCT profile shall also implement Order Filler actor in LTW and profile.	The Order Filler is storing point of care testing order in the same repository as regular orders, and is reporting the results from both categories.
Laboratory Point Of Care Testing (LPOCT)	*PAM or PDQ in ITI-TF*	The POCDM Actor of LPOCT profile shall be grouped with at least one of these combination of actors: Patient Demographics Supplier and Patient Encounter Supplier in PAM. Patient Demographics Consumer and Patient Encounter Supplier in PAM. Patient Demographics Consumer and Patient Encounter Consumer in PAM. Patient Demographics Consumer in PDQ.	The POCDM actor is responsible to control the patient identity at point of care testing time, and to enable the staff performing the test, to check it is the right patient.

Integration Profile	Depends on	Dependency Type	Purpose
Laboratory Code Set Distribution (LCSD)	*none*		
Laboratory Specimen Barcode Labeling (LBL)	*LTW*	The Label Information Provider Actor of LBL profile shall be grouped with either Order Filler or Order Placer from LTW profile.	The LIP Actor of LBL profile derives the specimen labeling instructions from the Order or the Order Group placed in the LTW profile.
Sharing Laboratory Reports (XD-LAB)	*Cross-Enterprise Document Sharing (XDS) in ITI-TF*	Implementers of XD-LAB Content Profile may implement the XDS Profile to enable sharing of the laboratory reports within an XDS Affinity Domain. When the XDS profile is used to provide document interchange, the Content Creator must be grouped with an XDS Document Source actor, and the Content Consumer must be grouped with an XDS Document Consumer actor.	Ensure that the sharing of laboratory reports within an XDS Affinity Domain can co-exist with the sharing of other types of documents (e.g., imaging, ECG, etc.)
Sharing Laboratory Reports (XD-LAB)	*Cross-Enterprise Document Media Interchange (XDM) in ITI-TF*	Implementers of XD-LAB Content Profile may implement the XDM Profile to enable sharing of the laboratory reports using media. When the XDM profile is used to provide document interchange, the Content Creator must be grouped with an XDM Portable Media Creator and the Content Consumer must be grouped with an XDM Portable Media Consumer.	Ensure that the sharing of laboratory reports on media can co-exist with the sharing of other types of documents (e.g., imaging, ECG, etc.)
Sharing Laboratory Reports (XD-LAB)	*Cross-Enterprise Document Reliable Interchange (XDR) in ITI-TF*	Implementers of XD-LAB Content Profile may implement the XDR Profile to enable sharing of the laboratory reports using reliable point-to-point network messages. When the XDR profile is used to provide document interchange, the Content Creator must be grouped with an XDR Document Source, and the Content Consumer must be grouped with an XDR Document Recipient.	Ensure that the sharing of laboratory reports through reliable point-to-point messages can co-exist with the sharing of other types of documents (e.g., imaging, ECG, etc.)
Sharing Laboratory Reports (XD-LAB)	*Audit Trail and Node Authentication (ATNA) in ITI-TF*	Content Creator and Content Consumer Actors shall be grouped with the ATNA Secured Node Actor.	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
Sharing Laboratory Reports (XD-LAB)	*Consistent Time (CT) in ITI-TF*	Content Creator and Content Consumer Actors shall be grouped with the CT Time Client Actor	Required to manage and resolve conflicts in multiple updates.

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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.

Note (2): Products supporting the XD-LAB profile SHALL support also at least one profile among XDS, XDM, XDR.

3.4 Profiles Overview

3.4.1 Laboratory Testing Workflow (LTW)

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The Laboratory Testing Workflow (LTW) integration profile covers the workflow related to tests performed by a clinical laboratory inside a healthcare institution, for both identified orders and unknown orders, related to both identified patients and unidentified or misidentified patients. This profile replaces the two deprecated profiles LSWF and LIR.

3.4.2 Laboratory Device Automation (LDA)

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

3.4.3 Laboratory Point Of Care Testing (LPOCT)

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The Laboratory Point Of Care Testing (LPOCT) integration profile covers the workflow related to clinical laboratory tests performed on the point of care or on patient's bedside, by ward staff, under supervision of a laboratory of the healthcare institution.

3.4.4 Laboratory Code Set Distribution (LCSD)

The Laboratory Code Set Distribution (LCSD) integration profile provides a way for an
530   application owning a code set in the domain of laboratory (battery, test and observation codes) to share it with other applications to further support data exchange between these applications.

3.4.5 Laboratory Specimen Barcode Labeling (LBL)

The Laboratory Specimen Barcode Labeling (LBL) integration profile covers the robotized process of container labeling and delivery for specimen collection related to an existing order or
535   order group for a patient in a healthcare institution. When coupled with the LTW profile, the LBL profile enables a LIS to provide to the ordering system the specimen collection plan corresponding to an order or an order group: The LIS having received a laboratory requisition (in the role of Order Filler) calculates the specimens and containers necessary to fulfill this requisition, and pre-assigns an identifier to each of these specimens. Then, when the ordering
540   application (in the role of Label Broker) queries in due time the LIS (in the role of Label Information Provider), the LIS replies with the specimens labeling instructions to the ordering application.

3.4.6 Laboratory Scheduled Workflow (LSWF) - Deprecated

The Laboratory Scheduled Workflow (LSWF) integration profile is retained for backward
545   compatibility in LAB-TF release 2.0 at the "Trial for Implementation" status and can be viewed here: ftp://ftp.ihe.net/Laboratory/Tech_Framework/V2/ihe_lab_TF_2.0_Vol1_FT_2006-12-04.doc.

3.4.7 Laboratory Information Reconciliation (LIR) - Deprecated

550   The Laboratory Information Reconciliation (LIR) integration profile is retained for backward compatibility in LAB-TF release 2.0 at the "Trial for Implementation" status and can be viewed here: ftp://ftp.ihe.net/Laboratory/Tech_Framework/V2/ihe_lab_TF_2.0_Vol1_FT_2006-12-04.doc.

3.4.8 Sharing Laboratory Reports (XD-LAB)

555   The Sharing Laboratory Reports (XD-LAB) content profile defines the laboratory report as an electronic content to be shared in a community of healthcare settings and care providers, using one of the document sharing profiles defined in ITI-TF.

3.5 Product Implementations

3.5.1 General guidelines

560 Developers have a number of options in implementing IHE actors and transactions in product implementations. The decisions cover three classes of optionality:

- For a system, select which actors it will incorporate (multiple actors per system are acceptable).
- For each actor, select the integration profiles in which it will participate.
- For each actor and profile, select which options will be implemented.

565 All required transactions must be implemented for the profile to be supported (refer to the transaction descriptions in LAB-TF-2).

Implementers should provide a statement describing which IHE actors, IHE integration profiles and options are incorporated in a given product. The recommended form for such a statement is defined in ITI-TF-1, Appendix C.

570 In general, a product implementation may incorporate any single actor or combination of actors. When two or more actors are grouped together, internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

575 When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface).

3.5.2 Usage of HL7 standards in Laboratory Technical Framework

The Laboratory Technical Framework leverages HL7 interoperability standards.

580 The LPOCT integration profile is based on POCT1-A standard from CLSI, which is also relying on HL7 standards.

Table 3.5.2-1 indicates which versions of standards are supported by the profiles of the Laboratory Technical Framework.

585 **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	

3.5.3 Relationships between units of work in the LAB-TF

3.5.3.1 Order Group or Laboratory Request

An Order Group is a set of orders that is a set of batteries and/or tests ordered together by a physician and/or a clinical ward for a patient. These batteries and tests are to be performed on specimens collected from that patient, by one or more laboratories.

The Order Group may be split as needed between the performing laboratories, each of which assuming a Laboratory Request composed of a subset of the Orders of the Order Group, corresponding to its own specialty and capacities.

When the Order Group exists it is materialized by what the standard calls its "**Placer Group Number**". This Placer Group Number is actually a pair of identifiers, one assigned by the Order Placer application, the other one accessioned by the Order Filler application. In that pair, any of the identifiers or both can be provided in the messages of the LAB TF related to laboratory orders. Every actor receiving these identifiers in an inbound message must register them and pass them along in messages sent downstream and upstream.

When a laboratory report is produced to fulfill an Order Group or a part of it, in case this report is shared in a document sharing resource, it will mention the Placer Group Number in its header. This is a responsibility of the Content Creator actor who shares this report. The responsibility of the Content Consumer actor reading this report is to display and/or to integrate this Placer Group Number associated with this report, depending of the options it supports.

3.5.3.2 Order

An Order is a battery or a test ordered by a physician and/or a clinical ward or generated by a laboratory for a patient. This battery or test is to be performed on specimens collected from that patient, by a laboratory.

When the battery or test was not ordered by the physician, but rather generated by the laboratory the order is called a reflex order.

An Order may be performed in laboratory, in a scheduled or unscheduled manner, as defined in the LTW profile.

An Order may also be performed on the point of care, as in the LPOCT profile.

In all cases the Order is assigned a unique identifier called the "**Placer Order Number**" by the Order Placer Actor, on the ward side.

As soon as it is known from the Order Filler Actor the Order is assigned a unique identifier for the laboratory side, called the "**Filler Order Number**" by this Actor.

An Order belongs to zero or one Order Group. In other words an Order can be a standalone order or be part of an Order Group.

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3.5.3.3 Work Order

A Work Order is a battery or a single test requested on one or more specimens by the Order Filler Actor to the Automation Manager Actor in the LTW profile. It is assigned a unique Work Order Number by the Order Filler application.

625   A Work Order belongs to zero or one Order Group.

3.5.3.4 Work Order Step (WOS)

A Work Order Step is an atomic operation belonging to a Work Order, to be performed on one specimen by a Laboratory Device (LD) handled by an Automation Manager (AM). It is assigned a unique WOS Number by the Automation Manager application. A WOS belongs to zero or one
630   Work Order.

3.5.3.5 Usage of work units by the actors of the workflow profiles

The figure below shows which actor assigns each work unit, the scope of each one in the messaging between actors, and the HL7 V2.5 fields carrying the identifier of this work unit.
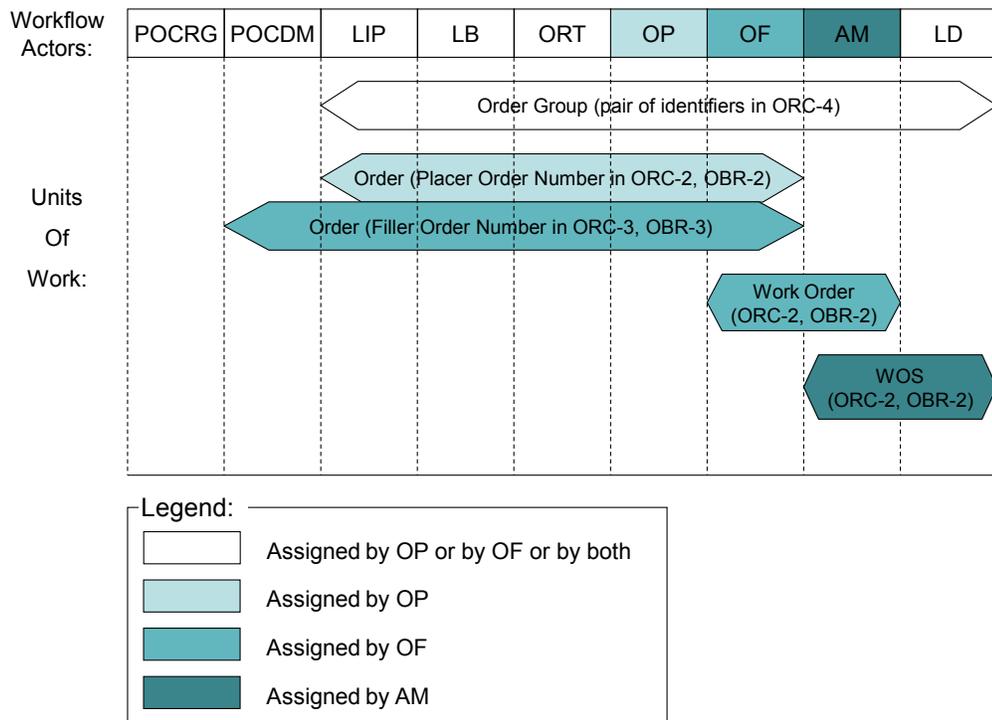
635   **Figure 3.5.3.5-1: Usage of work units by the actors of the workflow profiles**

Note: The Laboratory Code Set Distribution Profile does not deal with work units, therefore does not appear here.

3.5.3.6 Locating work units in the content module of XD-LAB profile

640   The laboratory report as a CDA R2 document contains only two units of work, located in the content module as shown in the table below.

Table 3.5.3.6-1: Work units in the content module of XD-LAB integration profile

Element in the CDA laboratory report (location as an Xpath expression)	Content
ClinicalDocument/inFulfillmentOf/order/id	In case the report fulfills an Order Group aka laboratory request, this is the identifier assigned to the Order Group by the Order Placer application. In case the report fulfills a single Order, this is the Placer Order Number.
ClinicalDocument/documentationOf/serviceEvent/id	In case the report fulfills an Order Group aka laboratory request, this is the identifier assigned to the Order Group by the Order Filler application. In case the report fulfills a single Order, this is the Filler Order Number.
ClinicalDocument/component/structuredBody/.. ../section/entry/act/entryRelationship/ ../organizer@classCode="BATTERY"/id	The Filler Order Number assigned to a battery

4 Laboratory Testing Workflow (LTW)

4.1 Scope

The *Laboratory Testing Workflow* Integration Profile establishes the continuity and integrity of clinical laboratory testing and observation data inside a healthcare institution. It covers the workflow related to tests performed by the clinical laboratories of the institution, for both identified orders and unknown orders, related to both identified patients and unidentified or misidentified patients.

The profile involves a set of transactions, to maintain the consistency of ordering and patient information, to track the specimen collection and specimen acceptance/rejection and to deliver the laboratory results and reports at various steps of validation.

4.2 Use cases

In the following use cases below, the Order Placer, Order Filler and Order Result Tracker Actors are assumed to be provided with up-to-date patient demographic and encounter data. This is achieved by grouping these actors with appropriate actors of PAM or PDQ profiles of the ITI-TF.

4.2.1 Order placed with identified specimens

Initial part of the scenario, specific to this use case:

A physician in a ward requests a set of laboratory tests (or batteries) for a patient. The Order Group (or single Order) is entered into the Order Placer application with pertinent information needed. The Order Placer determines what specimens are required to perform the tests, with collection (container type, preservative/anticoagulant, volume, time and patient status) and transportation conditions.

The Order Placer provides specimen identification labels with a unique specimen ID (usually bar coded), and other relevant information (e.g., patient name, encounter ID). A medical staff in the ward collects the specimens, identifies each one by placing the appropriate label on the container(s). This use case assumes a specimen identification scheme that ensures enterprise-wide unique identifiers to all specimens. The format and length of specimen IDs must be compatible with the laboratory organization and automation constraints.

The Order Placer sends a "New Order" message to the Order Filler, delivering the Order Group (or single Order) with associated relevant information.

Upon reception, the Order Filler application controls the content of each Order, and if accepted, assigns a Filler Order Number to it and notifies that number in the acknowledgement message sent back to the Order Placer application. If for some reason a battery or test cannot be accepted by the laboratory, the corresponding Order is rejected and notified as such to the Order Placer.

Specimens are brought to the laboratory after or before the related Order is accepted by the Order Filler application. The sequencing of the material flow (specimens/containers) and of the messaging flow depends upon the healthcare organization.

Using the Order Filler application, the laboratory staff checks each Order with the corresponding specimens. If the specimens are available and valid the Order is started and notified as such to the Order Placer application. In case a specimen is invalid or damaged (e.g., serum hemolyzed) this specimen is rejected and the Order(s) depending upon it may not be started.

Middle part of the scenario, shared by all three use cases:

The Order Filler splits the Order Group (or the single Order) into one or more Work Orders sent to the Automation Manager. The technical staff of the laboratory fulfills the various Work Orders using the Automation Manager and all accurate devices (aliquoters, robotic systems, analyzers…). The splitting of specimens (aliquoting) may require the printing of additional secondary labels (either by the Order Filler or by the Automation Manager), for the identification of aliquot containers. After technical validation the results are sent from the Automation Manager to the Order Filler.

Final part of the scenario, shared by all three use cases:

At various steps (depending on the organization), the Order Filler sends results to the Order Result Tracker, and notifies both Order Placer and Order Result Tracker of all status changes of each Order and its related results, and optionally a facsimile of the report fulfilling the Order Group.

4.2.2 Order placed with specimens identified by the LIS or by a third party

Initial part of the scenario, specific to this use case:

A physician in a ward requests a set of laboratory tests (or batteries) for a patient. The Order Group (or single Order) is entered into the Order Placer application with all pertinent information.

The Order Placer does not identify the specimens. Three different sub-use cases should be considered for the identification and collection of specimens:

1. The ward collects and supplies specimens labeled with an identification limited to patient ID and Placer Group Number or Placer Order Number. The Specimens are subsequently re-identified by the Order Filler application, and labeled with bar coded specimen ID, by the laboratory staff for processing.

2. The laboratory is in charge of the collection and identification of specimens.

3. The required specimens are determined and identified by the LIS and sent back in real time to the Order Placer in the acknowledgment of the order request message (as part of the LTW profile) or in due time by use of the query transaction from the LBL Integration Profile..

The middle and final part of this use case is the same as in use case 4.2.1.

4.2.3 Filler Order created by the laboratory

Initial part of the scenario, specific to this use case:

Two different sub-use cases are to be considered:

1. The laboratory staff receives an Order in paper form from a ward unable to access the Order Placer application.

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720   2. During the processing of an Order Group, the laboratory decides to add an additional battery or test to that Order Group. The new Order is to be performed on one of the existing specimens of the group.

In both sub-use cases, the generated Order has a Filler Order Number. The Order Filler application notifies it to the Order Placer application, which allocated a Placer Order number to
725   it, and sends it back to the Order Filler.

The middle and final part of this use case is the same as in use case 4.2.1.

4.2.4 Order Filler rejects a specimen prior to result testing

This use-case generalizes the above use-cases with the focus on the process when laboratory staff checks each order with the corresponding specimens and finds a non-conformity resulting in a
730   rejection of a specimen.

Case:

A physician in a ward requests a set of laboratory tests (or batteries) for a patient. The Order Group is entered into the Order Placer application with pertinent information.

The Order Placer sends a "New Order" message to the Order Filler, delivering the Order Group
735   with associated relevant information.

Upon reception, the Order Filler application controls the content of each Order, and if accepted, assigns a Filler Order Number to it and notifies that number in the acknowledgement message sent back to the Order Placer application.

Using the Order Filler application, the laboratory staff checks each Order with the corresponding
740   specimens. If the specimens are available and valid the Order is started and notified as such to the Order Placer application.

In case a specimen is invalid or damaged (e.g., tube is broken) this specimen is rejected and the Order(s) depending upon it are canceled by the Order Filler application.

Upon rejection of a specimen, the Order Filler may inform the Order Placer with supplemental
745   information why the specimen is seen as not valid.

The physician in a ward reviewing the rejection reason may decide to collect a new Specimen and re-order the missing set of laboratory tests (or batteries) for this patient.

The Order Placer sends a "New Order" message to the Order Filler containing the re-order requests within the already known Order Group.

750 ## 4.3 Actors/Transactions

Figure 4.3-1 shows the actors directly involved in the Laboratory Testing Workflow Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in other related profiles are not shown.
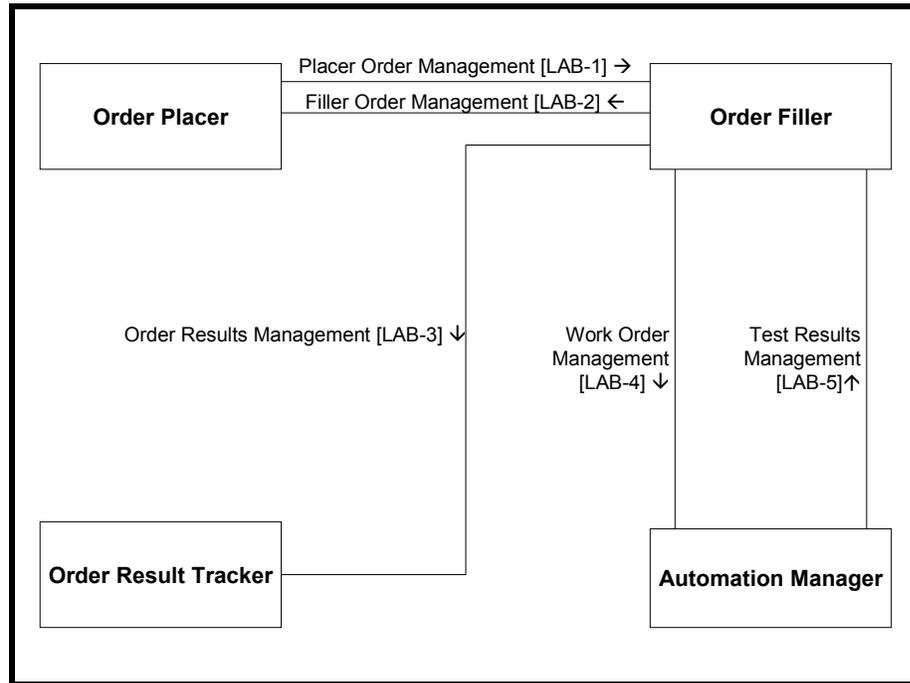
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Figure 4.3-1: Laboratory Testing Workflow Actor Diagram

Table 4.3-1 lists the transactions for each actor directly involved in the Laboratory Testing Workflow Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in Laboratory Point of Care Testing or in
760 Laboratory Specimen Barcode Labeling are not necessarily shown.

Table 4.3-1: Laboratory Testing Workflow – Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Order Placer	Placer Order management [LAB-1]	R	LAB TF-2a: 3.1
	Filler Order Management [LAB-2]	R	LAB TF-2a: 3.2
Order Filler	Placer Order management [LAB-1]	R	LAB TF-2a: 3.1
	Filler Order Management [LAB-2]	R	LAB TF-2a: 3.2
	Order Results management [LAB-3]	R	LAB TF-2a: 3.3
	Work Order Management [LAB-4]	R	LAB TF-2a: 3.4
	Test Results Management [LAB-5]	R	LAB TF-2a: 3.5
Automation Manager	Work Order Management [LAB-4]	R	LAB TF-2a: 3.4
	Test Results Management [LAB-5]	R	LAB TF-2a: 3.5

Actors	Transactions	Optionality	Section in Vol. 2
Order Result Tracker	Order Results Management [LAB-3]	R	LAB TF-2a: 3.3

4.4 Laboratory Testing Workflow Integration Profile Options

765 Options that may be selected for this Integration Profile are listed in the table 4.4-1 along with the Actors to which they apply.

Table 4.4-1: Laboratory Testing Workflow - Actors and Options

Actor	Options	Vol. & Section
Order Placer	*Report Facsimile For Order Group*	LAB TF-2a: 3.1
Order Filler	*Report Facsimile For Order Group*	LAB TF-2a: 3.2
Order Result Tracker	*Report Facsimile For Order Group*	LAB TF-2a: 3.3
Automation Manager	*none*	

4.4.1 Report Facsimile For Order Group Option

This option is associated with transactions LAB-1 "Placer Order Management" and LAB-3
770 "Order Results Management".

When this option is activated:

The Order Placer placing an Order Group (using transaction LAB-1) MAY request an additional service requesting the Order Filler to provide the facsimile of the report in every result message related to this Order Group sent to the Order Result Tracker over transaction LAB-3.

775 Having received this additional request from the Order Placer, the Order Filler SHALL provide in every result message carrying clinically validated results related to the Order Group sent to the Order Result Tracker, a link to the PDF report reflecting the results present in the message. This report MAY be preliminary or final, depending on the completeness of the results set available in the message.

780 Having received a result message providing a link to the PDF report associated with these results, the Order Result Tracker SHALL retrieve immediately this PDF file and SHALL store it associated with the set of results.

Using the ORT application, when viewing the results of an Order Group received from a laboratory, a caregiver may choose in addition to view the facsimile of the laboratory report, to
785 get a global view, organized by the laboratory manager for the clearest understanding. In addition, the caregiver may print out this image and take it along with them to the patient bedside, for examination and discussion.

The PDF facsimile of the laboratory report accompanying a results message SHALL NOT bring any extra clinical information (e.g., diagnostic, interpretation, conclusion, treatment advice)
790 which would not be already present in the ORC, OBR, OBX and NTE segments of the results message. It SHALL simply provide an additional synoptic view of the set of results, respecting the presentation designed by the laboratory for its paper reports.

4.5 Process Flow

795 Process flow is expressed with the following UML sequence diagrams, with time scale from top to bottom.

The blue message flows (Order status change notified by the Order Filler to the Order Placer) in the figures below happen only when the Order Placer and the Order Results Tracker are different applications.

800 Whenever the Order Placer and the Order Results Tracker are grouped in the same application, the LAB-3 message carrying the status change and possible new results is sufficient to inform that application of the new status of the Order. An "Order status change" message in LAB-1 would be redundant in that case.

Therefore, when exchanging with a grouped Order Placer/Order Results Tracker, the Order Filler
805 SHALL NOT send these redundant messages (marked in blue in all the figures below) over Transaction LAB-1.

4.5.1 LTW with the first two use cases: placer ordering

Figure 4.5.1-1 represents the basic process flow for use cases 4.2.1 and 4.2.2.
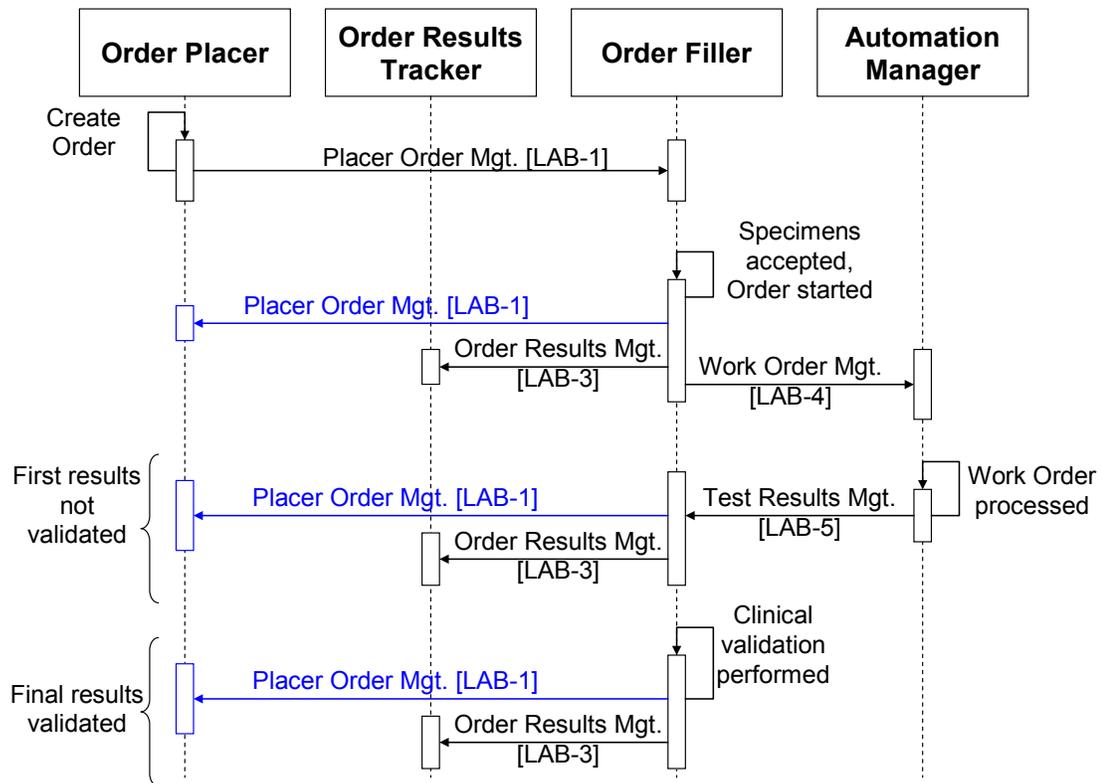
810 **Figure 4.5.1-1: Process flow for placer ordering**

4.5.2 LTW with the third use case: filler ordering

Figure 4.5.2-1 represents the basic process flow for use case 4.2.3.
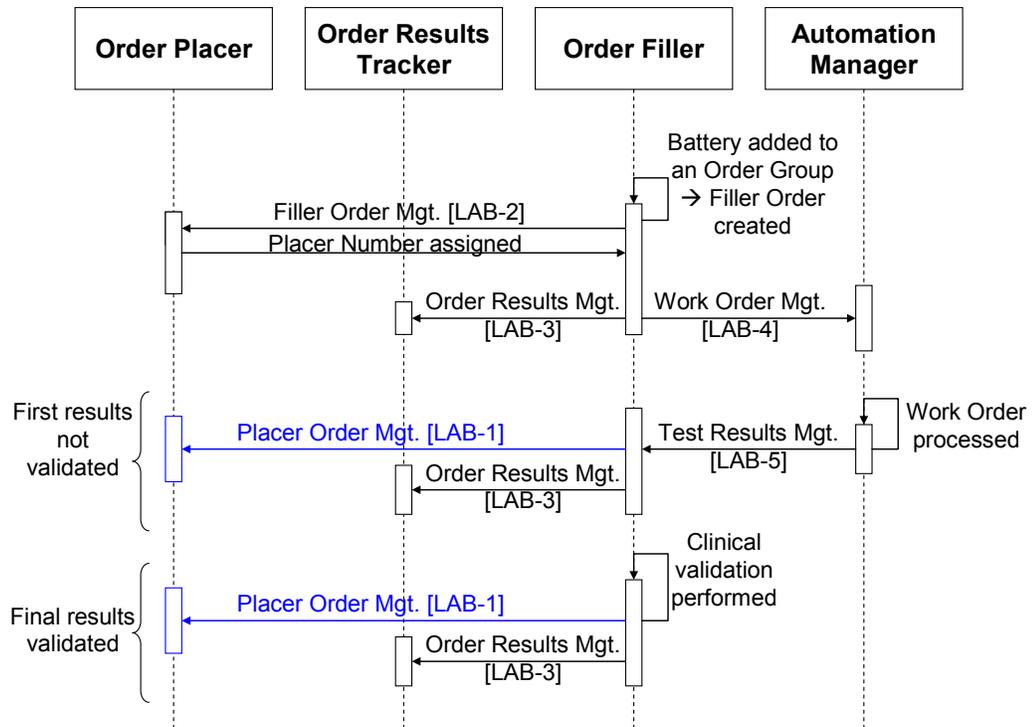
Figure 4.5.2-1: Process flow for filler ordering

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Note: In this use case, the Order is first created with a Filler Order Number on the Order Filler side, and then granted a Placer Order Number by the Order Placer. With this step achieved, transaction LAB-2 has fulfilled its mission: Both Order Placer and Order Filler know the order. The rest of the process flow regarding this Order uses only LAB-1 between Order Filler and Order Placer.

820 4.5.3 Patient update flow

These cases cover the situations where patient information updates are introduced into the system at various stages of the analytical process.

As shown in Table 3.1-1 "Integration Profiles Dependencies" in section 3.3, the three actors, Order Placer, Order Filler and Order Results Tracker, are grouped with appropriate actors of the
825 PAM profile and/or the PDQ profile from ITI TF. This grouping ensures that these three actors are provided at any time with up-to-date patient demographic and encounter data.

These three actors are committed to update their patient data automatically and without delay as soon as their paired PAM or PDQ actor is notified of this update. Thus the new patient data will be visible by the laboratory staff and by the ward staff as they are working on an order related to
830 that patient or viewing the results of that order.

Conversely, the Automation Manager actor receives patient demographic and encounter data only within the context of a Work Order.

Whenever some of this patient data changes (e.g., update patient name, change patient identifier…) it is the responsibility of the Order Filler to forward this update to the Automation
835 Manager for all Work Orders which are in process, related to that patient, using transaction LAB-4.

If there is no Work Order currently in process for that patient, the Automation Manager is not informed of the patient update.

Thus the new patient data will be visible by the laboratory technical staff in Work Orders of the
840 Automation Manager application.

Figure 4.5.3-1 shows the process flow of an Order, with patient data update occurring during this process. "Patient data update" is to be understood in a broad meaning: It can be an update of the patient demographics (trigger events A31 or A08 in PAM profile), a change of patient identifier (A47 in PAM), a merge of two patient records (A40 in PAM), a link between two patient records
845 (A24 in PAM), a change of patient class (A06 or A07 in PAM), a transfer (A02) or its cancellation (A12), a change of patient account (A44), and a few other trigger events…
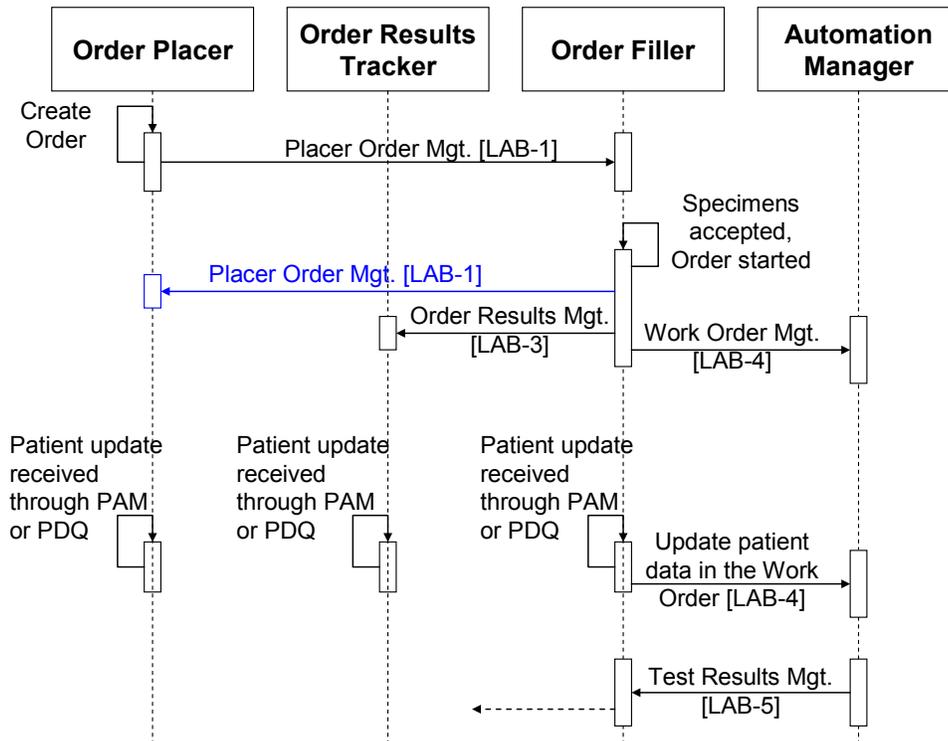
Figure 4.5.3-1: "Patient data update during the process of an Order"

The Order Filler SHALL at least forward to the Automation Manager the following events:

850
- Update patient information: A31 or A08

- Patient transfer: A02

- Transfer cancelled: A12

- Change inpatient to outpatient: A07

- Change outpatient to inpatient: A06

855
- Change patient identifier: A47

- Move patient account: A44

- Patients merge: A40

translating them into a LAB-4 "update Work Order" message, with the appropriate new information put in the patient related segments of the message. The Work Order Number is the
860   key information used by the Automation Manager to apply the update to the patient embedded in the right Work Order.

4.5.4 Updates and cancellations of orders and results

Every update, cancellation or status change that happens to an Order or to a Work Order, or to some of its results within an actor, must trigger the appropriate messages to push this update,
865   cancellation or status change to the other actors connected. These messages are supported by transactions LAB-1, LAB-3, LAB-4 and LAB-5. They are discussed in LAB TF-2.

4.5.5 Tests performed before order entry

In some cases (urgent tests performed at night by the attending technician in laboratory, LIS application temporarily disconnected from the CIS application) testing may be performed on the Automation Manager and its analyzers before the corresponding Order is placed to the LIS. The results are delivered by phone to the ward staff.

In these situations, when the Order is eventually entered in the Order Placer application and placed to the LIS application, this Order must be reconciled with the existing results produced by the anticipated testing process. Reconciliation SHALL take place in the latest system reached by the anticipated results:

- If the results obtained by the laboratory device were communicated only to the Automation Manager, then this Actor SHALL offer a user interface or an automated mechanism to link these results to a later upcoming Work Order. See section 5.6.7 of LDA integration profile.

- If the Automation Manager uploaded the anticipated results to the Order Filler, using transaction LAB-5 and without any Work Order Number, then the Order Filler SHALL offer a user interface and/or an automated mechanism to link these unsolicited results to an Order received afterwards from the Order Placer application.

5 Laboratory Device Automation (LDA)

5.1 Scope

885 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

890 their results. 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).

This LDA profile strictly addresses the workflow between Automation Managers and Laboratory

895 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).

900 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

905 of an automated device through an electromechanical interface. It only carries the Work Order Steps related information, 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

910 Work Order Steps (SWOS).

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

915 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

920 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.

925 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
930 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.

935 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

All the use cases for patient specimen testing defined in this section start with a Work Order sent
940 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 required by the target device to perform it: container identification, specimen information, target ID, operation to perform, scheduled time…)

945 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,
950 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
955 operating all necessary LDs. The technical staff performs 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.

960

5.2.1 WOS downloaded on the LD before specimen arrival

Initial part of the scenario:

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 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.

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).

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.

5.2.2 Query for the WOS at 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.

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.

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 5.2.1

1000 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.

1005 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).

1010 5.2.3 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 enters the WOS manually on the LD, from the paper sheet.

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

1015 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 5.2.1

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.

1025 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 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 1030 correct the WOS on the LD.

5.2.4 Rerun on the Analyzer

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 a second run or "rerun".

The need for a rerun may be decided:

1035 • 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 use cases are to be considered:

5.2.4.1 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

This rerun happens before the results upload to the Automation Manager. The results of the first run either do 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:

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

b) 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".

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

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

5.2.4.2 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:

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

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

c) 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 5.2.1 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 5.2.2 scenario (step a)

If the Analyzer only supports manual entry, the Automation Manager prints out the scheduled rerun. This starts a new 5.2.3 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.

5.2.4.3 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.

5.2.5 Summary of use cases on patient specimen WOS
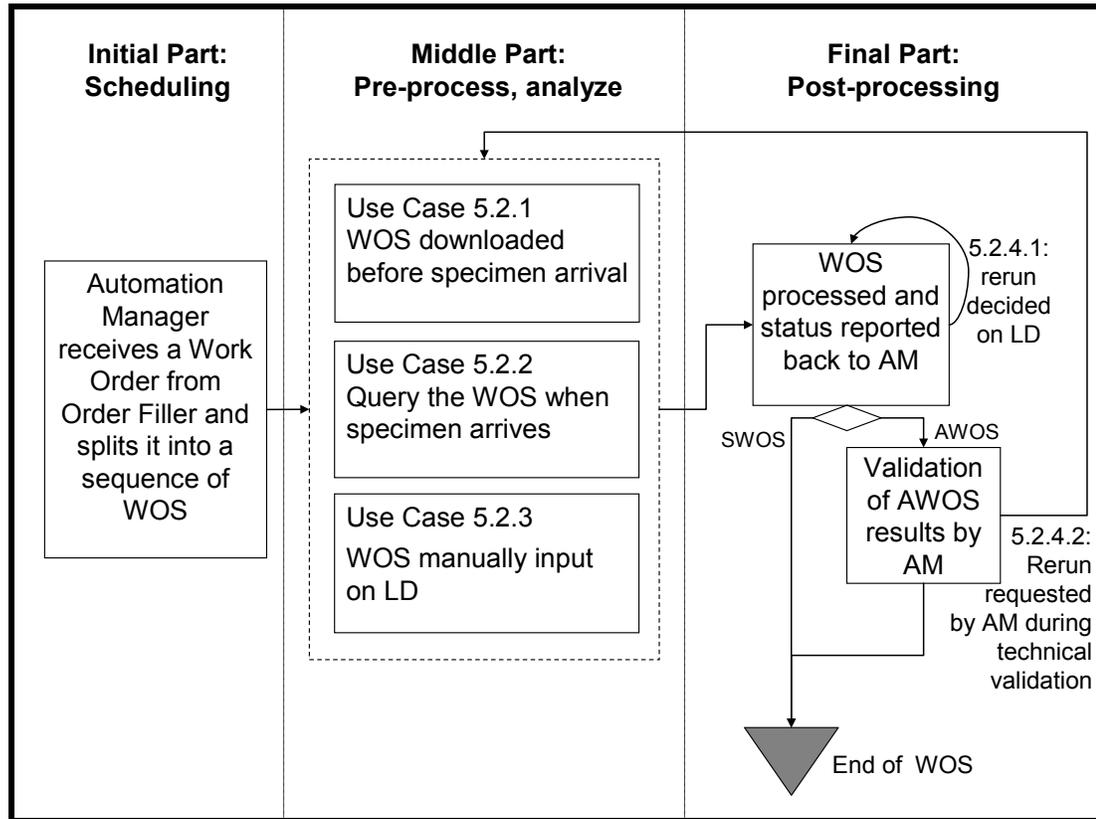
Figure 5.2.5-1: LDA use cases on patient specimen WOS

5.2.6 QC performed on an analyzer

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

5.2.6.1 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 transaction LAB-5 and a reflex QC Work Order.

5.2.6.2 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

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 transaction LAB-5 and a reflex QC Work Order.

5.2.6.3 Unsolicited QC results uploaded to the Automation Manager

a)   The analyzer recognizes a QC specimen (by position, and/or manual entry of the required 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 transaction LAB-5 and a reflex QC Work Order.

5.3 Systems interconnection in the laboratory

As formerly stated, a clinical laboratory uses an Order Filler (OF) application to fulfill its orders.
It handles its technical automation with the help of zero 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:
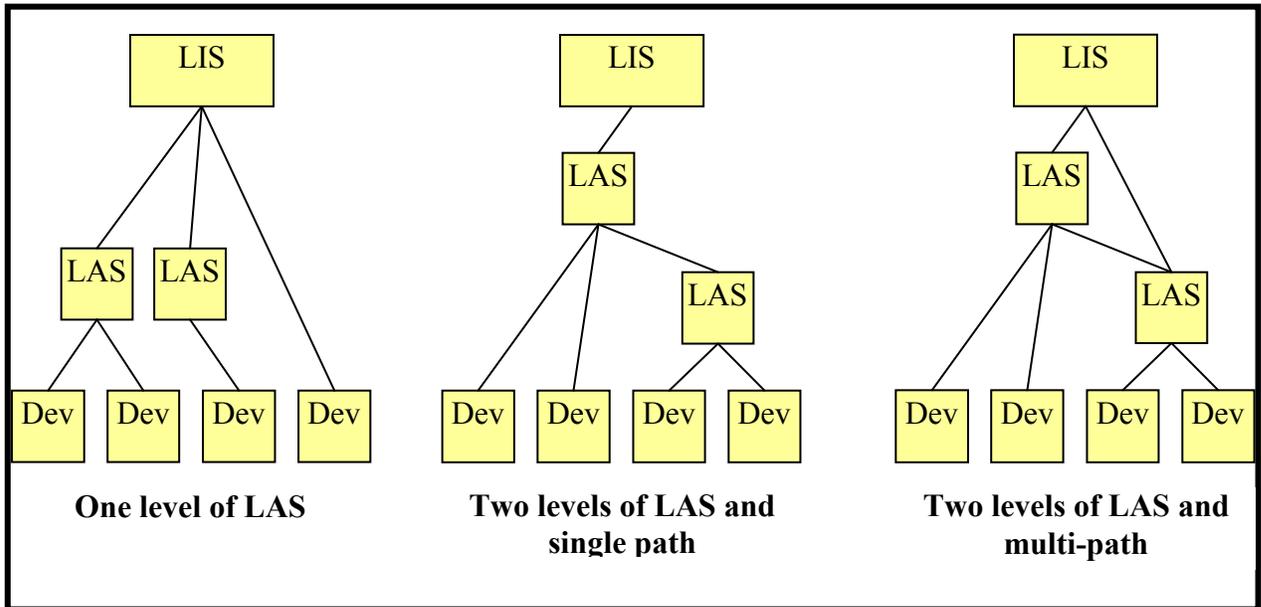
Figure 5.3-1: Systems interconnections in laboratory

Each of these architectures of interconnection is valid provided the systems implement the
appropriate actors. That is:
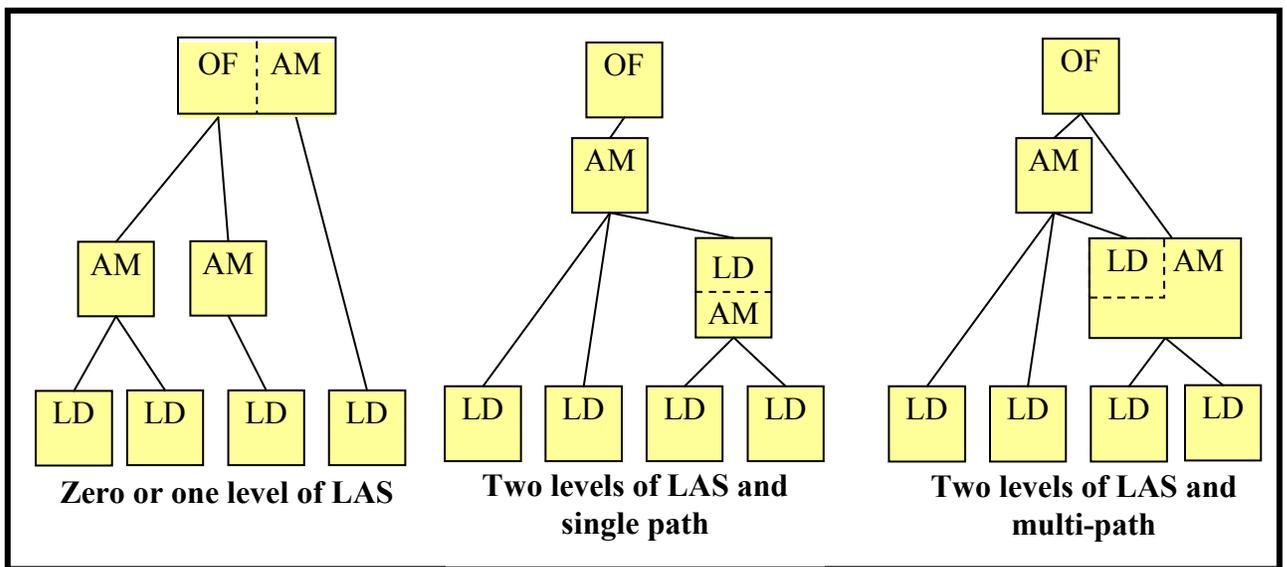
Figure 5.3-2: Actors grouping supporting systems interconnections

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The management of multi-path Work Orders is an internal matter of the Order Filler application. The management rules are not described by IHE.

5.4 Actors/ Transactions
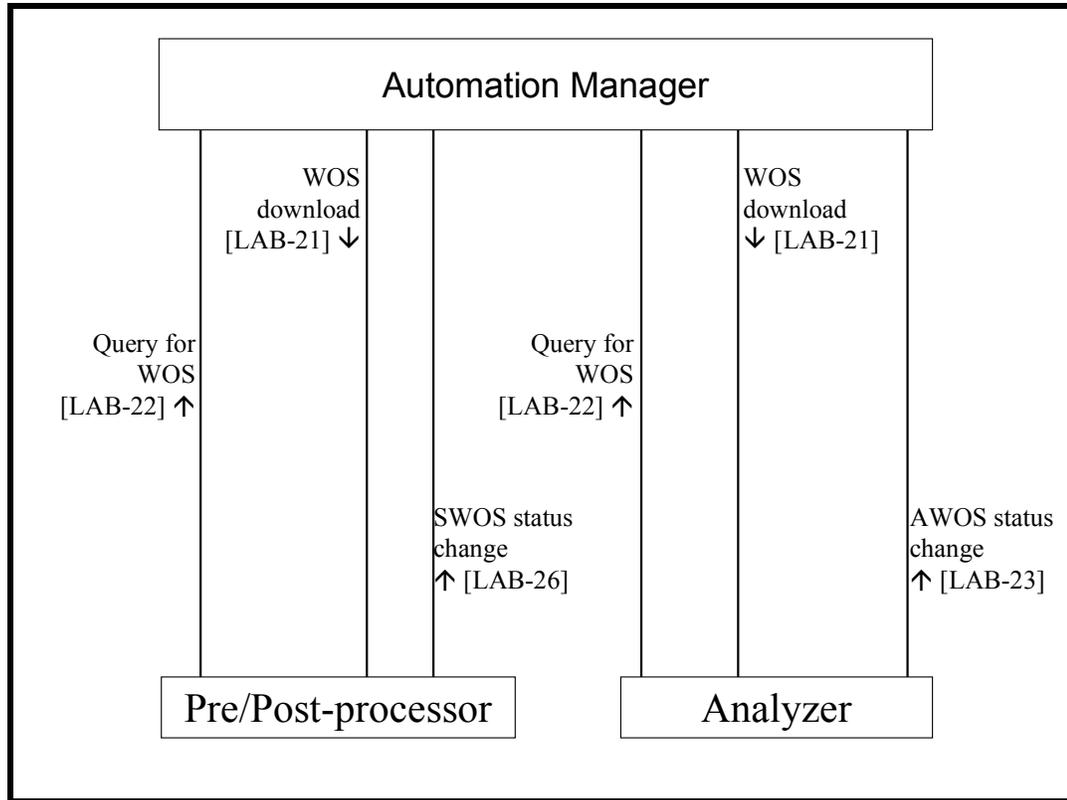
1165

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
1170 section 5.5 below.

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

Actors	Transactions	Optionality	Section in Vol. 2
Automation Manager	WOS Download [LAB-21]	R	LAB TF-2a: 3.6
	WOS Query [LAB-22]	R	LAB TF-2a: 3.7
	AWOS Status Change [LAB-23]	R	LAB TF-2a: 3.8
	SWOS Status Change [LAB-26]	O	LAB TF-2a: 3.9
Analyzer	WOS Download [LAB-21]	O	LAB TF-2a: 3.6
	WOS Query [LAB-22]	O	LAB TF-2a: 3.7
	AWOS Status Change [LAB-23]	R	LAB TF-2a: 3.8
Pre/Post-processor	WOS Download [LAB-21]	O	LAB TF-2a: 3.6

Actors	Transactions	Optionality	Section in Vol. 2
	WOS Query [LAB-22]	O	LAB TF-2a: 3.7
	SWOS Status Change [LAB-26]	R	LAB TF-2a: 3.9

5.5 LDA Integration Profile Options

1175   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	*Management of Pre/Post-processor*	
Analyzer (1)	*Query mode WOS*	
	Download mode WOS	
Pre/Post-processor (2)	*Query mode WOS*	
	Download mode WOS	

1180   **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 manage SWOS and support transaction LAB-26 with Pre/Post-processors.

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

1185   **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
1190   LAB-21.

Note 1: 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.

1195

Note 2: 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

1200   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.

5.6.1 Normal process of a specimen with all LD working in download mode

1205   This process flow is based on use case 5.2.1.
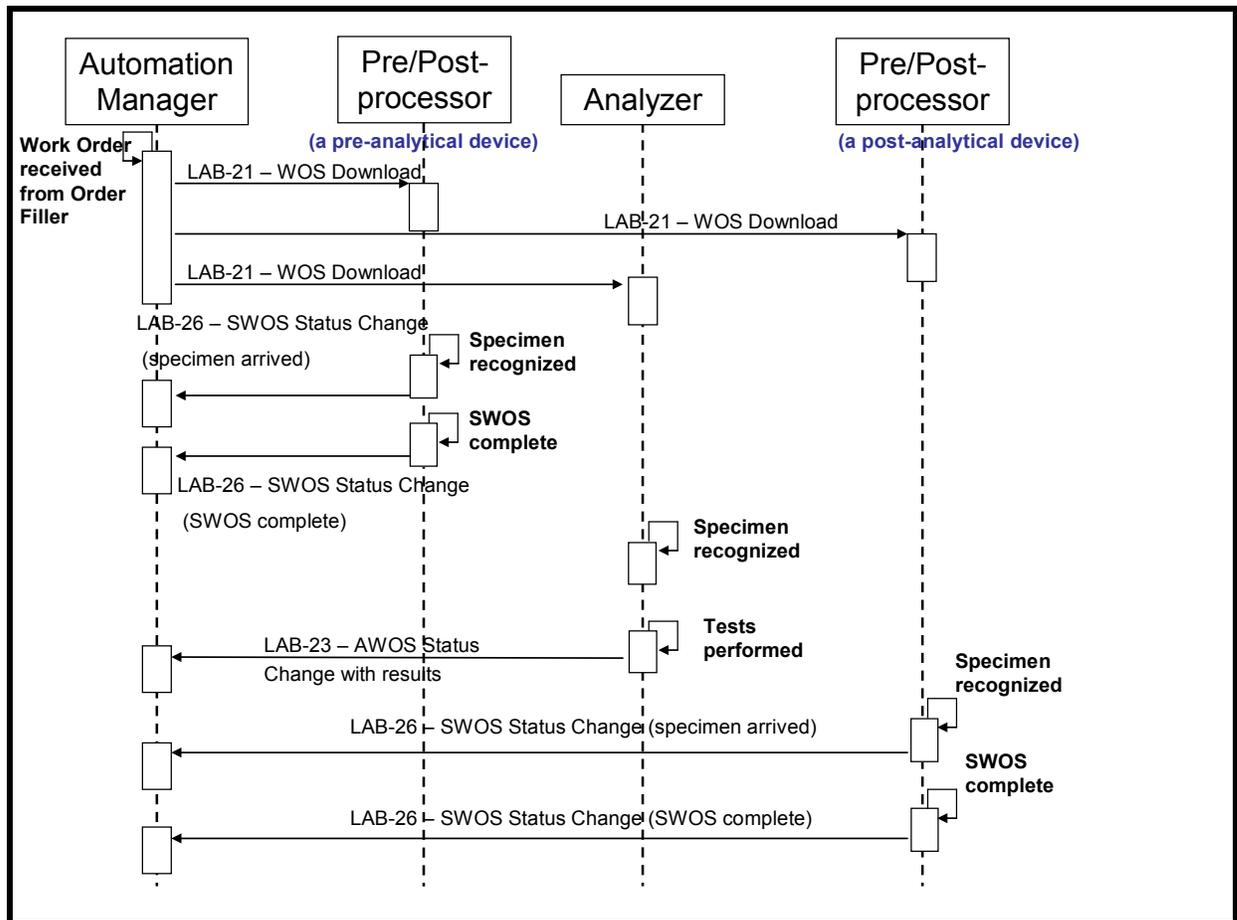
Figure 5.6.1-1: Normal process in download mode

This diagram shows a situation with one pre-analytical device, one analyzer and one post-
1210   analytical device.

5.6.2 WOS Update with all LD working in download mode

This process flow based on use case 5.2.1 shows the update of a Work Order triggering the update of its WOS.
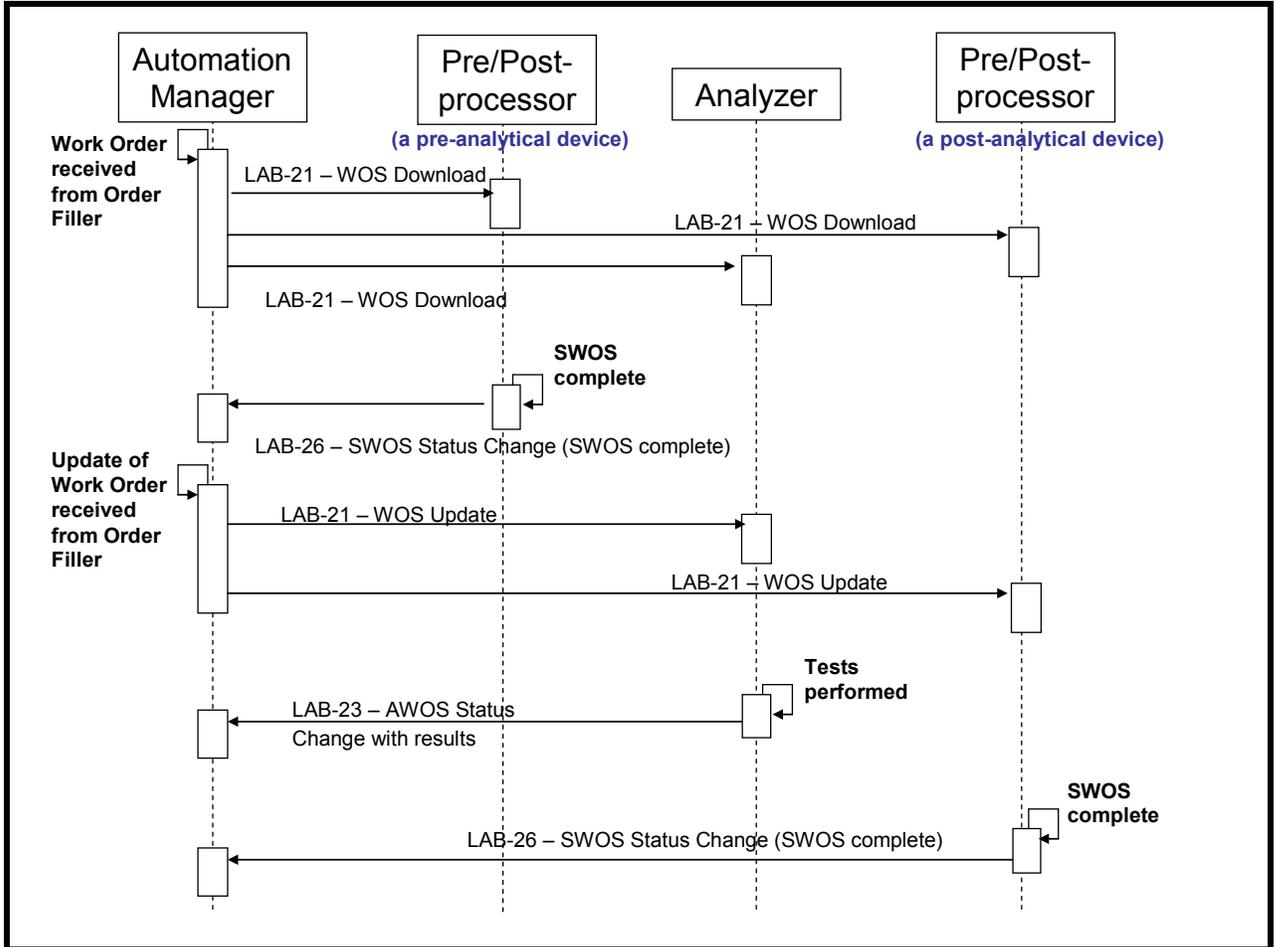
Figure 5.6.2-1: WOS Update in download mode

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

As explained in section 4.5.3, a Work Order update may be used to download patient information update. This download of patient information update, goes down to the LD embedded in the related WOS if this WOS is not completed and if the LD is concerned with the accuracy of patient information embedded in the WOS and if it is able to store an update of this information.

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1215

5.6.3 Normal process with AWOS manual entry and SWOS download

1225   This process flow is based on use case 5.2.1 for SWOS, and use case 5.2.3 for AWOS: Pre/Post-processors are working in download mode, whereas the Analyzer, has a one-way interface supporting only transaction LAB-23 to report its results.
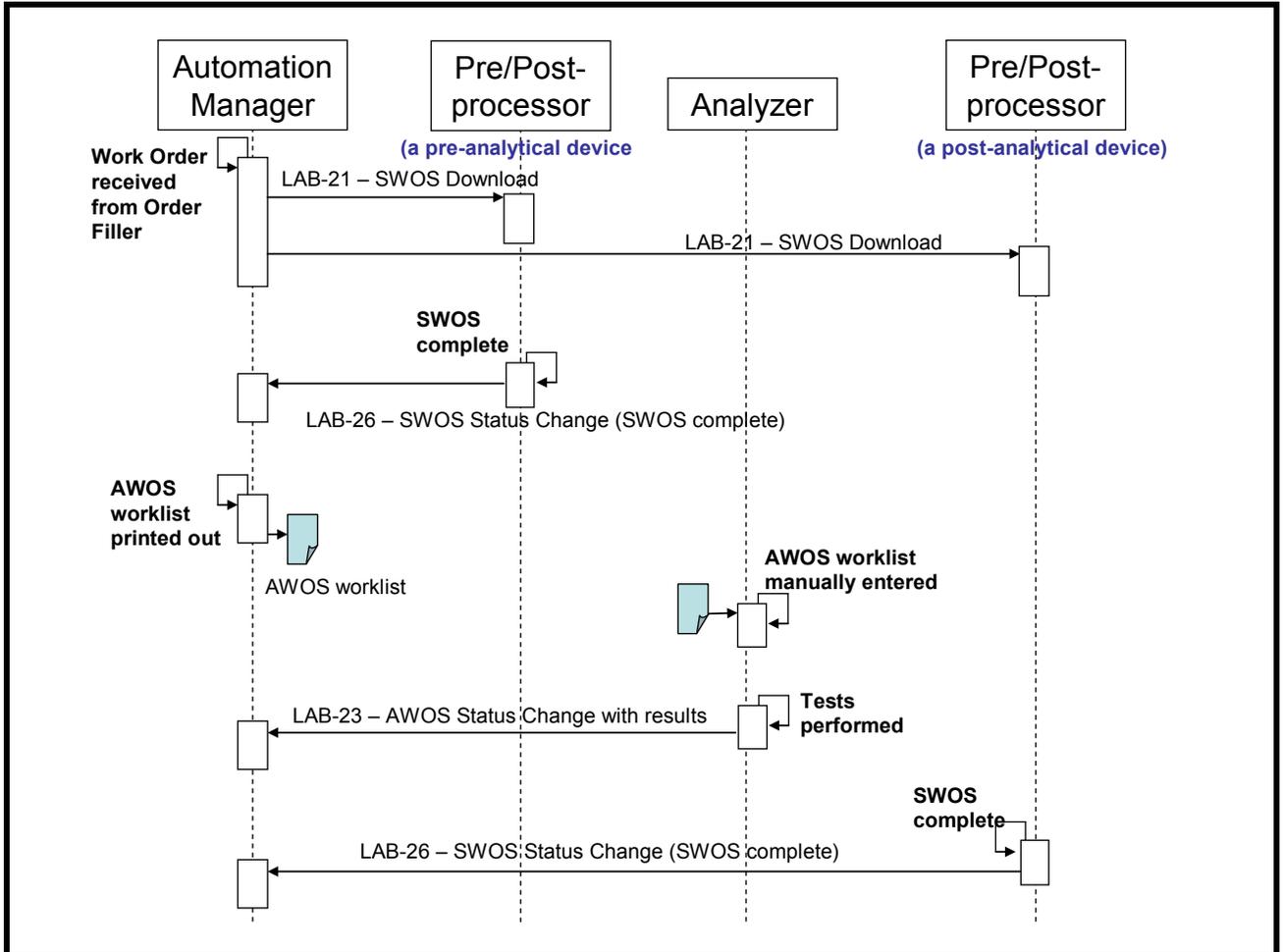
Figure 5.6.3-1: Normal process with AWOS manual entry

1230

5.6.4 Normal process of a specimen with all LD working in query mode

This process flow is based on use case 5.2.2, with all LD working in query mode.
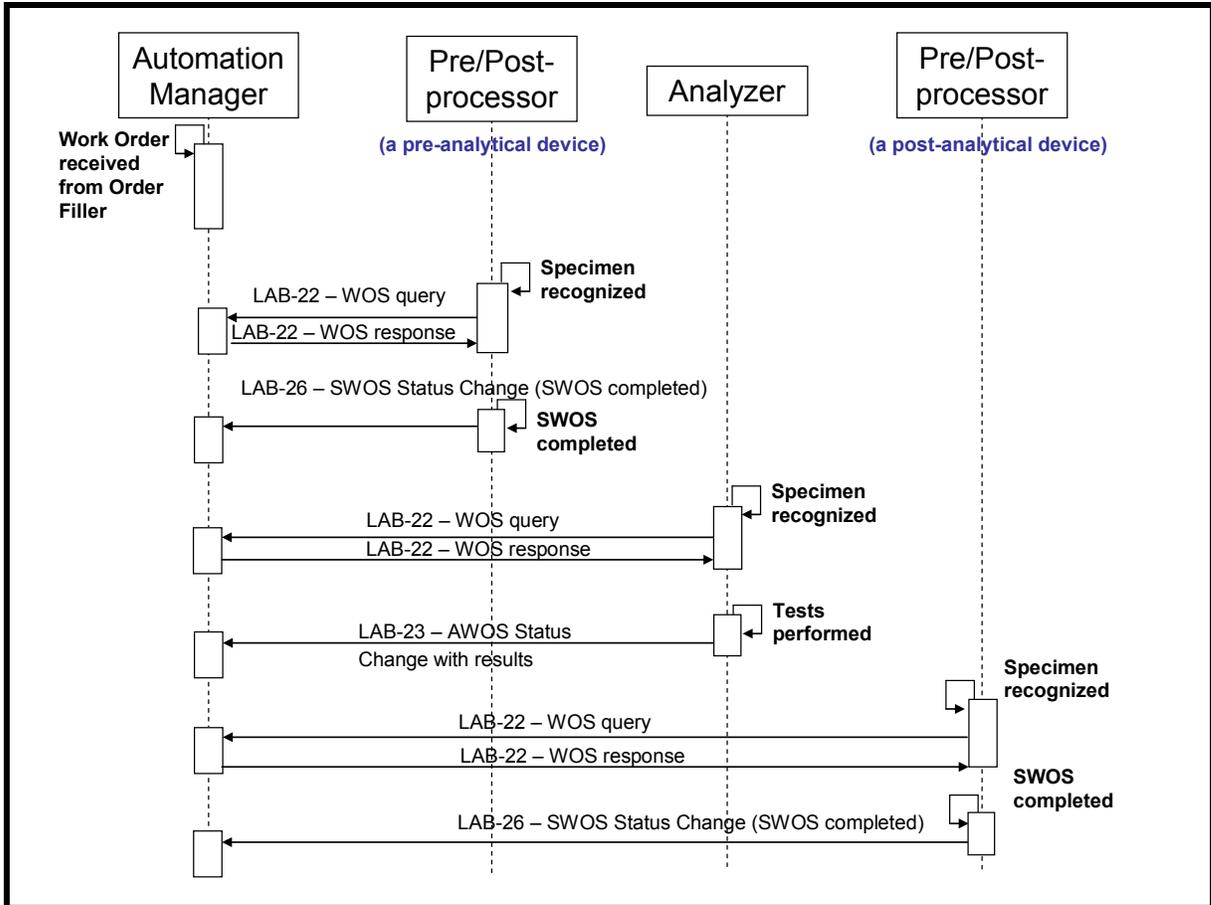
Figure 5.6.4-1: Normal process in query mode

1235

5.6.5 Automatic rerun on the Analyzer, triggered by out of range results

This process flow is based on sub-use case 5.2.4.1.
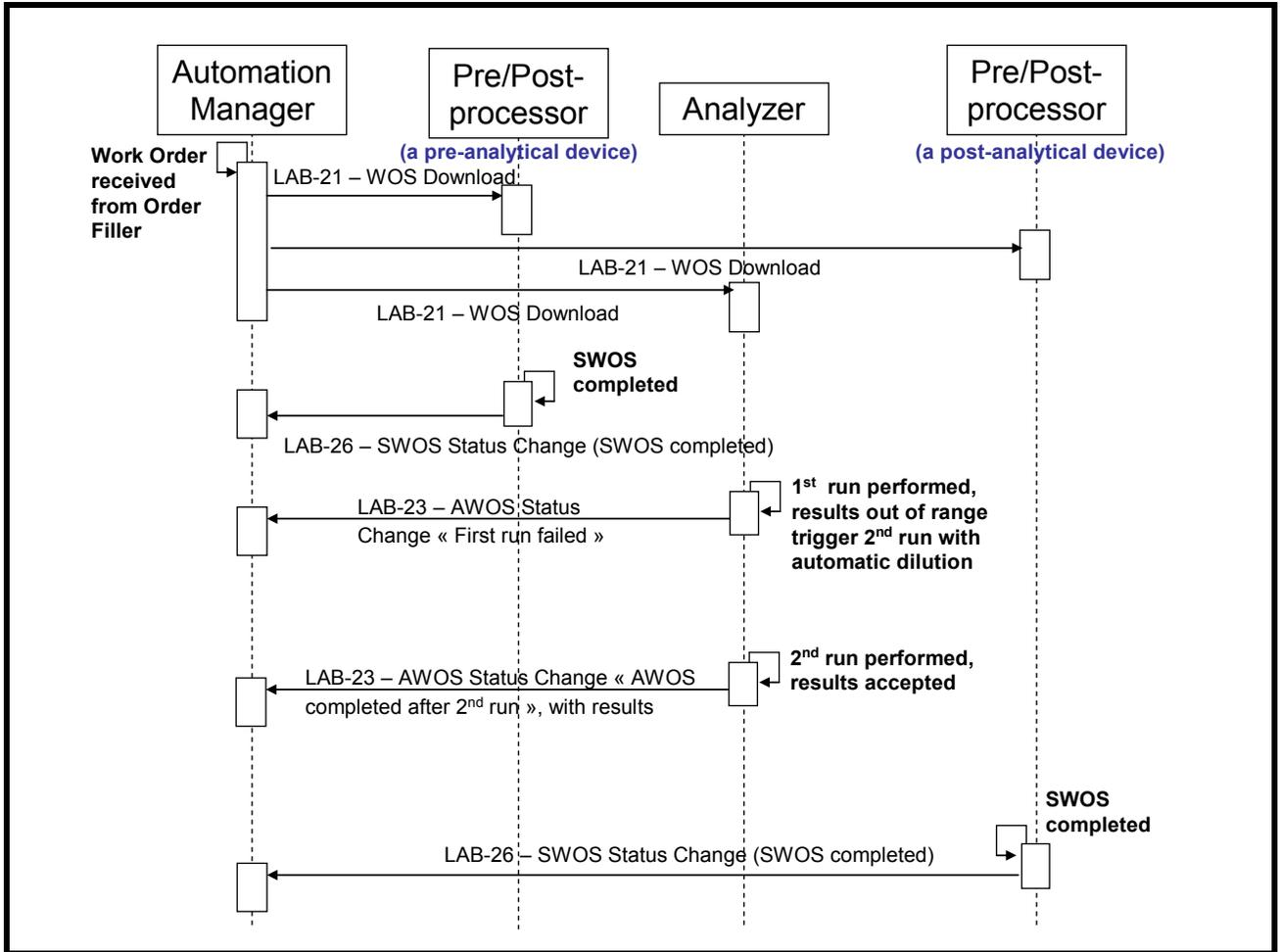
Figure 5.6.5-1: Rerun decided on the Analyzer immediately after first run

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5.6.6 Rerun requested by AM during technical validation

This process flow is based on sub-use case 5.2.4.2.
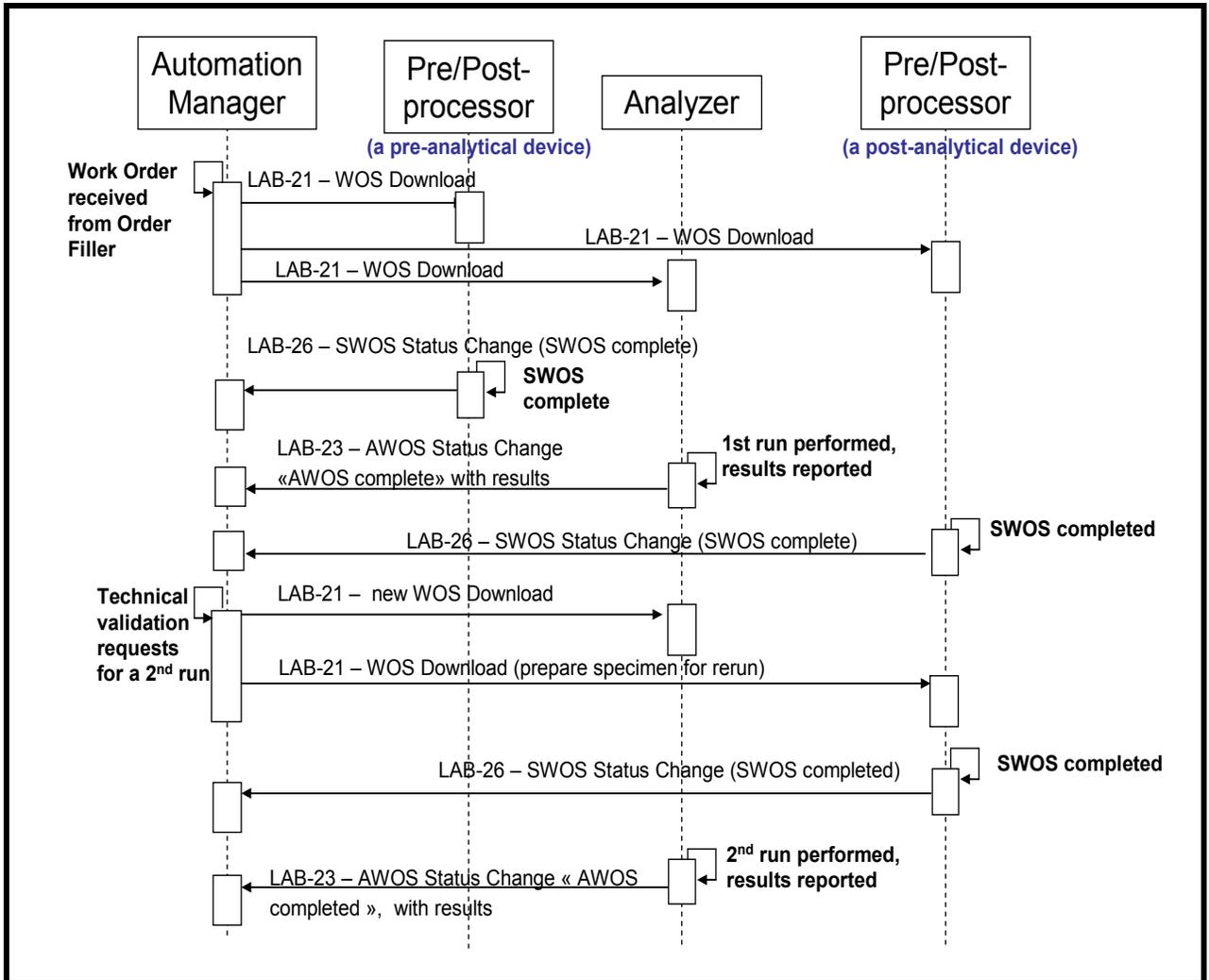
Figure 5.6.6-1: Rerun decided on the Automation Manager at technical validation time

1245   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 a Pre/Post-processor, requesting it to prepare the specimen for the second run (aliquoting, dilution, retrieval, transportation to the analyzer…)

5.6.7 Urgent tests performed before the arrival of the Work Order

1250 This process flow is based on use case 5.2.2 linked with use case 5.2.3, in combination with the Order Filler Actor of the LTW integration profile as described in section 4.5.5.
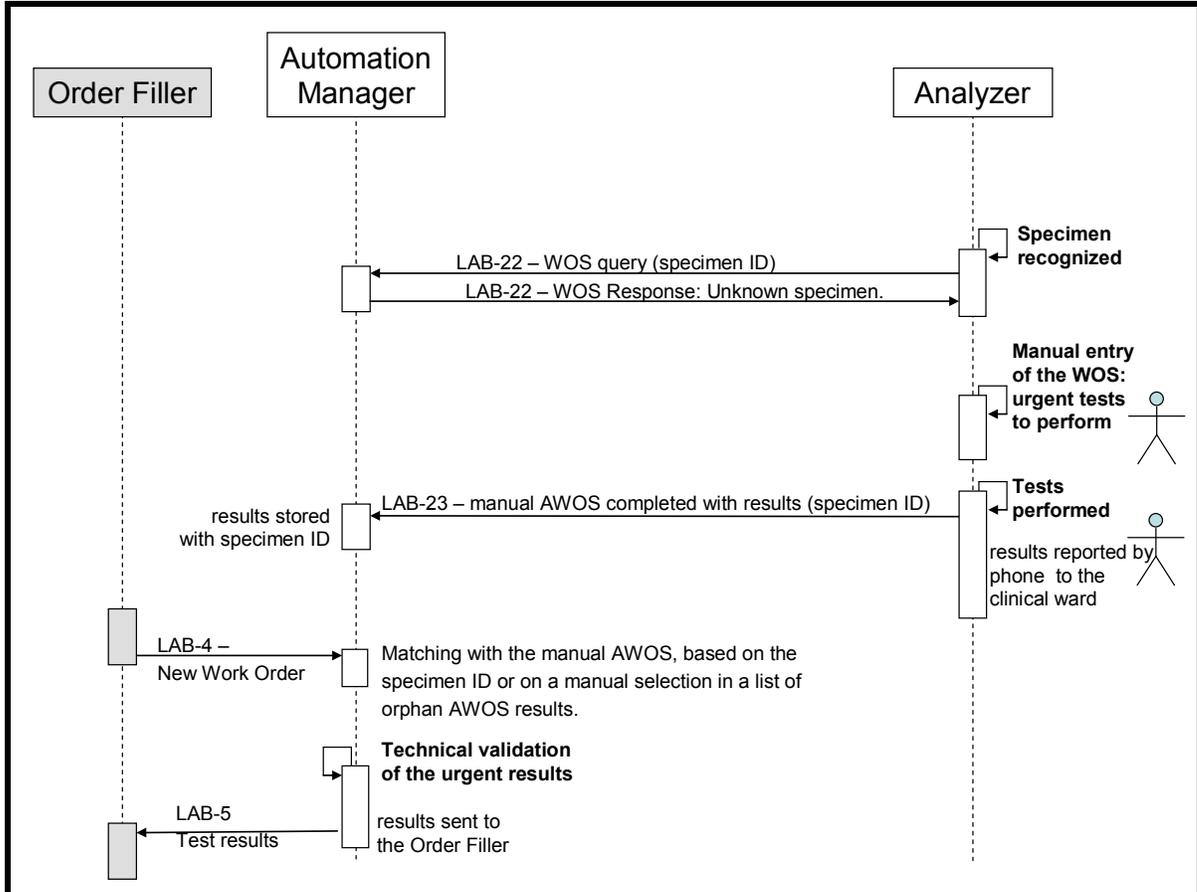
Figure 5.6.7-1: Manual urgent AWOS performed and used before arrival of Work Order

1255 ### 5.6.8 QC downloaded by the Automation Manager

The following diagram illustrates use case 5.2.6.1
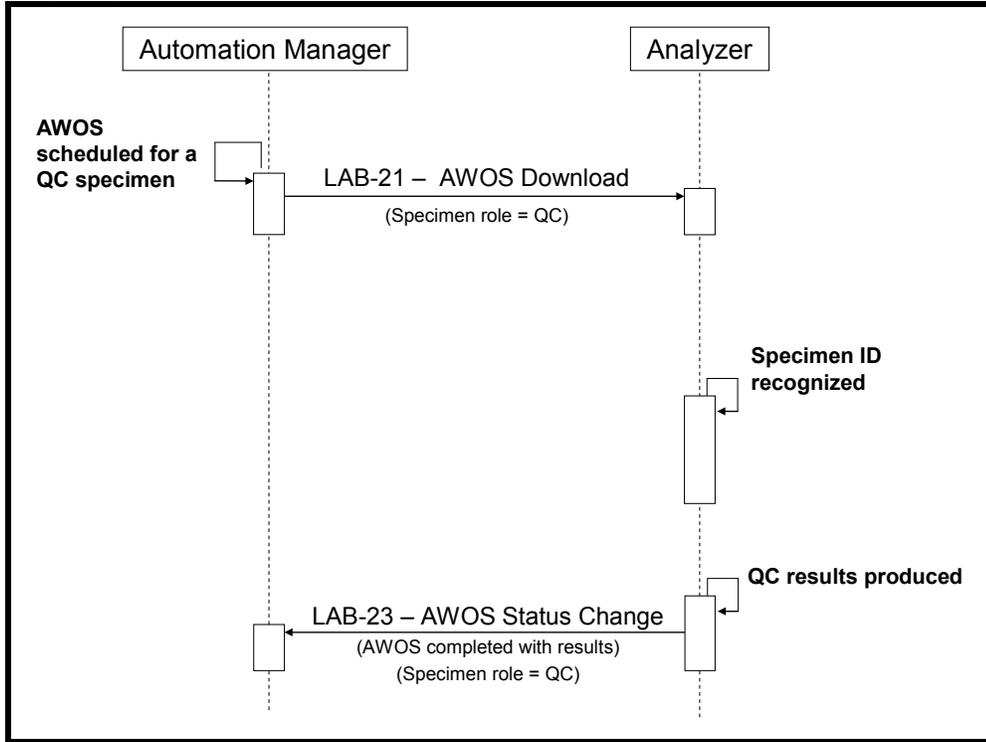
Figure 5.6.8-1: QC tests downloaded

1260 ## 5.6.9 QC scheduled by AM, and queried by the Analyzer

The following diagram illustrates use case 5.2.6.2
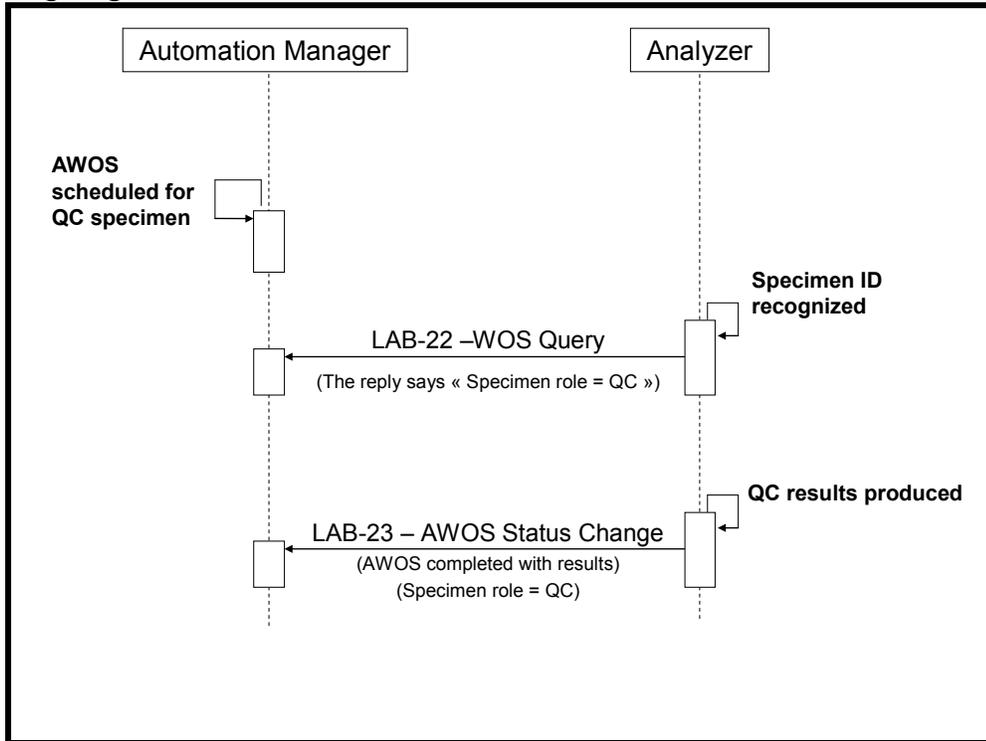
Figure 5.6.9-1: QC tests queried

6   Laboratory Point Of Care Testing (LPOCT)

6.1 Summary of LPOCT

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In some situations clinical laboratory testing can be performed straightforwardly on the point of care device or the patient's bedside by the ward staff, and even by patients themselves. These organizations enable the ward staff immediate access to common tests, whose specimen does not need any pre-analytic preparation. The results are used immediately in clinical decisions.

1270

The point of care analyzers located in the wards send their observations to a central Point Of Care Data Manager, using a connection that can be persistent or intermittent.

This profile addresses organizations, where point of care testing is placed under the overall supervision of a clinical laboratory of the healthcare enterprise. This supervision includes clinical validation of POCT results, Quality Control (QC) surveillance, reagent delivery, and education on good testing practices delivered to the ward staff.

1275

This profile can also support organizations that leave point of care testing under the responsibility of the ward medical staff using the point of care analyzers, and do not involve any laboratory in this process. These organizations will be referred as non-laboratory led organizations. (A subset of this profile will likely apply to these organizations.)

1280

To fulfill the laboratory led need, the POCDM must be able to forward point of care patient results to the Order Filler application of the clinical laboratory supervising the POCT process.

The workflows covered by this LPOCT profile depend upon the kind of organization chosen, and upon the type of connection (persistent or intermittent) used by point of care devices.

LPOCT profile uses the Order Filler actor defined in LTW profile, and introduces two new actors: Point Of Care Result Generator (POCRG), Point of Care Data Manager (POCDM).

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6.2 In scope of LPOCT

- Point of care testing within a healthcare enterprise, or in home care under the control of a healthcare enterprise.
- All specialties of clinical laboratory that can be performed on the point of care.

1290

- Testing on in vitro specimen, not on patients themselves.
- Tests of short time execution that do not need any significant pre-analytic process.
- Tests performed by the ward staff on the patient bedside or the point of care.
- Observations produced by a point of care analyzer, or manually entered on a system, or calculated by a system.

1295

- Point of care devices with persistent or intermittent link to the central point of care data manager.
- Overall supervision of the point of care testing process: This supervision may include QC surveillance, reagent management, operator certification, and centralization of results on the point of care data manager.

1300 • This profile enables to place this supervision under the responsibility of a clinical laboratory, including uploading to the LIS all patient results.

6.3 Out of scope of LPOCT

• The remote control of the point of care testing devices by the central point of care data manager (remote commands) is left out of the scope of this profile.

1305 • The identification process of the operators is left out of scope of this profile.

• The uploading of QC results from the POCDM to the LIS is left out of scope.

• When a POCT set of observations reaches the Order Filler, these results have already been used by the care provider at the point of care, and these results are assumed to be technically validated by the POCDM. Due to these two characteristics, LPOCT profile does not handle

1310 corrections or cancellations of observations.

• Given that the POCT observations are used at once by the ward staff or the clinician, the profile does not handle cancellations or corrections of previous point of care observations. The second run of a specimen on a point of care device produces a new set of observations. This second run is performed because the results of the first run have been rejected by the

1315 POCDM, and therefore have not been transmitted to the Order Filler.

6.4 Use cases

The 5 following use cases cover the various organizations and situations mentioned in the summary of this profile.

6.4.1 Observations to match with existing order, patient identity checking

1320 This use case involves a real-time patient identity checking. It requires a persistent link between the point of care testing device (POCRG) and the point of care data manager (POCDM).

The scenario covers the situation in which the order for point of care testing is created on the Order Placer application prior to the testing. The order number, though, is not entered on the POCRG, and is transmitted neither to the POCDM nor to the Order Filler. The Order Filler has

1325 to match an existing order in its data base.

Note 1: The use case in which the order number would be entered on the point of care device and transmitted to the POCDM and then to the Order Filler, is considered by the IHE LAB TF as a normal use case of scheduled clinical laboratory testing, supported by the Integration Profiles Laboratory Testing Workflow and Laboratory Device Automation. The point of care device in this use case is considered as an analyzer of the clinical laboratory, even if it is remote.

1330 See section 2.2 in this volume.

Part 1 of the scenario

The physician orders point of care tests for a patient. This order is entered on the Order Placer application and is assigned a placer order number. As part of the LTW profile, the Order Placer sends this new point of care order to the Order Filler, which assigns a Filler Order Number to it,

1335 and waits for point of care observations.

Part 2 of the scenario

To fulfill this Order, the operator (physician, nurse, patient) collects a specimen from the patient and puts it on the point of care device. The operator initiates the operation, providing its own

1340
identification, a patient/visit identifier and all information relevant for testing. In addition the operator enters the indication that an order already exists for the tests to perform.

Part 3 of the scenario

The POCRG notifies this information to the POCDM to check information provided, and to get the patient name. This patient name sent back to the point of care device is displayed so that the operator can check that he has entered the correct patient/visit identifier. If the patient is

1345
unknown to the POCDM or in other error cases, the operator will follow the enterprise policies. For instance the operator could key in the patient identity on the device.

Part 4 of the scenario

The point of care device performs the tests on the specimen, produces the results and displays them to the user.

1350
The POCRG sends the observation set with its related data to the POCDM, including the indication "existing order to be matched".

The POCDM checks the received observations against its own rules (result compared with normal ranges or scale limits, QC results obtained and correct …), accepts them, stores them, and acknowledges them to the POCRG (results accepted). The POCRG displays the

1355
acknowledgment received from the POCDM. In case the POCDM detected an erroneous or suspicious result, it rejects the results, and sends back a negative acknowledgement to the POCRG.

Part 5 of the scenario: – order matched

Having accepted the observation set, the POCDM forwards it to the Order Filler, accompanied

1360
by the indication "existing order to be matched".

The Order Filler searches for the existing order in its own data base, by matching a point of care testing order for the same patient, containing the same tests, and placed by the same ordering provider, at approximately the same time. It stores the received observation set into this order. If the Order Filler can't match any existing order in its data base, it generates a new order as in use

1365
case 5.5.2.

The Order Filler acknowledges the observation set to the POCDM, sending in the acknowledgment message its filler order number.

As part of the LTW profile, the Order Filler notifies the Order Placer that the results for the POCT order have arrived (status change of the order).

1370
Part 6 of the scenario: Clinical validation

Later on, the clinical validation of the results is performed. In the LTW profile, this triggers the sending of these results to the Order Result Tracker, and the notification "order completed" sent to the Order Placer.

6.4.2 Unordered observations, patient identity checking

1375
This use case involves a real-time patient identity checking. It requires a persistent link between the point of care testing device (POCRG) and the point of care data manager (POCDM). The tests are performed before the order is created. The order will be created automatically by the LIS on reception of the POCT observations.

Part 1 of the scenario

1380   The operator (physician, nurse,) sets a patient specimen on the point of care device implementing a POCRG actor. The operator initiates the operation, providing its own identification, a patient identifier and all information relevant for testing.
Part 2 of the scenario

Same as Part 3 of use case 6.4.1.

1385   **Part 3 of the scenario**

The point of care device performs the tests on the specimen, produces the results and displays them to the user. The POCRG sends the observation set with its related data to the POCDM.

The POCDM checks the received observations against its own rules (result compared with normal ranges or scale limits, QC results obtained and correct …), accepts them, stores them,
1390   and acknowledges them to the POCRG. The POCRG displays the acknowledgment received from the POCDM. In case the POCDM detected an erroneous or suspicious result, it rejects the results, and sends back a negative acknowledgement to the POCRG.
Part 4 of the scenario: supervision by a clinical laboratory – order generated

Having accepted the POCT observation set, the POCDM forwards them to the Order Filler of the
1395   laboratory supervising the point of care testing process. The Order Filler stores the received results into a new filler order generated right away. The Order Filler acknowledges the observation set to the POCDM, sending in the acknowledgment message its assigned filler order number.

Being also involved in LTW profile, the Order Filler obtains a placer order number from the
1400   Order Placer, using transaction LAB-2. During this transaction, the Order Placer application creates a placer order for this point of care observation set, and sends back the placer order number assigned.

In the case of an unknown patient, the reconciliation will be the task of the Order Filler application.

1405   **Part 5 of the scenario: Clinical validation**

Same as Part 6 of use case 6.4.1.

6.4.3 POCRG with intermittent link, supervision by lab, generate order

This variant of scenario 6.4.2, is met with POCT devices intermittently connected to the healthcare enterprise's network. In such a configuration, the tests are performed offline without
1410   real-time patient identity checking.
Part 1 of the scenario

Same as Part 1 of use case 6.4.2.
Part 2 of the scenario

The POCRG performs the tests on the specimen, produces the results, qualifies them against its
1415   own rules (such as normal ranges) displays them, and stores them in its memory.
Part 3 of the scenario

Later on, when a connection is established with the POCDM (e.g., when the point of care device is plugged on its docking station), the POCRG sends all the POCT observations accumulated in its memory.

1420   The POCDM receives the observation sets, checks their information, including patient IDs, stores them, and acknowledges them to the POCRG.

The POCRG displays the acknowledgment received from the POCDM.
Part 4 and 5 of the scenario

Same as in scenario 6.4.2.

6.4.4 Manual entry of point of care observations, generate order

1425

Some point of care observations are read and entered manually (e.g., urine sticks). This scenario is met when such POCT observations are entered manually directly on the central POCT system, which in this case, groups the two actors POCDM and POCRG.
Part 1 of the scenario

1430   The nurse identifies herself on the POCRG (grouped with POCDM) and enters the patient ID.

The POCRG grouped with POCDM checks this patient ID and displays the patient full identity, and visit information, enabling the operator to verify the patient's identity.

The operator enters the observations on the POCRG. The POCDM controls the observation set against its configuration rules, rejects them or accepts them, and stores them in the latter case.

1435   **Part 2 and 3 of the scenario**

Same as part 4 and 5 of scenarios 6.4.2 and 6.4.3.

6.4.5 QC Testing on a POCRG
Part 1 of the scenario

The operator initiates the operation by identifying himself (or herself) to the POCRG, entering

1440   (or scanning) the QC specimen ID.

The operator enters additional information required, such as specimen type, reagent lot number, tests to be performed.
Part 2 of the scenario

The POCRG performs the tests on the QC specimen and produces the results.

1445   At once if the POCRG has a persistent connection, or when the next connection with POCDM is established, the POCRG sends the set of QC observations to the POCDM.

The POCDM receives the set of observations, verifies it against its configuration rules, stores it, and acknowledges it to the POCRG.

 If the QC results fail verification the POCDM and POCRG might hide the results, just

1450   displaying "QC failed", and block further process from this device on patient specimens until the operator perform the corrective action, and start again the QC test.

6.5 Actors/ Transactions
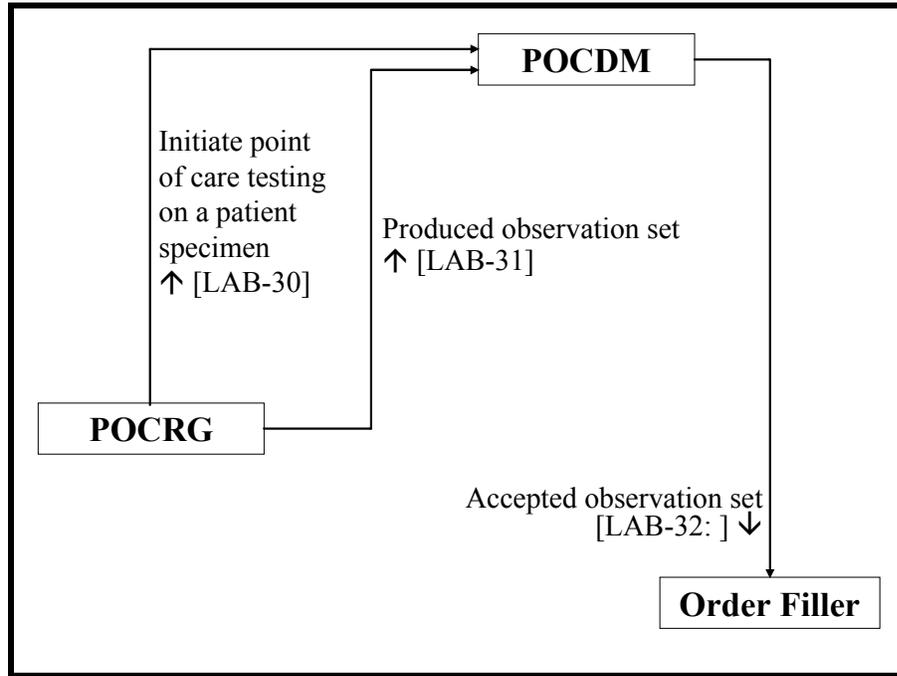
Figure 6.5-1: Laboratory Point Of Care Testing Actor Diagram

1455

Table 6.5-1 lists the transactions for each actor directly involved in the LPOCT Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in

1460   section 6.6 below.

Table 6.5-1: LPOCT Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Order Filler	Accepted Observation Set [LAB-32]	R	LAB TF-2b: 3.32
Point Of Care Data Manager	Initiate POCT on a patient specimen [LAB-30]	O (see note 3)	LAB TF-2b: 3.30
	Produced Observation Set [LAB-31]	R	LAB TF-2b: 3.31
	Accepted Observation Set [LAB-32]	R	LAB TF-2b: 3.32
Point Of Care Result Generator	Initiate POCT on a patient specimen [LAB-30]	O (see note 3)	LAB TF-2b: 3.30
	Produced Observation Set [LAB-31]	R	LAB TF-2b: 3.31

1465   Note 3: Initiate POCT on a patient specimen [LAB-30] is required for POCRG and POCDM supporting the "patient identity checking" option. See section 6.6.

6.6 LPOCT Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table 6.6-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in
1470   notes.

Table 6.6-1: Laboratory Point Of Care Testing - Actors and Options

Actor	Options	Vol. & Section
Order Filler	*No options defined*	
Point Of Care Data Manager	*Patient identity checking*	
Point Of Care Result Generator	*Patient identity checking*	

Patient identity checking:

1475   This option requires a persistent link between the point of care device implementing the POCRG actor and the central point of care data manager implementing the POCDM actor. In this situation, the POCRG and the POCDM use transaction LAB-30 to check the patient's identity, before performing the tests on a patient specimen, ensuring that the correct patient/visit ID has been entered (or scanned) on the point of care device.

1480

6.7 Process Flow

The actors involved from LTW profile appear in grey boxes.

6.7.1 Observations matched with existing order, patient identity checking
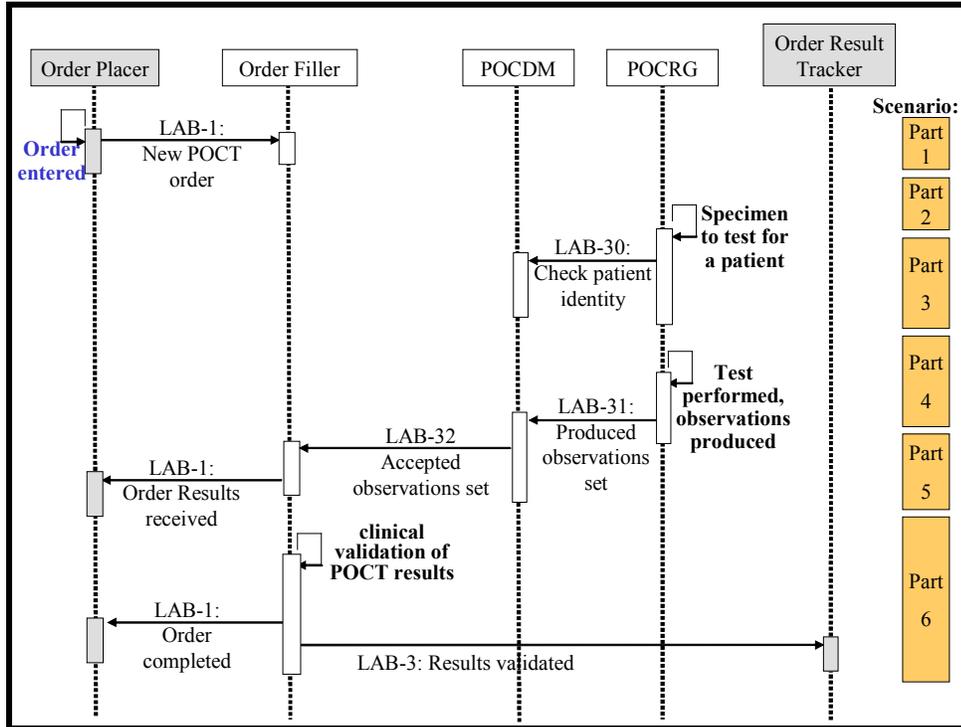
1485

Figure 6.7.1-1: Process flow for use case 6.4.1

6.7.2 Unordered observations with patient identity checking
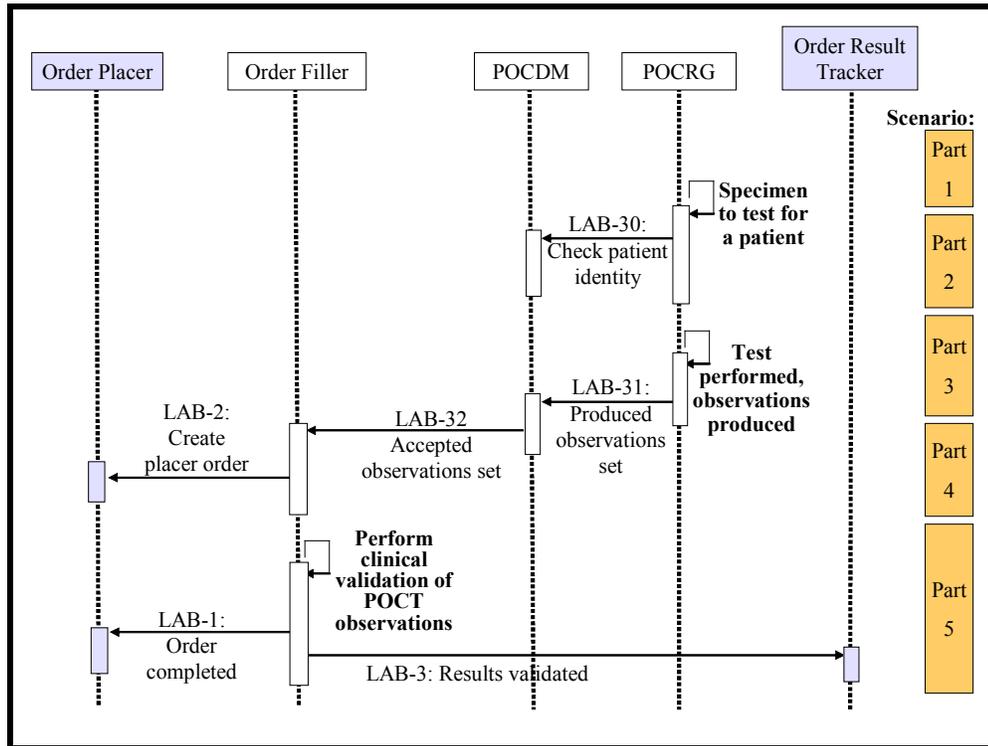
Figure 6.7.2-1: Process flow for use case 6.4.2

1490 ## 6.7.3 POCRG with intermittent link, unordered observations
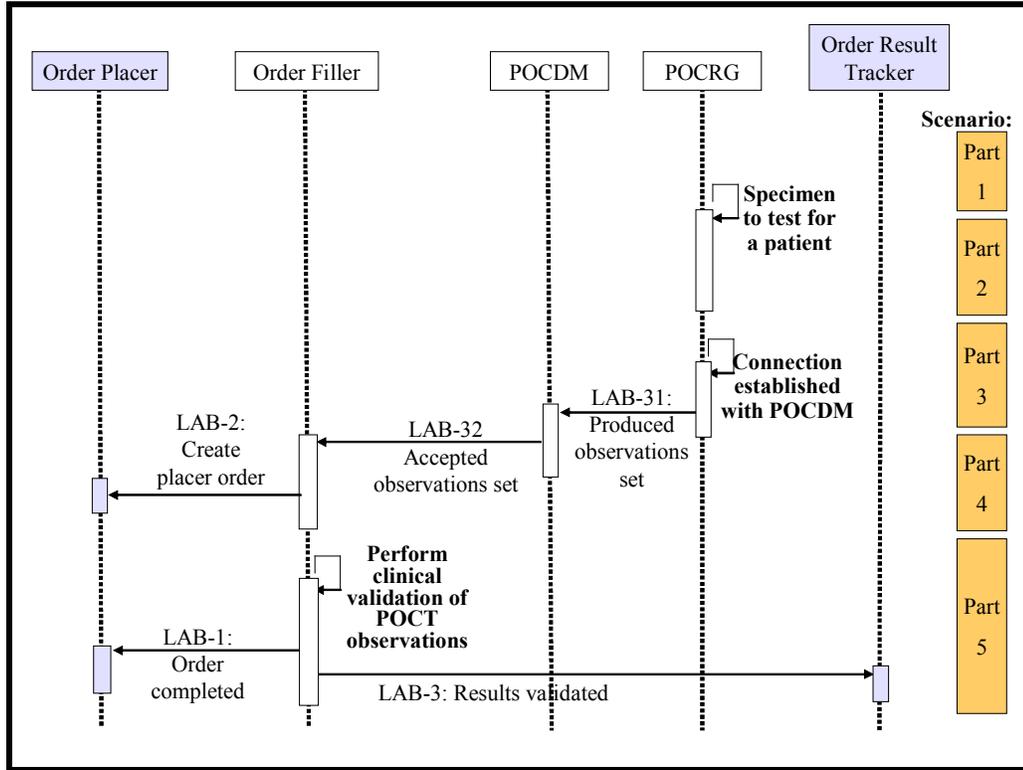
Figure 6.7.3-1: Process flow for use case 6.4.3

1495

1500

1505

1510

6.7.4 Manual entry of unordered point of care patient observations
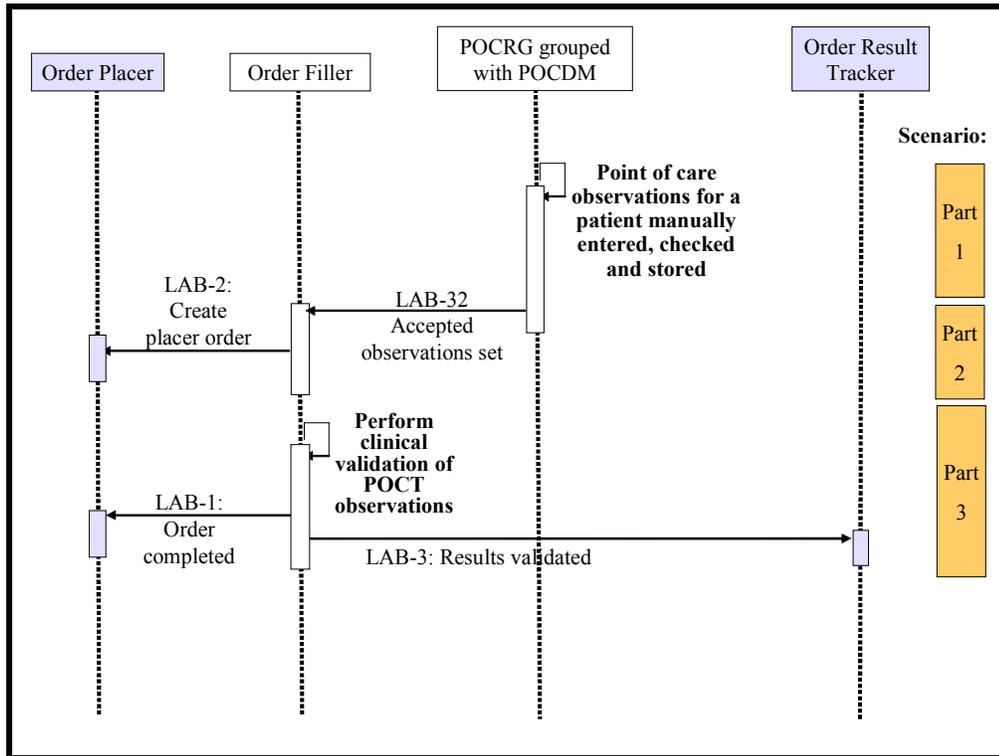
Figure 6.7.4-1: Process flow for use case 6.4.4

1515 ## 6.7.5 QC Testing on a POCRG
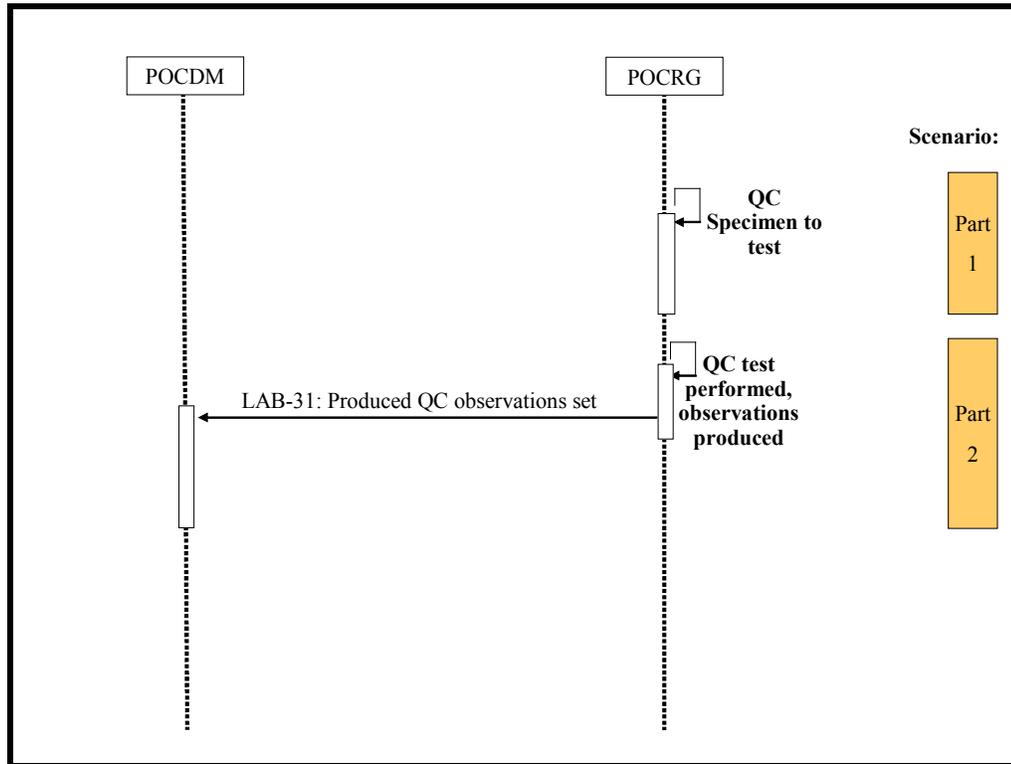
Figure 6.7.5-1: Process flow for use case 6.4.5

1520

7 Laboratory Specimen Barcode Labeling (LBL)

7.1 Scope

The Laboratory Barcode Labeling Integration Profile supports this workflow: A robotic system delivers specimen containers pre-identified with a bar coded label, for the specimen collection related to a laboratory test order. This robotic system receives patient, test order and specimen data from another system (HIS, CIS, LIS), and issues a label for each (specimen, container) needed, with the specimen identifier bar coded on the label, and possibly other information printed on this label.

This workflow is supported by two new actors, Label Information Provider (LIP) and Label Broker (LB).

The Label Broker receives label information, and delivers these labels in appropriate operations, and may notify the status of this process. The Label Information Provider is usually grouped with the Order Filler or the Order Placer from the Laboratory TestingWorkflow Integration Profile.

The Label Broker may be notified passively with the labeling instructions or may query the Label Information Provider to get these instructions.

This profile addresses only specimen container labeling within the scope of the Laboratory Domain. It does not address labeling workflows in other domains.

7.2 Use cases

Five use cases are addressed by this profile, depending upon which system implements the business rules to compute the needed specimen and containers for a particular test order.

7.2.1 LIP grouped with OP, request mode

The Label Information Provider is grouped with the Order Placer, generates the label information, and sends it to the Label Broker.

a) The Order Placer generates a test order and calculates the needed containers and associated barcode labels for this order.

b) The Order Placer places the order to the Order Filler, and the Order Filler accepts it.

c) In due time, the Label Information Provider sends the labeling instructions to the Label Broker.

d) The Label Broker issues the containers with barcode labels.

e) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.2 LIP grouped with OF, request mode

The Label Information Provider is grouped with the Order Filler, generates label information, and sends it to the Label Broker.

a) A test order is generated either on the Order Placer side or on the Order Filler side.

b) In both cases, the Order Filler gets this order, and in due time, schedules it and calculates the needed containers and associated barcode labels for this order. Then the Order Filler sends the labeling instructions to the Label Broker.

c) The Label Broker issues the containers with barcode labels.

1560   d) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.3 LIP grouped with OP, informed by OF, request mode

The Order Filler generates label information. The Label Information Provider is grouped with the Order Placer to send label information to the Label Broker.

1565   a) A test order is generated either on the Order Placer side or on the Order Filler side.

b) The Order Filler accepts this order and generates the specimen information, and sends the confirmation back to the Order Placer. This confirmation carries the specimen information.

c) In due time, the Label Information Provider grouped with the Order Placer sends the
1570   labeling instructions to the Label Broker.

d) The Label Broker issues the containers with barcode labels.

e) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.4 LIP grouped with OP, query mode

1575   The Label Broker requests label information from the Label Information Provider grouped with the Order Placer.

a) A test order is generated either on the Order Placer side or on the Order Filler side.

b) The patient arrives at the specimen collection point. The patient id is entered (scanned) into the Label Broker. This triggers a query from the Label Broker to the Label
1580   Information Provider to get labeling instructions for the specimens to be collected from this patient.

c) The Label Information Provider grouped with the Order Placer responds with the labeling instructions.

d) The Label Broker issues the containers with barcode labels.

1585   e) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.5 LIP grouped with OF, query mode

The Label Broker requests label information from the Label Information Provider grouped with the Order Filler.

1590   a) A test order is generated either on the Order Placer side or on the Order Filler side.

b) In both cases, the Order Filler gets this order, and in due time, schedules it and calculates the needed containers and associated barcode labels for this order.

c) The patient arrives at the specimen collection point. The patient id is entered into the Label Broker. This triggers a query from the Label Broker to the Label Information Provider to get labeling instructions for the specimens to be collected from this patient.

d) The Label Information Provider grouped with the Order Filler responds with the labeling instructions.

e) The Label Broker issues the containers with barcode labels.

f) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.6 LIP grouped with OF, LB grouped with OP, query mode

The Label Broker grouped with the Order Placer requests label information from the Label Information Provider grouped with the Order Filler.

a) A test order is generated on the Order Placer side.

b) The Order Filler gets this order, schedules it and calculates the needed containers and associated barcode labels for this order.

c) In due time (preparation of the containers for an order group), a query from the Order Placer/Label Broker to the Order Filler/Label Information Provider is issued to get labeling instructions for the specimens to be collected for this order group number.

d) The Label Information Provider grouped with the Order Filler responds with the labeling instructions.

e) The Label Broker issues the barcode labels. The labels are attached to the corresponding containers.

f) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.3 Actors/ Transactions
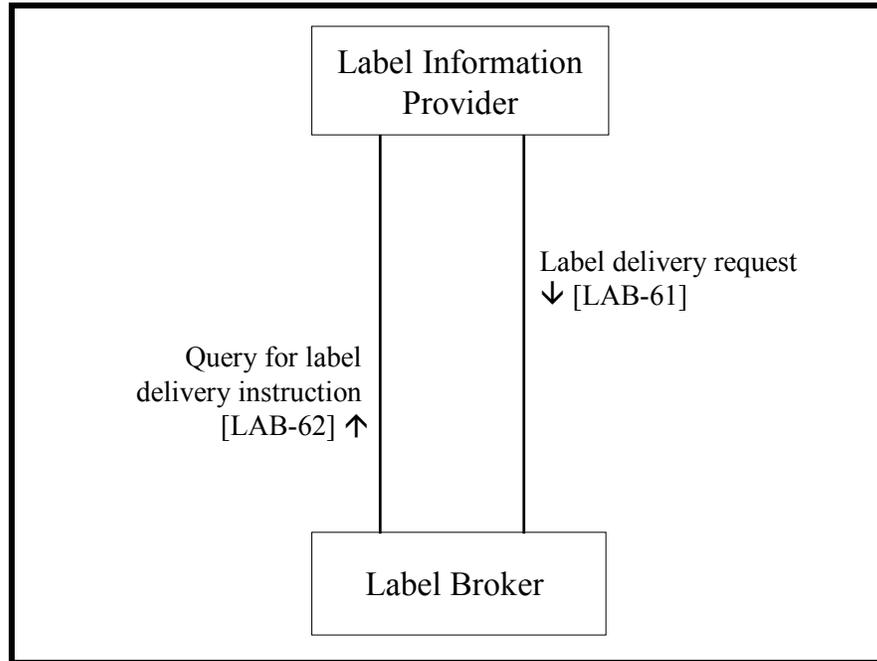
Figure 7.3-1: Laboratory Barcode Labeling Actor Diagram

1620

Table 7.3-1: LBL Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Label Information Provider	Label Delivery Request [LAB-61]	R	LAB TF-2b: 3.33
	Query for Label Delivery Instruction [LAB-62]	R	LAB TF-2b: 3.34
Label Broker	Label Delivery Request [LAB-61]	R	LAB TF-2b: 3.33
	Query for Label Delivery Instruction [LAB-62]	O (Note 1)	LAB TF-2b: 3.34

1625

Note 1: The Label Information Provider SHALL support both request mode and query mode. For the Label Broker the request mode is mandatory, and the query mode is optional. The query mode supported by Transaction Query for Label Delivery Instruction LAB-62 corresponds to use cases 4 and 5.

7.4 LBL Integration Profile Options

Table 7.4-1: Laboratory Barcode Labeling - Actors and Options

Actor	Options	Vol. & Section
Label Broker	*Query for labeling instructions*	

1630   Query for labeling instructions:

A Label Broker operating in query mode uses transaction Query for Label Delivery Instruction LAB-62 to support the workflows of use cases 4 and 5.

7.5 Process Flow

Actors from LTW integration profile appear as grey boxes.

7.5.1 Use case 7.2.1: LIP grouped with OP, request mode
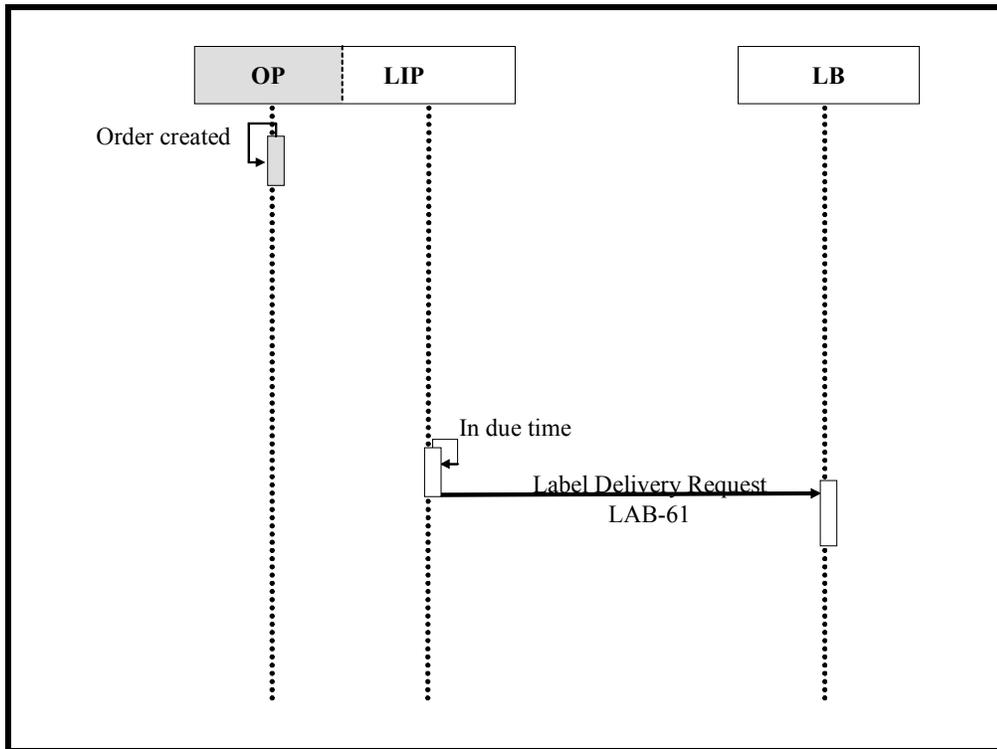
Figure 7.5.1-1: LIP grouped with OP – request mode

7.5.2 Use case 7.2.2: LIP grouped with OF, request mode
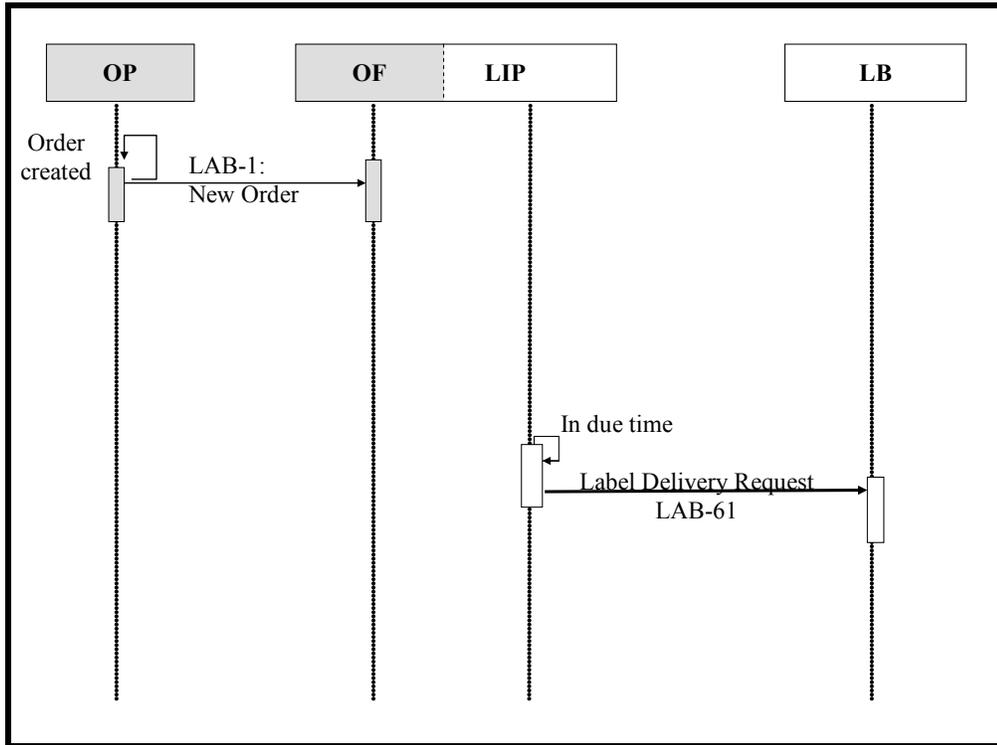
1640

Figure 7.5.2-1: LIP grouped with OF – request mode

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7.5.3 Use case 7.2.3: LIP grouped with OP, informed by OF, request mode
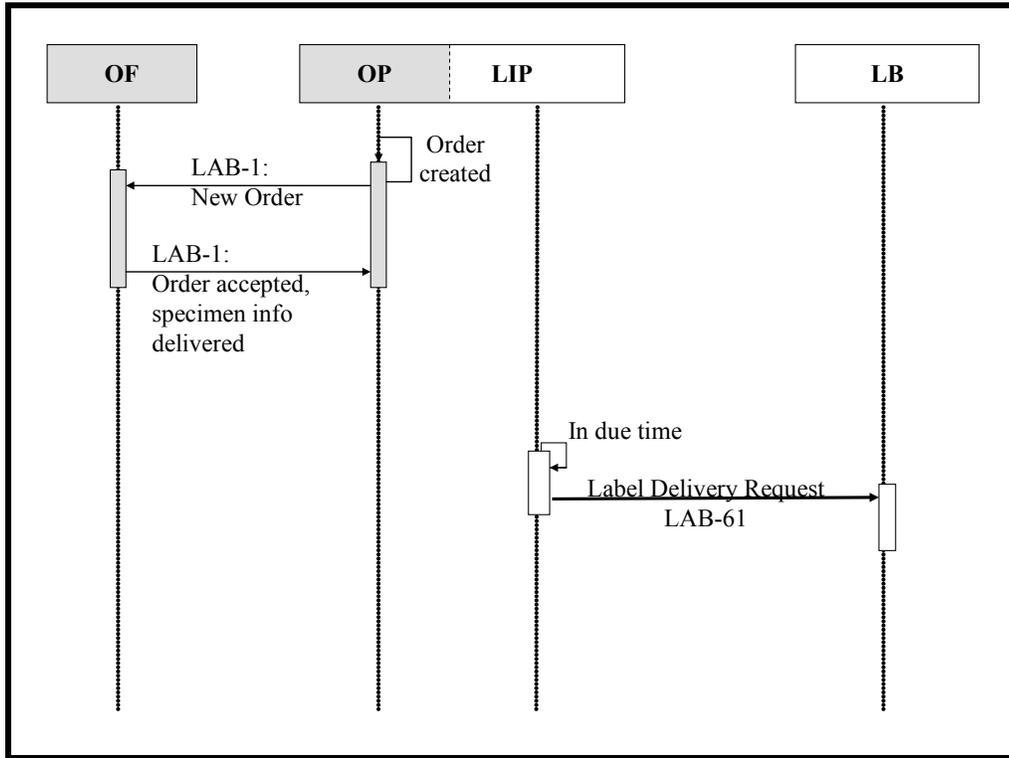
Figure 7.5.3-1: O LIP grouped with OP, informed by OF, request mode

1645

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## 7.5.4 Use case 7.2.4: LIP grouped with OP, query mode
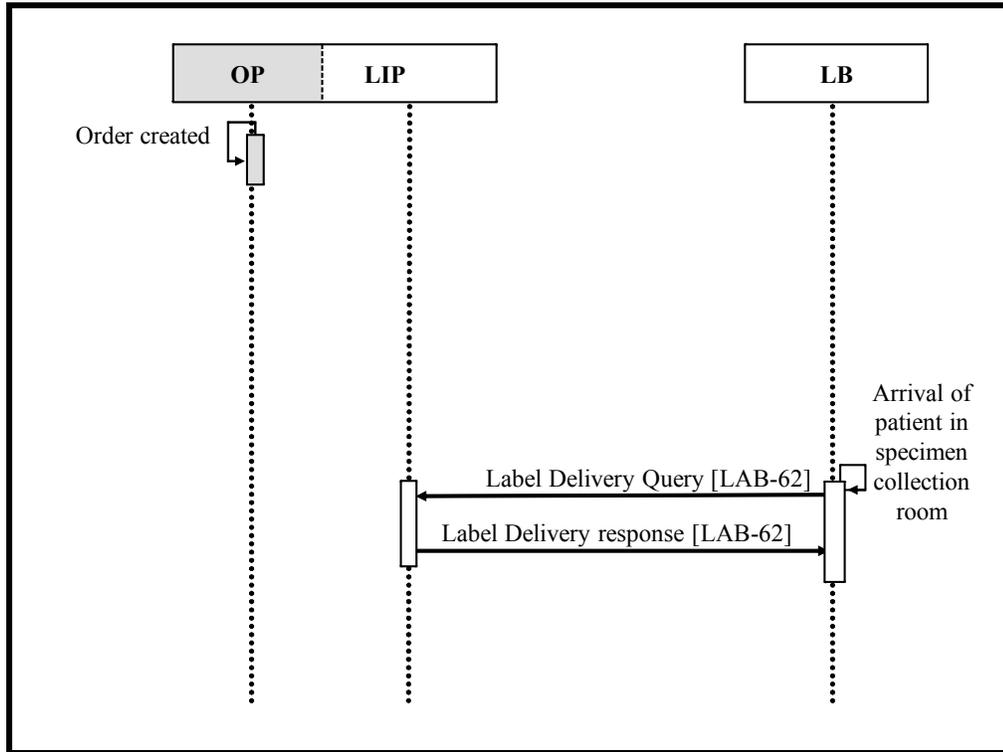
Figure 7.5.4-1: LIP grouped with OP, query mode

1650 ## 7.5.5 Use case 7.2.5: LIP grouped with OF, query mode
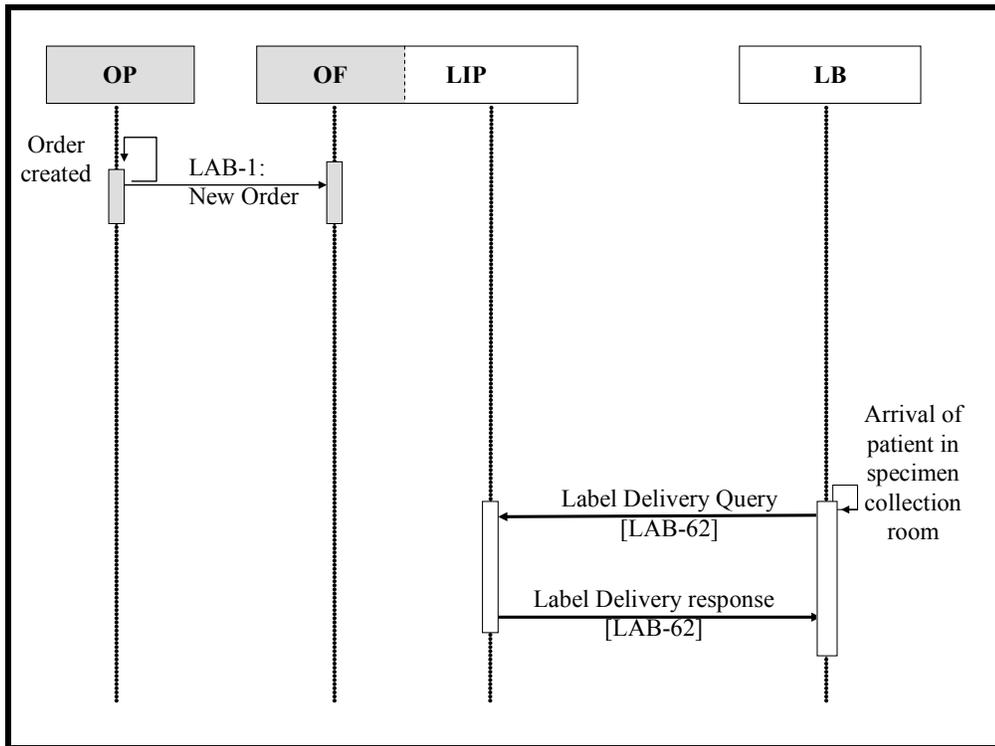
**Figure 7.5.5-1: LIP grouped with OF – query mode**

## 7.5.6 Use case 7.2.6: LIP grouped with OF, LB grouped with OP

1655
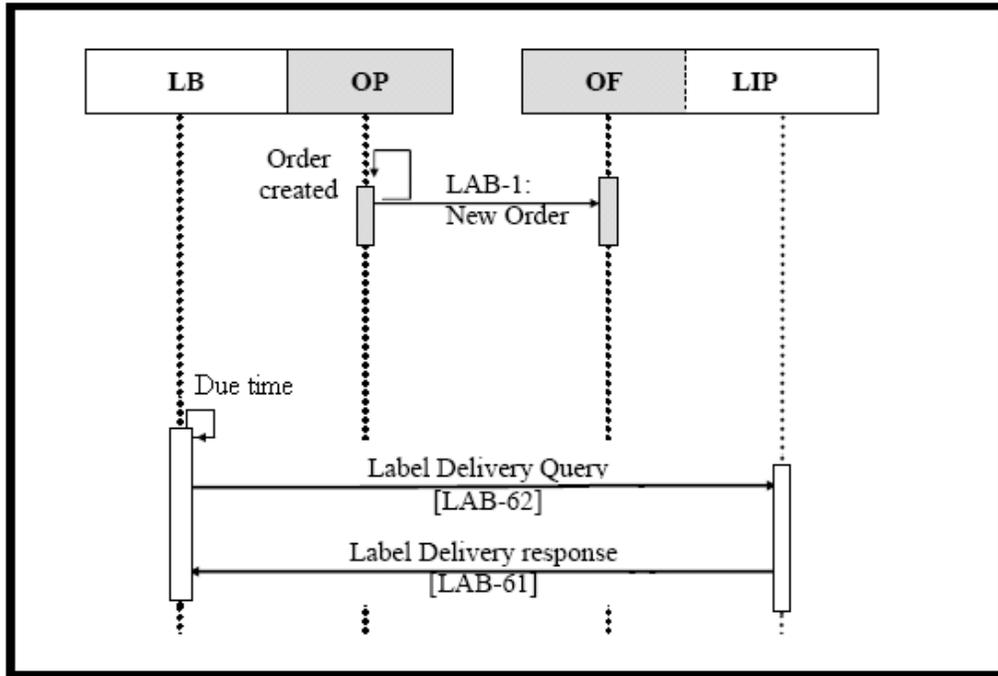
Figure 7.5.6-1: LIP Grouped with OF, LB grouped with OP – Query Mode

8 Laboratory Code Set Distribution (LCSD)

8.1 Scope

1660 A set of common codes is generally used by multiple application systems in a laboratory workflow environment. These common codes need to be synchronized across the various applications at a given site. In many implementations, one application system will be the author (the "owner") of the code set. The responsibility for managing a code set may also be distributed among different systems.

1665 This profile provides a way for the owner of a code set (battery, test and observation codes) to send the code set to other applications.

8.2 Actors/ Transactions

Figure 8.2-1 shows the actors directly involved in the Laboratory Code Set Distribution Integration Profile and the transaction between them. Other actors that may be indirectly

1670 involved due to their participation in other profiles are not shown.
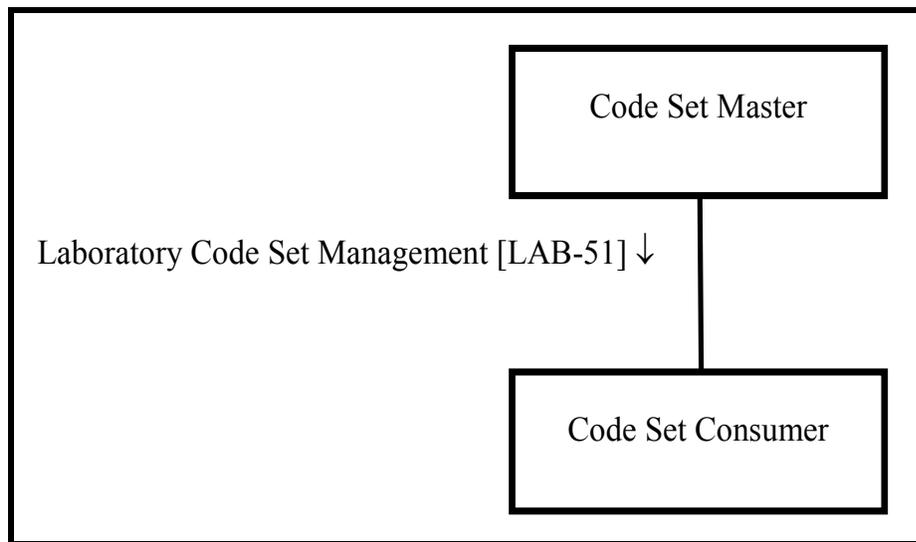
Figure 8.2-1: Laboratory Code Set Distribution Actor Diagram

Table 8.2-1 lists the transactions for each actor directly involved in the Laboratory Code Set

1675 Distribution Profile. In order to claim support of this Integration Profile, an implementation must perform the required transaction (labeled "R").

Table 8.2-1: Laboratory Code Set Distribution Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Code Set Master	Laboratory Code Set Management [LAB-51]	R	LAB TF-2b: 3.35
Code Set Consumer	Laboratory Code Set Management [LAB-51]	R	LAB TF-2b: 3.35

8.3 Laboratory Code Set Distribution Integration Profile Options

1680

Table 8.3-1: LCSD - Actors and Options

Actor	Options	Vol. & Section
Code Set Master	*Batch*	LAB TF-2b: 3.35
Code Set Consumer	*Batch*	LAB TF-2b: 3.35

8.3.1 Batch Option

The batch option enables to group the set of messages carrying a new release of a code set into a batch, so as to synchronize the two actors, and let the Code Set Consumer make sure that it has received the complete code set. This option SHALL be supported by both actors or by none.

1685 New implementers of this profile are strongly recommended to support this option.

8.4 Process Flow

The Code Set Master manages a set of laboratory codes (battery, test and observation). Three use cases are identified:

Use case 1: the entire code set is sent to subscribing systems. These systems must replace the
1690 current code set by the new one. Codes which have been removed from the code set are not to be used by the receiving system any more. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes may be used from the effective date/time given in the transaction.

Use case 2: a single battery, a single test or a single observation is added, removed or changed by
1695 the Code Set Master. The full code set is not sent to the subscribers but only those parts which describe the changes.

Use case 3: upon receipt of an unknown code, the receiver queries the Code Set Master for the full details associated with the code.

The IHE Laboratory Technical Framework currently only supports Use case 1. The other use
1700 cases may be added to later versions of this profile.
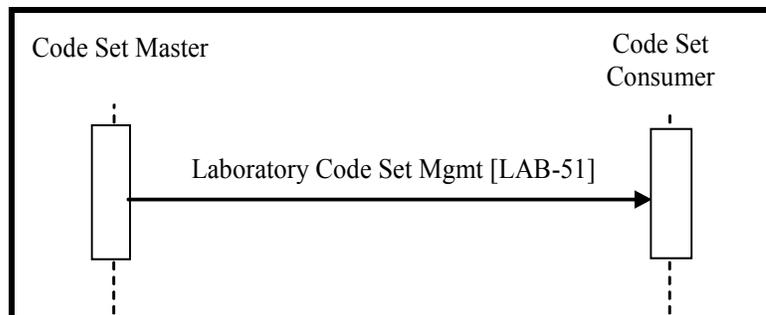
Figure 8.4-1: Basic Process Flow in the Laboratory Code Set Distribution Profile

9 Sharing Laboratory Reports (XD-LAB)

1705 This Content Integration Profile describes a laboratory report as an electronic document to be published towards a document sharing resource such as an Electronic Health Record (EHR) or in Personal Health Record (PHR) shared by a community of care providers, using one of the document sharing profiles defined in ITI-TF.

Such an electronic document contains the set of releasable results produced by a clinical
1710 laboratory or by a public health laboratory in fulfillment of one or more test Orders for a patient. The report is shared in a human-readable format. In addition, this electronic laboratory report SHALL contain test results in a machine-readable format, to facilitate the integration of these observations in the database of a consumer system.

The scope covers all laboratory specialties except anatomic pathology.

1715 The human rendering of the laboratory report defined in this Integration Profile is compatible with laboratory regulations in numerous countries, including CLIA in the USA, GBEA in France.

The laboratory report described in this profile, with its set of test results in a machine-readable format, may also be used to share historical results with appropriate content anonymization and
1720 patient identification pseudonimization to create shared distributed repositories of laboratory information.

9.1 Use cases

9.1.1 Hospital physician feeding the patient record of an affinity domain

During his stay in a hospital, patient John Smith has had several clinical laboratory orders. At
1725 discharge time, a hospital physician selects the most significant reports produced by various facilities, including lab reports, and issues these reports individually to a health information exchange (e.g., XDS Affinity Domain) shared by a number of healthcare enterprises and primary care providers. Thus later on, during a new episode of care, the care provider of John Smith (e.g., his family doctor) will be able to access the previous lab reports of the patient through a
1730 health information exchange (e.g., XDS Affinity Domain).

In this example, the electronic laboratory report is produced by the system that played the role of Order Result Tracker, and sent to the external health information exchange upon request from the medical staff preparing the discharge summary.
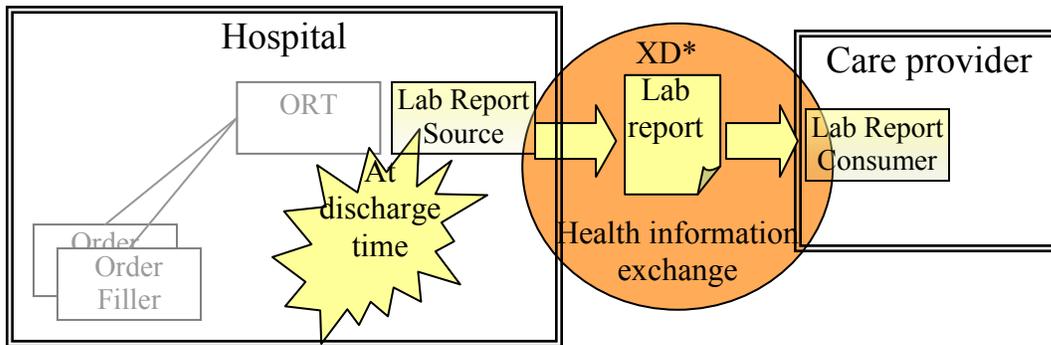
9.1.2 Private laboratory feeds the patient record of an affinity domain

Patient Jane Smith with a suspected urinary infection has been sent by her family doctor to any private laboratory downtown, with an order for a CBC and a urine microscopy and culture. Jane Smith enters into the nearest laboratory with a urine specimen, sees a phlebotomist who collects a venous blood specimen from her, and then leaves the laboratory. In this laboratory all the work on the request (hematology and microbiology) is reported together. Two days later the clinical laboratory addresses its paper report to Jane's family doctor (outside of this use case) and in the same time sends this report in an electronic format to the national EHR to feed the record of Jane Smith.
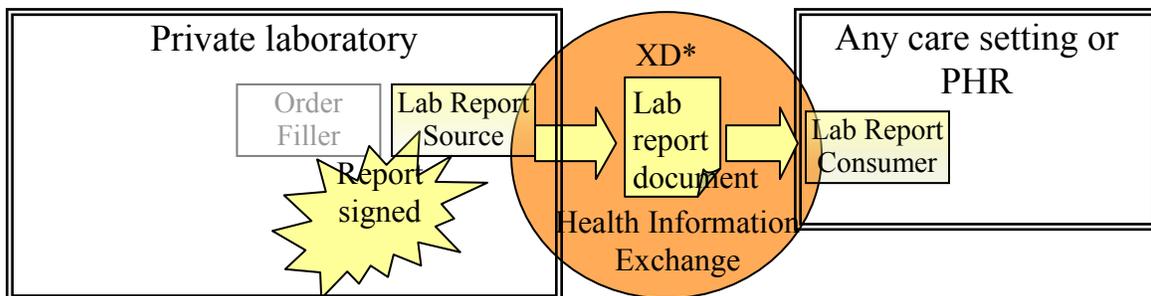
9.1.3 Ambulatory physician shares a lab report in an affinity domain

Patient Jane Smith, with a suspected urinary infection is seen by her family doctor who collects a urine sample and sends it to a reference laboratory with an order for a urine microscopy and culture. The laboratory returns the tests results (outside of this use case) to the family doctor who reviews the results, and notifies Jane Smith of her treatment. The doctor, as requested by Jane Smith, shares this laboratory report in Jane's personal health record in an electronic format.
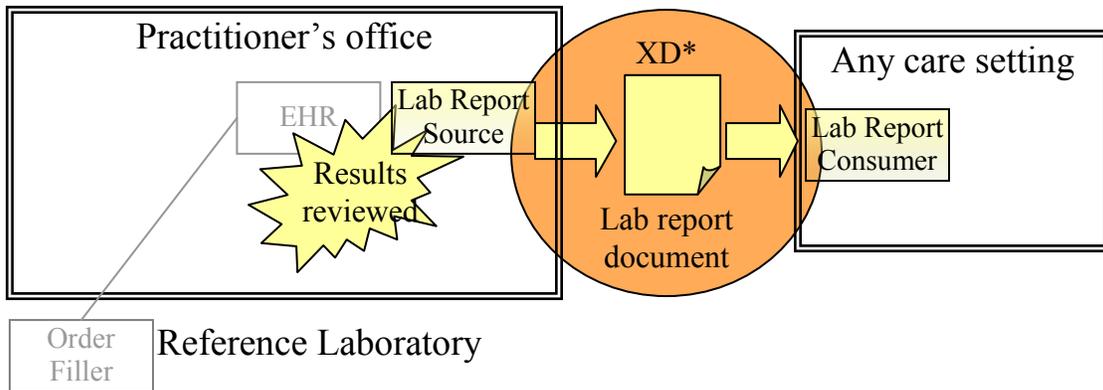
9.1.4 Reports systematically shared by a private or hospital lab

A community or hospital laboratory, systematically (with some degree of automatism) shares its
1755   reports with a regional healthcare network. The trigger event for this is the decision to issue any
releasable laboratory report, at which point a copy is sent to the regional healthcare network
repository.
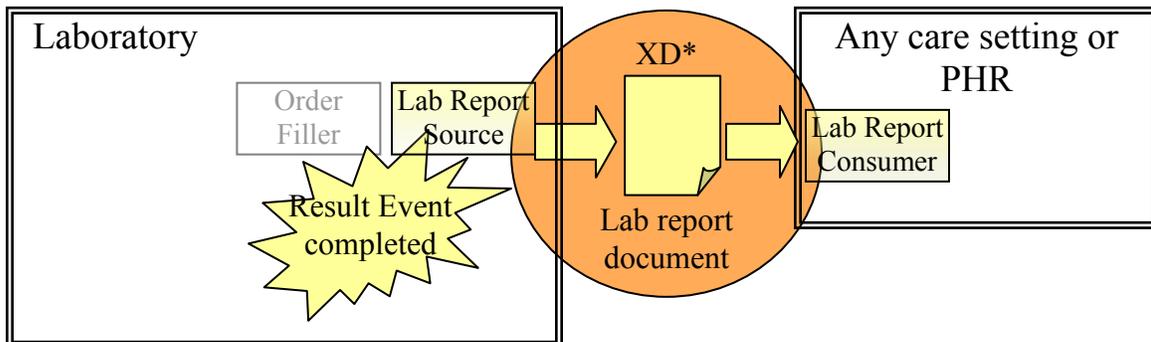
1760   ### 9.1.5 Cumulative report built and shared at discharge time

At discharge time of an inpatient, a hospital physician selects the most significant lab results,
produced by one or more laboratories of the healthcare enterprise, and builds a cumulative report
sent to a health info exchange shared by a number of healthcare enterprises and primary care
providers. This cumulative report aggregates the observations related to one or more order
1765   groups. It is made available to anybody having access to the EHR, for instance the patient's
family doctor.
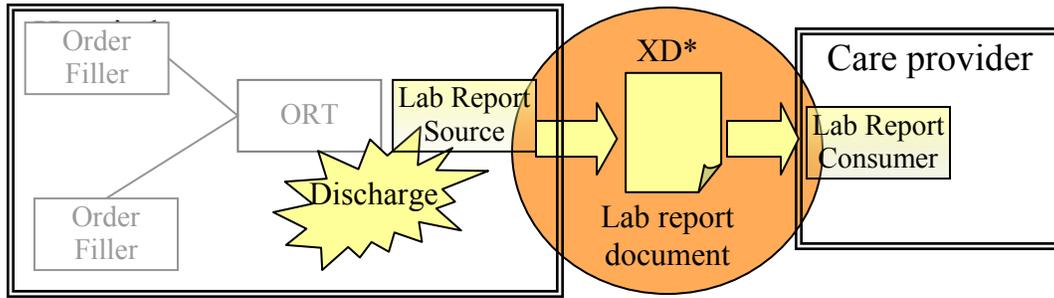
1770   Note 1: A Content Integration Profile for discharge summaries will be built by PCC domain. This use case and the cumulative laboratory report it carries, is intended for deployment where the PCC discharge summary is not utilized. It is not a replacement for a full multi-disciplinary discharge summary. The structure of the body of a cumulative laboratory report is also candidate to be used as the laboratory results section of a PCC discharge summary.

1775   Note 2: This cumulative laboratory report may be produced at other times than discharge time (e.g., Multi-Disciplinary Team meetings, patient referral)

9.1.6 Public Health Laboratory Report
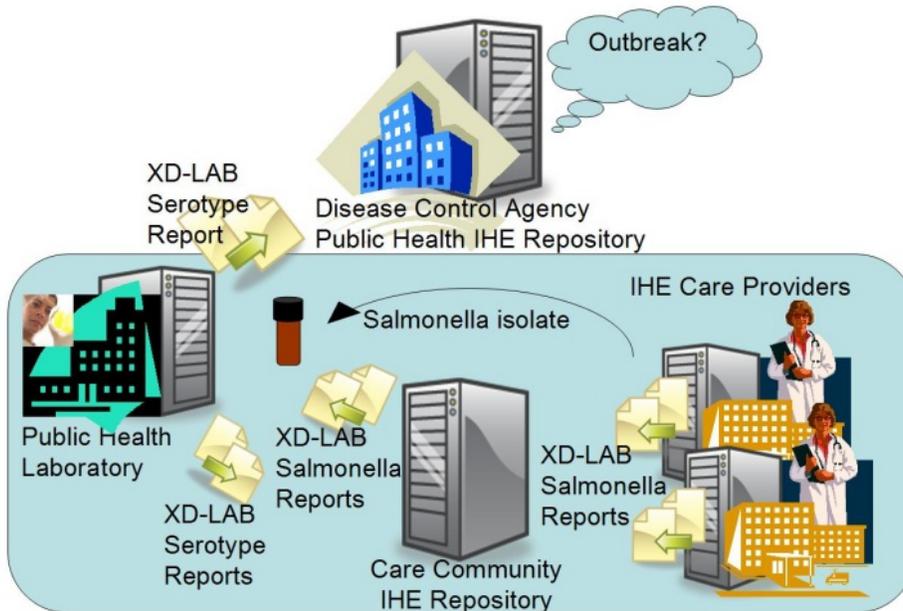
John Doe, MD, sees a patient and suspects that this patient has an enteric pathogen. The patient
1780   follows through on the doctor's orders and submits a stool specimen to the clinic's laboratory. Upon completion of laboratory analysis, the laboratory confirms the presence of Salmonella and performs susceptibility testing. When a microbiologist has time in the week, they gather all the reportable results and complete the forms for submission to the public health agency.

1785 Additionally, the clinical laboratory needs to submit the Salmonella specimen to the public health laboratory for serotyping and outbreak surveillance. This specimen is mailed along with a hand written requisition to the public health laboratory for epidemiological serotyping.

Preconditions: The clinical laboratory creates a laboratory report identifying the organism as a Salmonella isolate and that further serotyping will be done at the Public Health Lab. The
1790 laboratory report is sent to the clinician, stored within the patient's electronic medical record, and registered in a clinical interoperability registry. The isolate is mailed to the public health lab.

Events: Upon arrival, the public health laboratory receiving department queries the clinical interoperability registry with the submitter's patient ID and views the initial laboratory report.
1795 The public health laboratory information system pulls forward the patient's demographic and specimen data from the initial laboratory report. The public health laboratory creates a new laboratory report identifying the Salmonella serotype. This report is sent to the clinician, stored within the patient's electronic medical record, registered in the clinical interoperability registry, registered in the regional public health interoperability registry, and registered in the national
1800 public health interoperability registry.

The Disease Control agency monitors the national public health registry for new cases of Salmonella. An anomaly is immediately detected in the number of new cases for this particular Salmonella serotype when observed across regional surveillance boundaries and an outbreak protocol is started immediately to investigate the potential cross-border outbreak. The Disease
1805 Control agency requests PFGE (pulse field gel electrophoresis) on the current samples and alerts all public health laboratories to perform PFGE on new samples of this serotype. The outbreak is confirmed quickly and new cases are identified and tracked seamlessly.

Post conditions: Local, regional, and national epidemiologists and case workers have access to
1810 all laboratory reports within their respective interoperability registries and may potentially gain further access to the clinical interoperability registry for additional information, such as the ordering provider and care location, for initiating further investigation.

Key improvements include:
1815 • avoid handwritten forms and data re-entry

• ease transition of data to and from clinical care and public health agencies

• ease transition of data from one public health agency to another

• monitor registries for anomalies in a real-time basis

• response protocols focus on response, not the access to data
1820
Laboratory reportable conditions can be specified at local and national levels. Common laboratory criteria diagnostic of a reportable condition include (but are not limited to):

• Anthrax - Bacillus anthracis

• Botulism - Clostridium botulinum

1825
- Brucellosis - Brucella species
- Campylobacter
- Chlamydia trachomatis
- Cholera - Vibrio cholerae
- Dengue Fever - Dengue virus

1830
- Diphtheria - Corynebacterium diphtheriae
- Escherichia coli O157:H7
- Giardiasis - Giardia lamblia
- Gonorrhea - Neisseria gonorrhoeae
- Haemophilus ducreyi

1835
- Hepatitis virus
- Herpes Simplex virus
- HIV virus
- Legionellosis - Legionella pneumophila
- Leprosy - Mycobacterium leprae

1840
- Leptospirosis - Leptospira
- Listeriosis - Listeria monocytogenes
- Lyme Disease - Borrelia burgdorferi
- Malaria - Plasmodium species
- Measles virus

1845
- Meningococcal Disease - Neisseria meningitidis
- Mumps virus
- Pertussis - Bordetella pertussis
- Plague - Yersinia pestis
- Psittacosis - Chlamydia psittaci

1850
- Rabies virus
- Rickettsia - Rickettsia rickettsii
- Rubella virus
- Salmonella
- Shigella

1855
- Schistosomiasis
- Syphilis - Treponema pallidum
- Tuberculosis - Mycobacterium tuberculosis

9.1.7 Outstanding use cases

Sharing laboratory reports supports a majority of preliminary and final laboratory reporting
1860 requirements. Specifications for how to report appended, edited, and corrected reports is

intentionally left out of scope with the expectation of addressing these requirements in a later supplement. We have identified the following use cases for consideration:

Use Case 1 – A laboratory report was issued on the wrong patient.

1865   *Today two documents shall be issued. For the wrong patient, the previous report shall be deprecated and replaced by a new laboratory report communicating the error and negating the results. For the correct patient, a new laboratory report shall be approved. The specification to communicate error and negate results has been left out of scope of the current specification.*

Use Case 2 – A laboratory report was issued with incomplete or incorrect non-result data,
1870   defined as the information found in the CDA Header or specimen information, such as the collection date and time. The results and interpretation are unchanged by the addition, edit, or correction of non-result data.

Use Case 3 – A laboratory report was issued with incomplete or incorrect non-result data. The results and interpretation are changed by the addition, edit, or correction of non-result data.

1875   Use Case 4 – A laboratory report was issued with incomplete or incorrect result data, defined as the information found in an observation, organizer, or multimedia.

Use Case 5 – A laboratory report was issued with incomplete or incorrect non-result and result data.

Today in use cases 2-5 the previous report is deprecated and replaced by a new laboratory
1880   *report communicating the update that was made and related additions/corrections to results and/or interpretation. The specification to express what exact data was corrected, added or negated in the new report, for traceability and patient safety purpose, has been left out of scope of the current specification.*

9.2 Actors and Transactions for the XD-LAB Integration Profile

1885

This section references two other IHE Technical Frameworks:

- IT Infrastructure Technical Framework
- PCC Technical Framework

Both are available here: http://www.ihe.net/Technical_Framework/.

9.2.1 Actor/Transaction Relationships

1890

There are two actors in this profile, the Content Creator and the Content Consumer.

Content Creator   A Content Creator Actor is responsible for the creation of content and transmission to a Content Consumer.

Content Consumer   A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor

1895

Content (i.e., a laboratory report) is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor.

1900

The sharing or transmission of laboratory reports or updates from one actor to the other is addressed by the use of appropriate Content Bindings with XDS, XDM and XDR Integration Profiles, described in Volume 3 of the Laboratory Technical Framework.

1905
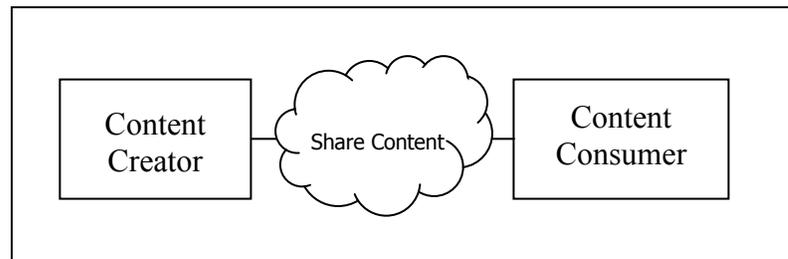
Figure 9.2.1-1: XD-LAB Actor Diagram

9.3 XD-LAB Integration Profile Options

Table 9.3-1 summarizes the options that actors may take for this Integration Profile. Dependencies between options when applicable are specified in notes. These options are summarized below the table, and further detailed in PCC Technical Framework Volume 2 as indicated in the rightmost column.

1910

Table 9.3-1: Actors and Options

Actor	Options	Domain, Vol. & Section
Content Consumer	*View Option (1)*	PCC TF-2:3.4.1.1
	Document Import Option (1)	PCC TF-2:3.4.1.2
	Section Import Option (1)	PCC TF-2:3.4.1.3
	Discrete Data Import Option (1)	PCC TF-2:3.4.1.4

Note 1: The Actor shall support at least one of these options.

9.4 Content Bindings with XDS, XDM and XDR

It is expected that the sharing of laboratory reports will occur in an environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).

- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.

- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.

- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework

Such an infrastructure is assumed by the use cases described in this Profile.

A content binding describes how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. The Sharing Laboratory Reports Profile applies one binding, which is used when grouping the Content Creator with the IHE ITI XDS, XDM or XDR Integration Profiles.

The content and the binding are described in Volume 3 of the IHE Laboratory Technical Framework.

9.5 Relationship of XD-LAB with other Integration Profiles

Relationships among IHE Integration Profiles exist when implementation of one integration profile is a prerequisite for achieving the functionality defined in another integration profile.

9.5.1 Links with Workflow messaging

Table 3.3-1, in section 3.3 of this volume 1, lists the dependencies of the profiles of the Laboratory Technical Framework.

9.5.1.1 Links with the IHE Laboratory Testing Workflow

The laboratory report is built with a set of releasable results. The report may be preliminary or final. Further updates of this report SHALL be supported (e.g., replacement by a new version of the report).

When the report is published by a hospital, the Content Creator Actor MAY be coupled with either Order Filler or Order Result Tracker actor, depending on the use case.

9.5.2 Relationships with other IHE Domains

The dependencies of XD-LAB profile require that each actor of XD-LAB be grouped with one or more actors supporting other integration profiles.

- Content Creator SHALL be grouped with XDS Document Source or XDM Portable Media Creator or XDR Document Source.
- Content Consumer SHALL be grouped with XDS Document Consumer or XDM Portable Media Consumer or XDR Document Recipient.
- Both Content Creator and Content Consumer SHALL be grouped with Time Client from CT profile and Secure Node from ATNA profile.

Appendix A: Actor descriptions

Analyzer: An automated instrument that performs testing on biological specimens upon request from the Automation Manager managing this instrument. Each request for testing on a specimen sent by the Automation Manager to the Analyzer is called an Analytical Work Order Step (AWOS). The instrument sends back to the Automation 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 Manager. This actor is involved in the LDA 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.

Code Set Master: A system which owns (is responsible for the maintenance of) one or several code sets. This system may be a LIS, a CIS, a HIS, a LAS or an Enterprise Common Repository. Code sets can be sent on a routine basis (e.g., every week) or every time the code set changes. A code set may contain battery, test and observation codes. This actor is involved in the LCSD profile.

Code Set Consumer: A system which receives code sets from Code Set Master(s) and updates its internal tables to reflect the code set as maintained by the Code Set Master. This actor is involved in the LCSD profile.

Content Consumer: An application responsible for viewing, importing, or other processing of content created by a Content Creator Actor. This actor is involved in the XD-LAB profile to consume laboratory reports.

Content Creator: An application responsible for the creation of content and transmission to a Content Consumer. This actor is involved in the XD-LAB profile to issue laboratory reports for sharing purpose.

Label Broker: A robotic system delivering and identifying the containers required for the specimens collection related to an Order or an Order Group for a patient. This system receives its instructions from another system called the Label Information Provider. This actor is involved in the LBL profile.

Label Information Provider: An information system owning the specimen labeling instructions related to an Order or an Order Group, and sending these instructions to a Label Broker. This actor is involved in the LBL profile.

Order Filler: A system used by a laboratory, that receives test orders from Order Placer actors, collects or controls the related specimens, accepts or rejects the order, schedules work orders, and sends them to one or more Automation Managers, receives the results from each Automation

2000   Manager, performs the clinical validation, appropriately manages all state changes of the order and sends the results to the Order Result Tracker(s). In some cases, the Order Filler will create test orders itself (e.g., a paper order received by lab from a department not connected to an Order Placer, or a paper order was received from a physician external to the organization, or a reflex order generated by the laboratory). In some cases the Order Filler is responsible for collecting and identifying the specimens. An Order Filler may receive test orders from more than one Order

2005   Placer in the institution and may send the order results to more than one Order Result Tracker. In organizations supporting point of care testing, this actor is also involved in the LPOCT profile to upload the point of care observations to the designated laboratory in charge with the supervision of the process. This actor is involved in the LTW and LPOCT profiles.

2010   In the LPOCT Integration Profile this actor receives the point of care observation sets from the POCDM, and stores them within orders, either matched or generated for the occasion. These POCT orders are also submitted to clinical validation, and are archived for quality assurance and responsibility purposes only, since they have already been used by the medical staff in its care decisions. The clinical validation process triggers the sending of these results to the Order Result Tracker, using transaction Order Results Management LAB-3 of profile LTW. POCT orders are

2015   associated to orders on the Order Placer side by means of transactions Placer Order Management LAB-1 or Filler Order Management LAB-2 of profile LTW.

Order Placer: A system that generates test Orders and Order Groups for various clinical laboratories, places each of these to the correct laboratory, and appropriately manages all state changes. In some cases the Order Placer is responsible for identifying the specimens. Therefore,

2020   the transaction between Order Placer and Order Filler may carry specimen related information. There may be more than one Order Placer actor in a healthcare institution. In organizations supporting point of care testing, this actor is also identifying the point of care test orders, either before testing or after it is done, upon request from the Order Filler. This actor is involved in the LTW profile.

2025   **Order Result Tracker**: A system that stores laboratory observations obtained for the patients of the healthcare institution, registers all state changes in the results notified by Order Fillers. This actor stores observations the context of their Order or Order Group. This actor is involved in the LTW profile.

2030   **Point Of Care Data Manager (POCDM)**: A system managing a set of POCRG and centralizing their results. The POCDM is ready to react to any conversation from a POCRG. The POCDM receives point of care observations from POCRG actors. It controls these observations within their context, stores them and forwards them to the Order Filler.

The POCDM is supporting the technical review (technical validation) of the results.

The POCDM offers features to control the activity of its set of POCRG.

2035   It stores the quality control results of each POCRG and supervises this QC on all POCRG.

The POCDM lets the authorized staff configure its application, and its related set of POCRGs.

Point Of Care Results Generator (POCRG): A system that produces results by automatic measure, manual entry or calculation. It identifies the results with the related patient or QC specimen ID, the operator who performs the tests, the ordering provider and the care unit. It

2040   sends this information to the POCDM.

In addition, the POCRG is able to send its internal process control information to the POCDM.

Pre/Post-Processor: An automated device that performs some elementary steps on biological specimens upon request from the Automation Manager managing this device. Each request for a step on a specimen sent by the Automation Manager to the Pre/Post-Processor is called a

2045 Specimen Work Order Step (SWOS). The instrument sends back to the Automation Manager the status of the operation. Examples of Pre/Post-Processors are sorters, aliquoters, decappers, recappers, specimen conveyors, specimen storage systems. This actor is involved in the LDA profile.

Appendix B: Transaction descriptions

2050

[LAB-1] Placer Order Management: This transaction provides all the messages needed between the Order Placer and the Order Filler Actors for the management of the life cycle of an Order Group or of a standalone Order. Its main goal is to keep a consistent vision of the Order, (content and status), between these two Actors.

2055 **[LAB-2] Filler Order Management**: This transaction provides the messages needed between the Order Filler and the Order Placer to allocate a new Placer Order Number to an Order created on the laboratory side by the Order Filler application.

[LAB-3] Order Results Management: This transaction carries the results of an Order, as well as status changes, modifications, cancellations of these results, from the Order Filler to
2060 the Order Result Tracker. Optionally, it may provide a facsimile of the report presenting the results of the Laboratory Request.

[LAB-4] Work Order Management: This transaction provides the messages needed between Order Filler and Automation Manager Actors for the execution of a Work Order by the latter. The goal of this transaction is to distribute the work to the Automation Manager,
2065 and to keep this Actor informed of all updates happening to the patient related to that Work Order.

[LAB-5] Test Results Management: This transaction carries the technically validated test results obtained for a Work Order, as well as status changes, modifications, cancellations of these results, from the Automation Manager to the Order Filler.
2070 **[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.
2075 **[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.
2080 **[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.

2085 **[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"…

[LAB-30] Initiates point of care testing for a patient specimen. This transaction is used on a
2090 persistently connected POCRG: A POCRG sends to the POCDM a message containing its own ID, the care unit ID, the ordering provider ID, the operator ID, the patient/visit ID (or QC ID) and other information related to the test to start. The POCDM identifies the operator, and checks the patient identification (not in case of QC). It then sends the answer back to the POCRG. The answer may be positive and carry the patient's identity
2095 (unless in case of QC), or negative and carry the reject reason.

[LAB-31] **POCT observations produced**. The POCRG sends an observation set to the POCDM. The POCDM checks the content of this observation set, stores it and acknowledges it to the POCRG.

[LAB-32] POCT observations accepted. The POCDM sends an observation set completed with
2100 the patient information, to the Order Filler. The Order Filler acknowledges it. The acknowledgement carries the filler order number attributed to this observation set.

[LAB-51] Laboratory Code Set Management: Code set distribution (battery, test, observation).

[LAB-61] Label delivery request: This transaction contains the messages for label delivery
2105 sent by the Label Information Provider to the Label Broker. These messages include the Label information, patient information and specimen information.

[LAB-62] Query for label delivery instruction: This transaction contains the message used by the Label Broker to query the Label Information Provider with a patient identification, and the response message sent back by the Label Information Provider, including the
2110 label information, patient information and specimen information.