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Integrating the Healthcare Enterprise

IHE Laboratory Technical Framework Supplement 2004-2005

10

Laboratory Information Reconciliation (LIR)

Public Comment Version

June 15, 2005

Comments due July 15, 2005

Foreword

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 established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. IHE maintain formal relationships with several standards bodies including HL7, DICOM and refers recommendations to them when clarifications or extensions to existing standards are necessary.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Francaise de Radiologie (SFR), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), and the European Society of Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

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

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

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

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

Comments shall be submitted before July 15, 2005 on the "Public Comment Lab Supplement" sheet, addressed by email to:

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The IHE Laboratory Technical Committee will address these comments and publish the Trial Implementation version in November 2005.

Document production

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Introduction

Laboratory Information Reconciliation (LIR) is a new integration profile added to Volume I of the IHE Laboratory Technical Framework in 2005. As LIR implements only transactions already created and described in the LSWF or the LDA, no new transaction is associated with this profile; consequently therefore there is no need to add new descriptions and chapters to Volume II of the IHE Laboratory Technical Framework.

Open Issues and Questions

- Where a patient is not known to the healthcare system and orders are entered directly by the Order Placer (OP) then it is logical for the OP to initiate ADT transactions. However, in many implementations this information is 'mastered' by the ADT actor and subordinate systems are not trusted to initiate ADT patient demographic updates.
- How can the OF update the patient details through an OML message?? How does the AM understand that it is a Pt update??

Closed Issues

- Case 3: in case of Work Order created by the AM, LAB 5 could not be possible if the Technical validation is not performed due to patient information absence.
  The **solution** is to send the results to the OF which will perform both technical and clinical validation.

Profile Abstract

The Laboratory Information Reconciliation profile seeks to extend the Laboratory Scheduled Work Flow to permit the management of special cases that are commonly treated every day by the laboratory staff (such as the trauma cases, the unidentified or misidentified patient analysis and the unsolicited test results).

This profile offers the possibility to match the clinical lab observations, produced on specimens collected from misidentified or unidentified patient, with the correct patient's record. This could happen in a typical trauma case when the proper patient details are not available and some temporary general information is entered into an ADT.

This profile also deals with the urgent lab analyses that cannot be requested of the laboratory because neither real nor temporary patient information is available in the main actors (ADT, OF, OP).
By means of this profile unsolicited clinical lab observations, produced on specimens, and orders created afterwards can be matched in the AM or in the Order Filler application and then shared with the Order placer and the Order Result Tracker systems.
Finally this integration profile is designed to support the reconciliation of the patient record with lab results that are produced (either without a prior registration or under a generic registration) before the patient's identity can be determined. Thus, observations can be produced, validated, immediately used and then, when the patient's official registration and order information is entered into the laboratory main actors, the identity information is matched with the previously obtained result set.

GLOSSARY

LDA: Laboratory Device Automation profile

LIR: Laboratory Information Reconciliation profile

LIS: Laboratory Information System

LSWF: Laboratory Scheduled Work Flow profile

ADT: Admit, Discharge, Transfer

OP: Order Placer

OF: Order Filler

AM: Automation Manager

ORT: Order Result Tracker

LD: Laboratory Device

Volume I – Integration Profiles

<This section describes the changes required in Volume I of the Technical Framework that result form including this Integration Profile.>

Changes to Sections 1 – 1.X

<Include a subsection for each section/ subsection changed>

1.6 History of Annual Changes

Add the following bullet to the end of the bullet list in section 1.7

- Added the Laboratory Information Reconciliation Profile which extends the LSWF and the LDA to what can be considered as the Unscheduled Work Flow. Misidentified or unidentified patients can have their analysis performed and unordered analyses can be executed in case of urgency.

2.1 Scope

Add the following text somewhere at the end of paragraph:

The LIR profile deals with unexpected but typical situations in which the patient is not correctly registered in the hospital information system or is not present at all so that no order can be created to require a lab analysis. This profile solves most of the cases that cannot be managed by the LSWF because they are considered "unscheduled workflow".

2.3 Integration Profiles overview

Add the following line to the existing table:

Integration Profile	Depends on	Comments
Laboratory Information Reconciliation	Laboratory Scheduled Workflow	Laboratory Information Reconciliation is an extension to this profile requiring that the process be completely supported.
	Laboratory Device Automation	Laboratory Information Reconciliation relies on all the transactions of LDA.

2.4 Actors in Laboratory Technical Framework

NO new actor is needed by the profile but some extra information should be added to some actors

Add the following lines to the AM

The Automation Manager can match unexpected results produced by an analyzer with the appropriate incoming Work Order, or create a new Work Order to fit the unsolicited observations and send them to the OF.

Add the following lines to the OF

Only in the case of urgent analyses, can this actor create a new patient with a local (lab identified) Id to permit the creation of a Filler Order. This local patient Id must be restricted to the laboratory domain (transactions possible only with AM) and no transactions regarding this local patient will take place with OP and ORT until such time as the patient details are entered in the ADT system and distributed by that system. At which point the enterprise identified Id is matched with the local one.

OF checks all the previously created Filler Orders or enters a new one to manage unexpected Order Results originating from AM.

X Laboratory Information Reconciliation

X.1 Use cases

X.1.1 Unidentified Patient registered at ADT

This use case seeks to give a simple but concrete solution to the very common case of the misidentified or unidentified Patient in a healthcare center. As this use case is a natural extension of chapter 3.5.3 (see LSWF), the following sub cases will describe only the most critical cases.

As the patient information is an important part of an Order, this use case can impact into two different scenarios which involve either the Placer Order or the Filler Order:

- Clinical lab tests ordered at Order Placer
- Clinical lab tests ordered at Order Filler

X.1.1.1 Clinical lab tests ordered at Order Placer.

Initial part of the scenario

a) The operator (admission staff) registers an unidentified or misidentified patient at ADT.

b) This information is transmitted to Order Placer, Order Filler and Order Result Tracker.

Middle part of the scenario

c) The operator (ward staff) enters an order at Order Placer.

d) The order is transmitted to Order Filler and then consequently to other recipients, i.e. Automation Manager and Laboratory Devices if needed.

Final part of the scenario

e) The operator (admission staff) updates patient data at ADT. During this process the patient may…
… need a correction of name, address or other known but incorrect data
⇒ Update Patient.
…be identified as a formerly known patient
⇒ Merge or link source patient Id and target patient ID

f) This information is submitted to Order Placer, Order Filler and Order Result Tracker. If specimen examination is not finished or the final results have not been returned yet, the AM shall be sent the new patient details by the Order Filler (LAB-4).

g) The recipients are required to execute the update / merge request or simply integrate their records.

NOTE 1: the LD will be forwarded the patient new details according to the AM internal rules in case a patient is updated or merged by the OF.

X.1.1.2 Clinical lab tests ordered at Order Filler.

The initial part and final part of this scenario are the same as in the previous use case. Only the middle part has a specific development:

Middle part of the scenario

c) The operator (laboratory staff) enters an order at Order Filler.

d) The order is submitted to the Order Placer which returns the placer order number. The Automation Manager is informed about the order creation.

NOTE 1: same as NOTE 1 in X.1.1.1.

X.1.2 Patient not registered at ADT.

This use case considers the situation of a ward staff or user of an order entry system that needs to create a laboratory request to have urgent analyses performed, but where the patient is not yet registered. Neither the patient Id nor details are available and consequently no order can be entered.

X.1.2.1 Clinical lab tests ordered at Order Placer.

The IHE LAB Committee assumes that there is always a patient record created by the ADT if the patient references (Id, name, date of birth, …) must be used to share information among different facilities, multiple domains or in separated healthcare units. Consequently, as the OP is not a lab specific actor but a shared multi-domain actor, no new local patient can be registered by the OP operator.

This approach avoids the risk of spreading the Id or details of a patient who is unknown to the ADT among the healthcare enterprise systems.

In order to work around this limitation, the ward staff or the lab staff may have to use the ADT application to create a patient record and then use it to insert a new lab order.

X.1.2.2 Clinical lab tests ordered at Order Filler.

In this use case there is no limitation to create a new local patient record because this local Id is restricted to the lab actors only.

The enterprise patient registration may arrive from the ADT actor at any point in time, however this is of no consequence to the workflow because the new patient details will be reconciled with the lab Id when the results are stored in OF, or during the clinical validation stage.

In this case the patient details and a filler order are reconciled within the laboratory.

Initial part of the scenario

a) Specimen of an unregistered patient must be examined.

b) The patient is registered at Order Filler with a local Id.

Middle part of the scenario

c) The operator (lab staff) enters a Filler Order into OF.

d) A Work Order is sent to the AM

e) The AM splits the Work Order into several Work Order Steps and sends them to the Laboratory Devices, i.e. Analyzers and Pre/Post Processors.

f) The Analyzer returns the test results.

g) Results are sent back to the OF.

Final part of the scenario

h) After the correct patient details have arrived, the filler order is matched with the right patient information by the lab staff or by the expert system (e.g. LIS). This step may be undertaken either before or at the same time as the clinical validation (step i).

i) The clinical validation is performed.

j) The Filler Order is sent to the OP by means of a Filler Order Management Transaction (LAB-2).

k) The Filler Order and its results are submitted to the ORT (LAB-3).

Note 1: the LAB-2 (step j) and LAB-3 (step k) transaction could take place before the clinical validation but never before the patient and the order is matched. A very strict assumption is made in this use case; no transaction towards OP or ORT can be performed unless the patient is registered by the ADT and the lab Id is correctly matched with the enterprise Id (ADT patient id).

Note 2: the local Id policy is defined within the laboratory which has sole responsibility for it. The patient Identity can have various status such as "lab identified" (= local), "enterprise identified" (= valid) or whatever the lab authority would decide.

Note 3: where the lab identified patient is matched with an enterprise identified patient (manually or automatically) then it will be a laboratory governed decision whether to transmit prior results or orders for the matched patient.

Note 4: it is strongly recommended that the local and enterprise patient reconciliation be performed after the final results have been produced. This recommendation excludes the need to inform the technical actors of lab (i.e. AM, LD) about the new patient identity and avoids a repeated LAB-4 transaction in case the matching process is not successful.

X.1.3 Clinical lab tests performed on laboratory devices before creation of the order.

Typical case of a very urgent specimen examination. The examination request can arise when the lab systems are not in an active state and so the process should start from the Laboratory Devices or, if possible, from the AM.

X.1.3.1 Starting point on the analyzer

Initial part of the scenario

a) The specimen is placed on an analyzer, with a specimen Id scanned or entered manually
b) The tests are selected by the technician

Middle part of the scenario

c) The analyzer processes the results and sends them to the Automation Manager
d) AM stores these results flagged with "results not matched with a Work Order".

Final part of the scenario: see chapter X.1.3.3

X.1.3.2 Starting point on the Automation Manager

Initial part of the scenario

a) A Work Order is created manually and flagged as "unsolicited Work Order" at the AM.

b) The specimen is placed on a Laboratory Device, which can query for a WOS (LAB-22) or wait for a WOS download (LAB-21) by the AM.

Middle part of the scenario

c) The analyzer processes the results and sends them to the Automation Manager

d) AM stores these results in the manually created Work Order.

Final part of the scenario: see chapter X.1.3.3

NOTE 1: the term "flagged" does not necessarily mean that a specific real flag has to be created for such a Work Order but, depending on the system rules, it could simply be the absence of a Placer Order Number. The final goal is the easy identification of this unsolicited Work Order.

X.1.3.3 Final part of the scenario

Once the AM has received the results from the Lab Devices, the final task is to perform a technical validation and to submit them to the OF for the clinical validation. These final steps can be performed in two different ways which are based on the usual workflow. The first approach considers the AM as a passive actor which cannot initiate a transaction without a prior OF Work Order. The second approach considers the AM as an active actor that can force the OF to produce a Filler Order although a Work Order has never arrived.

OPTIONS:

1) AM waits for the incoming Work Order

e) The OF schedules a Filler Order and produces the suitable Work Orders for AM.

f) AM receives the Work Order and matches it with the flagged stored results or Work Order.

g) AM sends the Order Results to OF which behaves in the usual way, like in LSWF, and informs both the OP and the ORT.

NOTE 1: it does not matter the way the Filler Order has been generated (by OP or internally by OF); the OF will have a new Work Order to deal with in both cases.

2) AM submits the results with no reference to a Work Order produced by OF

e) AM performs the technical validation depending on the initial part of the scenario:
- The unsolicited Work Order is technically validated as usual.
- A new Work Order is created to fit the stored results (flagged "results not matched with a Work Order"). This Work Order is validated and also flagged as "unsolicited Work Order".

f) AM sends the Order Results to OF which generates a Filler Order to permit the consequent results distributed among the actors. From this point, the procedure follows that described by the LSWF profile.

NOTE 1: As a consequence of this approach, the OUL Message from AM to OF will not carry the OBR-2 and ORC-2 fields.

NOTE 2: good practice for the OF would be the preliminary check of the already existing Filler Orders to discover if one of them can match the incoming results. This practice could avoid an unnecessary Filler Order creation.

NOTE 3: if the technical validation is not performed due to the lack of patient information, the AM will submit the results anyway, so that the technical and clinical validation will be performed by OF. In this case the PID segment of the OUL message will be absent.

X.2 Transactions / Actors

There is neither new actor nor transaction defined by this integration profile but it derives all the actors from the LSWF and the LDA profiles as displayed in figure X.2-1.

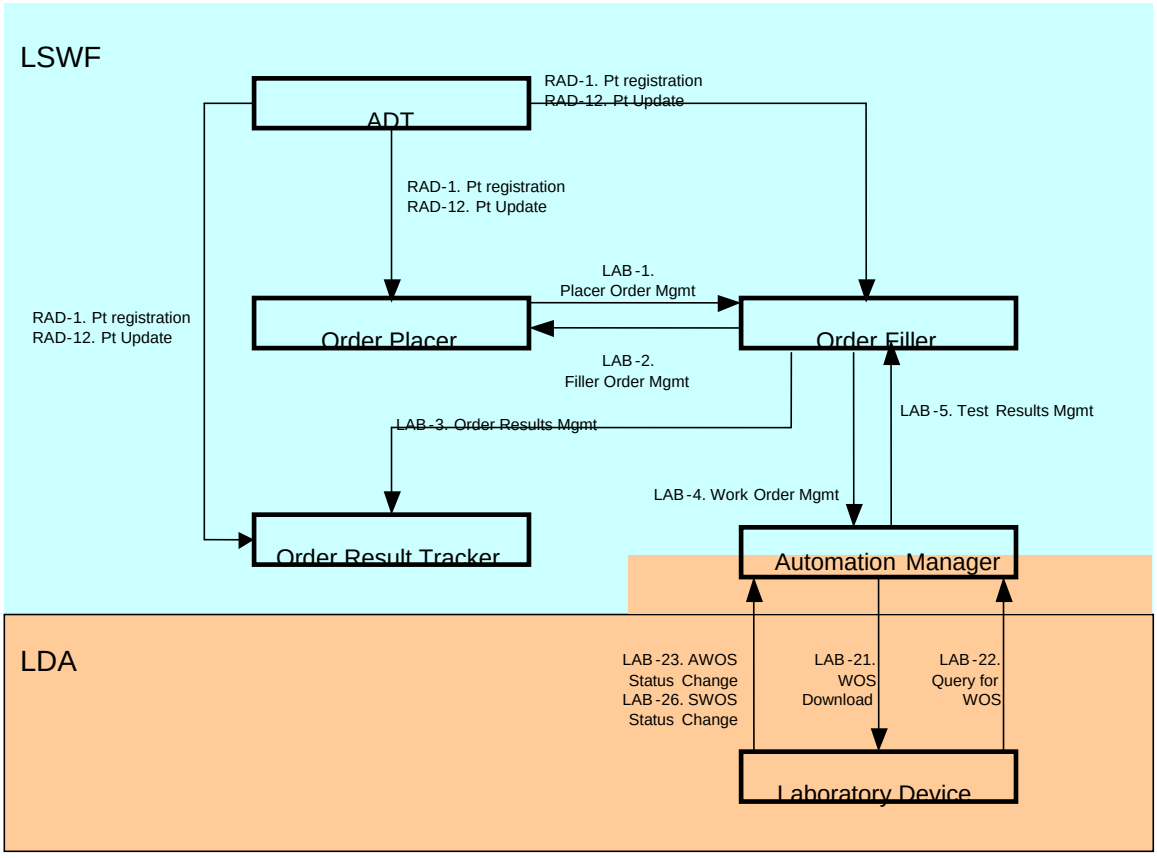

Figure X.2-1. LIR Actors and Transactions Diagram

In the LDA box the Pre/Post-processor and the Analyzer are collapsed into one unique Actor: the Laboratory Device. Consequently, in case of LAB-21 LAB-22 the collapsed actor can represent either the Analyzer or the Pre/Post-processor whereas a LAB-23 will certainly deal with an Analyzer and a LAB-26 with a Pre/Post-processor.

Although in this profile the Laboratory Device is mostly represented by the Analyzer, this general notation is preferred to take into account the possibility for the OF interacting with a Pre/Post-processor.

As the support of this profile can be claimed only if the LSWF and the LDA are contemporarily supported, the optionality on the transactions are the same as described in those profiles.

Table X.2-1 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”).

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Table X.2-1. LIR Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
ADT	RAD-1 : Patient Registration	R	Radiology TF sect 4.12
	RAD-12 : Patient Update	R	Radiology TF sect 4.12
Order Placer	RAD-1 : Patient Registration	R	Radiology TF sect 4.12
	RAD-12 : Patient Update	R	Radiology TF sect 4.12
	LAB-1 : Placer Order Management	R	Laboratory TF sect 4
	LAB-2 : Fillerer Order Management	R	Laboratory TF sect 5
Order Result Tracker	RAD-1 : Patient Registration	R	Radiology TF sect 4.12
	RAD-12 : Patient Update	R	Radiology TF sect 4.12
	LAB-3 : Placer Order Management	R	Laboratory TF sect 6
Order Filler	RAD-1 : Patient Registration	R	Radiology TF sect 4.12
	RAD-12 : Patient Update	R	Radiology TF sect 4.12
	LAB-1 : Placer Order Management	R	Laboratory TF sect 4
	LAB-2 : Fillerer Order Management	R	Laboratory TF sect 5
	LAB-3 : Placer Order Management	R	Laboratory TF sect 6
	LAB-4 : Work Order Management	R*	Laboratory TF sect 7
	LAB-5 : Test Results Management	R*	Laboratory TF sect 8
Automation Manager	LAB-4 : Work Order Management	R	Laboratory TF sect 7
	LAB-5 : Test Results Management	R	Laboratory TF sect 8
	LAB-21 : WOS Download	R	Laboratory TF sect X
	LAB-22 : WOS Query	R	Laboratory TF sect Y
	LAB-23 : AWOS Status Change	R	Laboratory TF sect W
	LAB-26 : SWOS Status Change	O	Laboratory TF sect Z
Laboratory Device	LAB-21 : WOS Download	O	Laboratory TF sect X
	LAB-22 : WOS Query	O	Laboratory TF sect Y
	LAB-23 : AWOS Status Change	R	Laboratory TF sect W
	LAB-26 : SWOS Status Change	R	Laboratory TF sect Z

Note 1: See tables regarding the LSWF and the LDA

X.3 Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table X.3-1 along with the Actors to which they apply.

Table X.3-1 Evidence Documents - Actors and Options

Actor	Options	Vol & Section
ADT	*No options defined*	- -
Order Placer	*No options defined*	- -
Order Filler	*No options defined*	- -
Order Result Tracker	*No options defined*	- -
Automation Manager	*Wait for an incoming Work Order from OF to match the results*	Vol. 1 Ch. X.1.3.3 option 1
	Active submission of unsolicited results to the OF	Vol. 1 Ch. X.1.3.3 option 2
Laboratory Device	*No options defined*	- -

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X.4 LIR Integration Profile Process Flow

The workflow diagrams shown in this section represent each of the use cases described in section X.1. This is a high level work flow that tends to explain graphically what was already expressed in the referenced chapters.

X.4.1 Unidentified Patient registered at ADT. Clinical lab tests ordered at Order Placer.

This process flow is based on use case X.1.1.1.

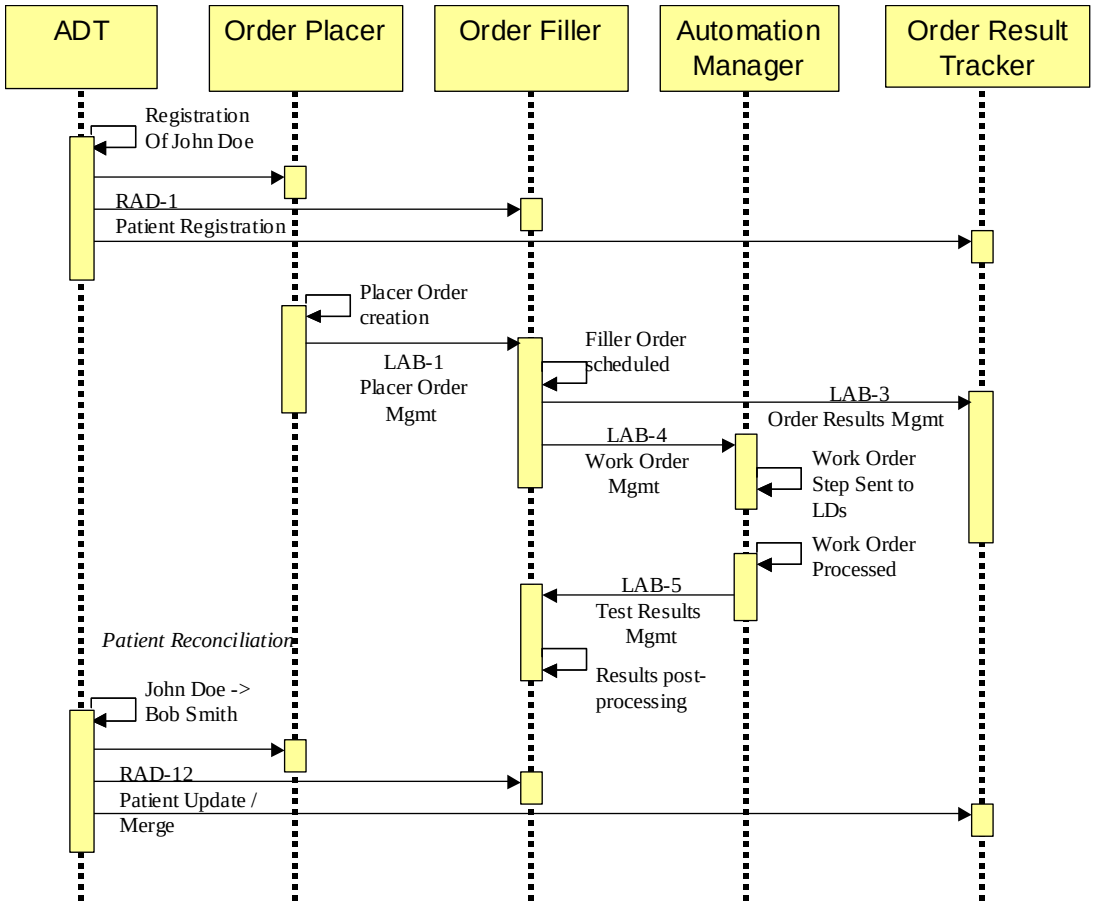

Figure X.4-1. LIR Profile: process flow for unidentified or misidentified patient

In this sequence diagram the assumption is that the Patient Update/Merge is executed after the AM has finished processing the specimen and the results are already stored with a final status (OBX11 = F or C) by the OF actor.

In case the Patient Update/Merge arrived before AM finished, this diagram would be affected exactly as described in the next section.

X.4.2 Unidentified Patient registered at ADT. Clinical lab tests ordered at Order Filler.

This process flow refers to the use case in chapter X.1.1.2.

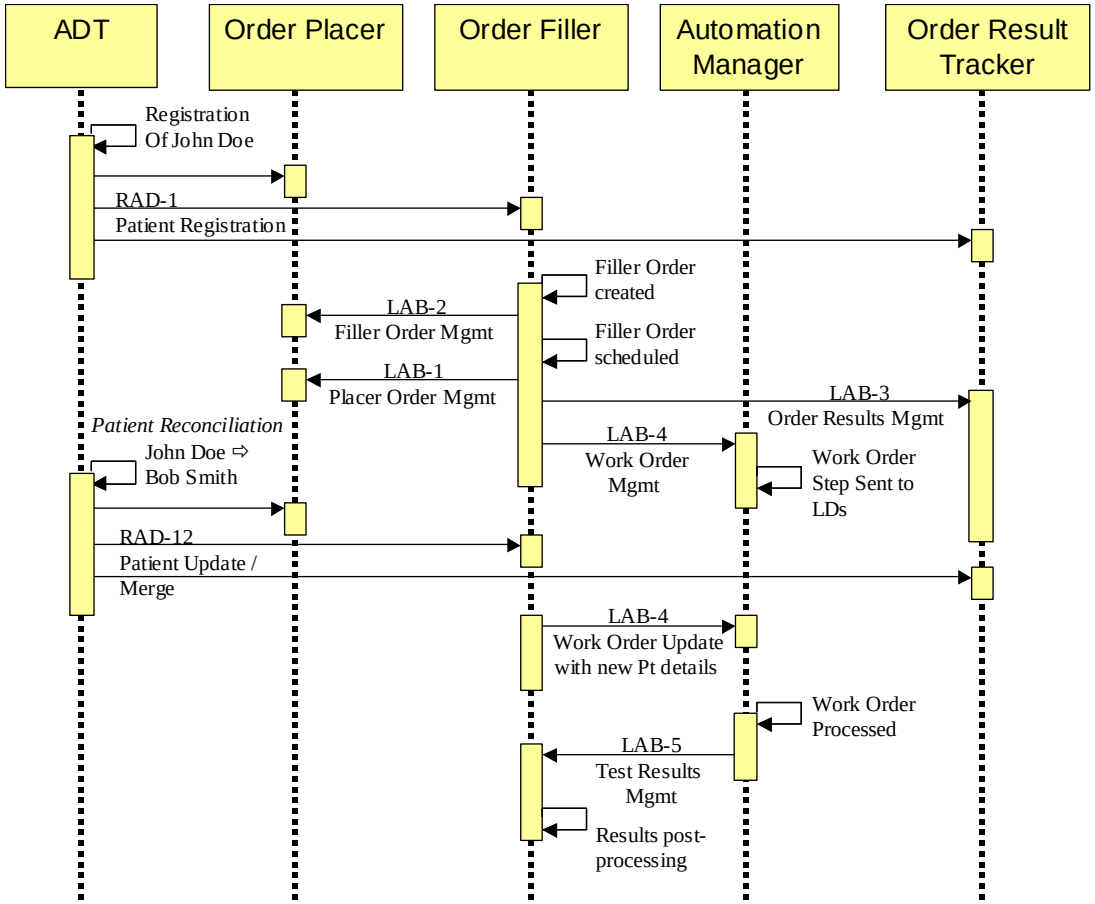

Figure X.4-2. LIR Profile : process flow for unidentified or misidentified patient

This process flow considers the case of Patient Update / Merge while the AM is still processing a specimen or the final results are missing in the OF actor.

As the AM actor is not directly connected to the ADT system, it must be informed by the OF about the new patient identity or details. Conversely, when the Work Order process is complete, the technical actors of the laboratory are no longer concerned with the patient's identity, until a new work order comes down for the same patient, with the correct identity.

X.4.3 Patient not registered at ADT. Clinical lab tests ordered at Order Filler.

This process flow is based on the use case in chapter X.1.2.2.

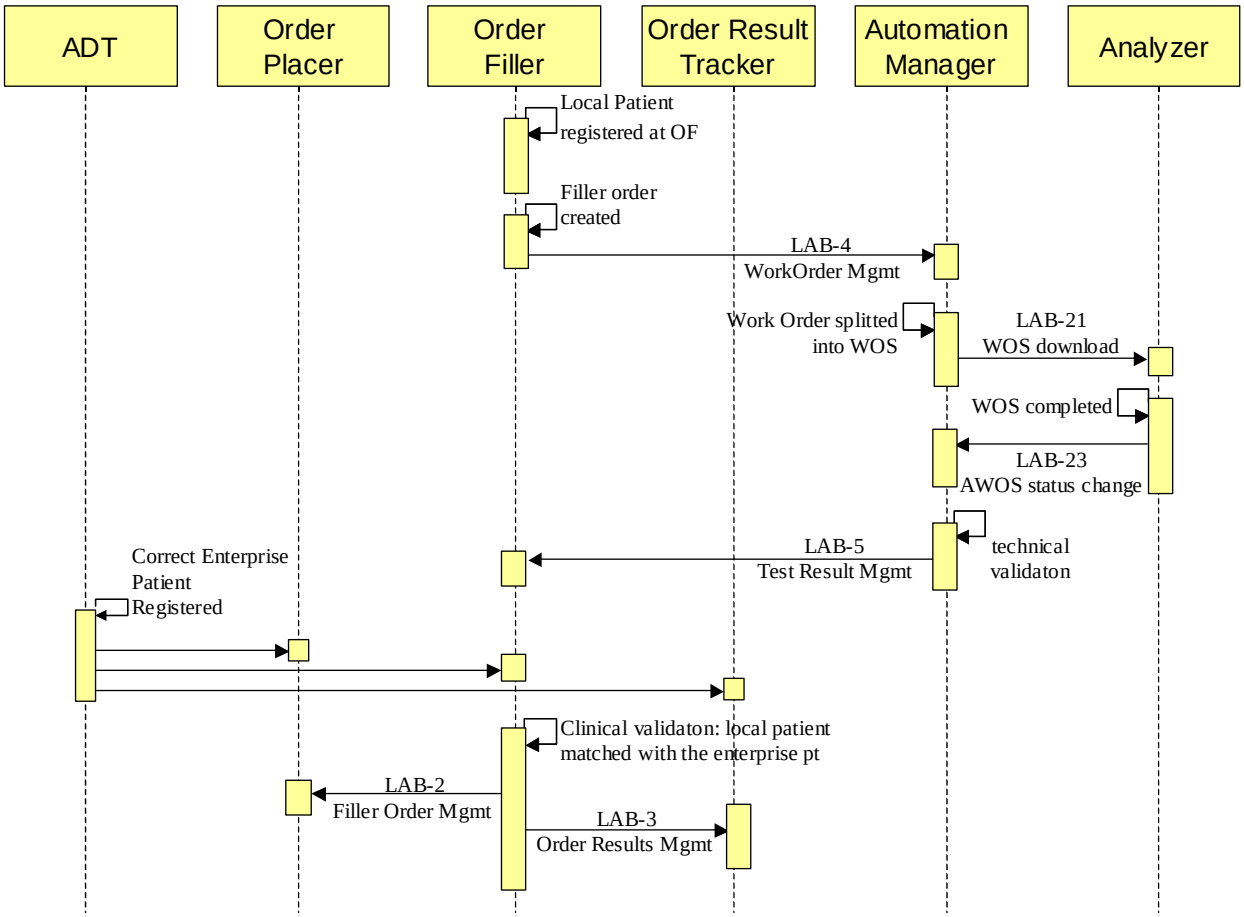

Figure X.4-3. LIR Profile : local patient Id reconciled with enterprise Id

The Analyzer could query for a WOS instead of waiting for the WOS download.

420 This sequence diagram considers a manual reconciliation of the local patient with its enterprise identity. As a human intervention is needed, the most convenient moment to reconcile could be during the clinical validation step.

X.4.4 Clinical lab tests performed on laboratory devices before creation of the order. Starting point on the analyzer

The following diagrams are based on the use case in chapter X.1.3.1 but they consider separately the two possible final parts of the scenario.

X.4.4.1 First final part of the scenario

Use case in chapter X.1.3.1 and 1st option in chapter X.1.3.3.

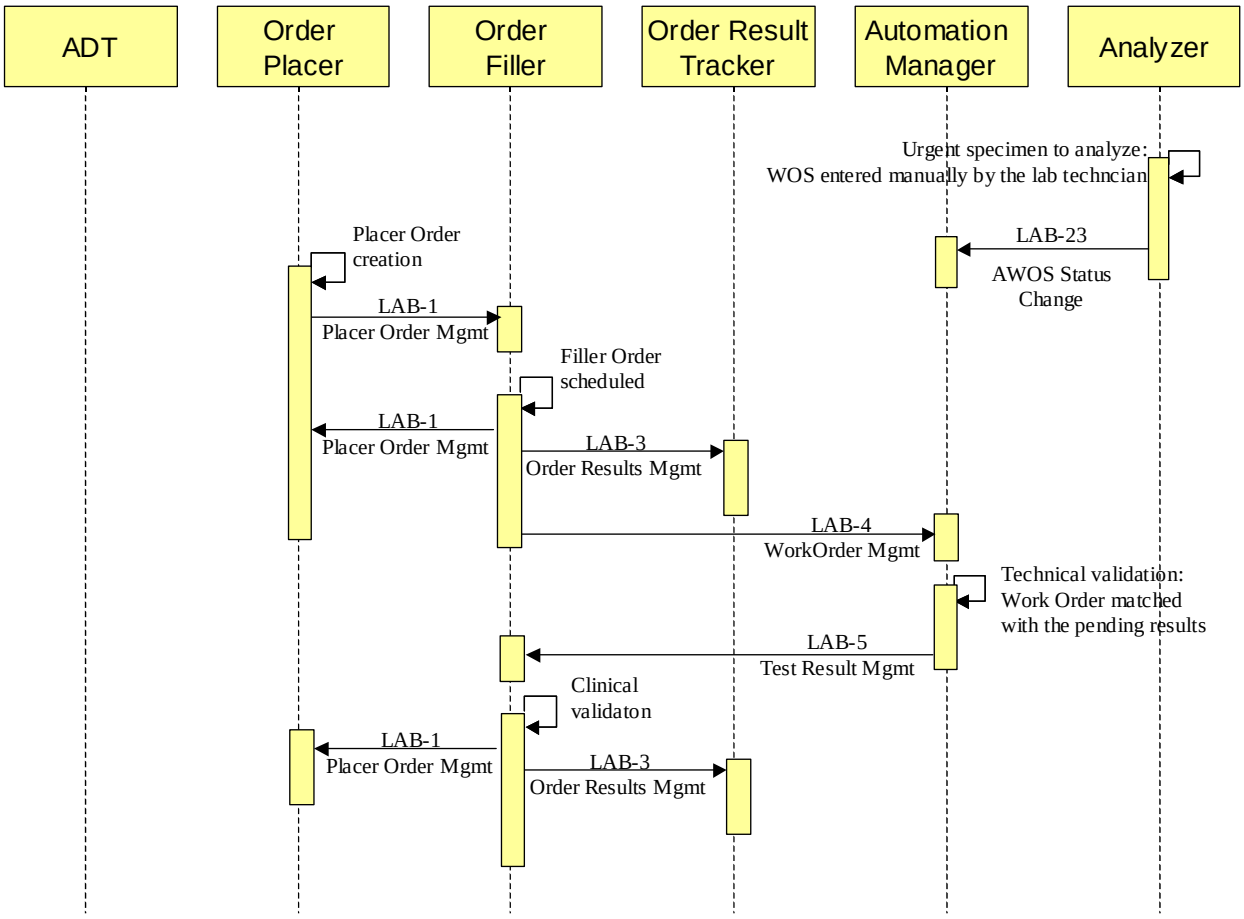

Figure X.4-4. LIR Profile: process started on Analyzer and reconciliation at AM

In this case the Filler Order is produced due to an OP request, and the 'technical validation' step is the point at which matching the pending results with the incoming Work Order is undertaken on the AM.

X.4.4.2 Second final part of the scenario

Use case in chapter X.1.3.1 and 2nd option in chapter X.1.3.3.

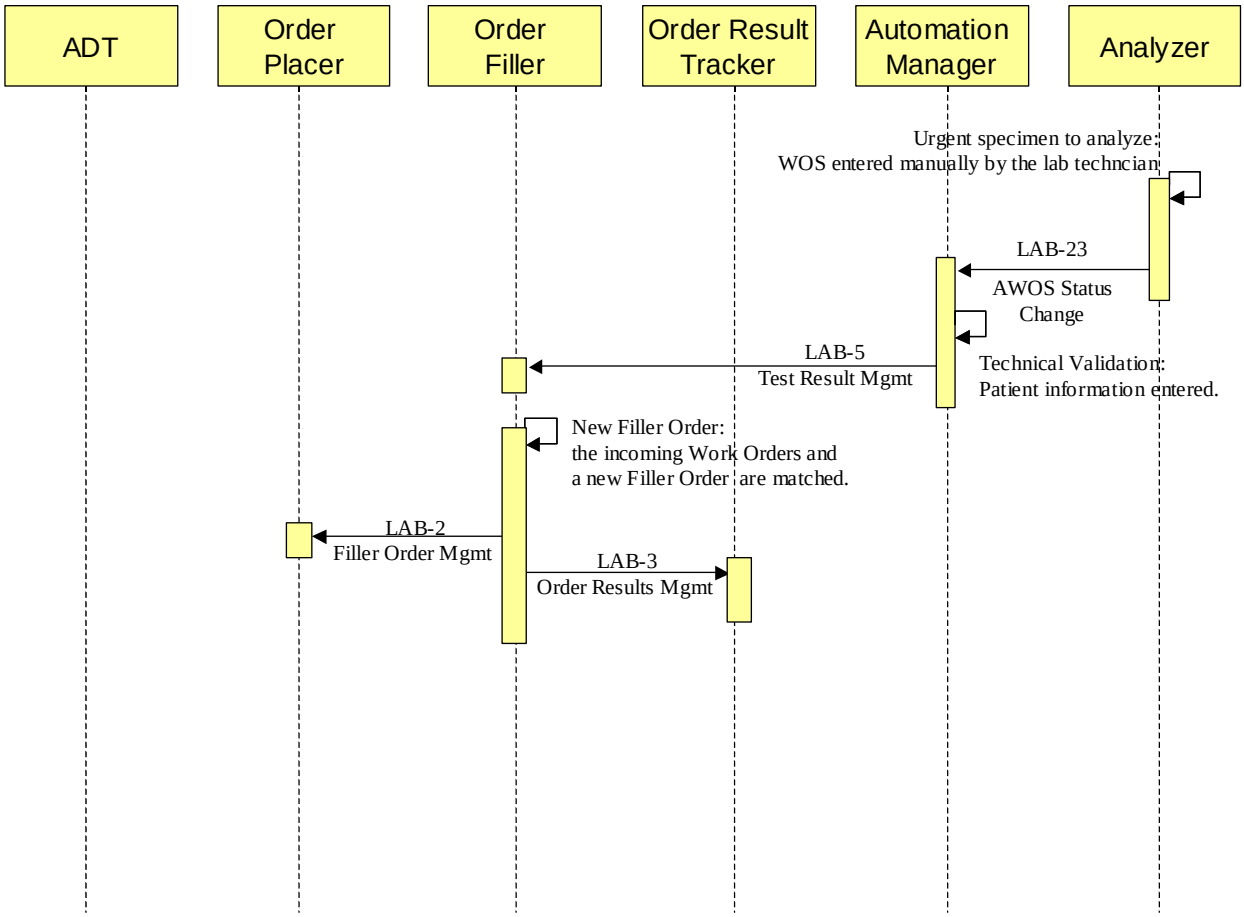

Figure X.4-5. LIR Profile : process started on Analyzer and reconciliation at OF

450 In this case the OF cannot find an existing Order to match the incoming Test Results and so a new Filler Order will necessarily be created.

X.4.5 Clinical lab tests performed on laboratory devices before creation of the order. Starting point on the Automation Manager

The following diagrams are based on the use case in chapter X.1.3.2 but they consider separately the two possible final parts of the scenario (see chapter X.1.3.3).

X.4.5.1 First final part of the scenario

Use case in chapter X.1.3.2 and 1st option in chapter X.1.3.3.

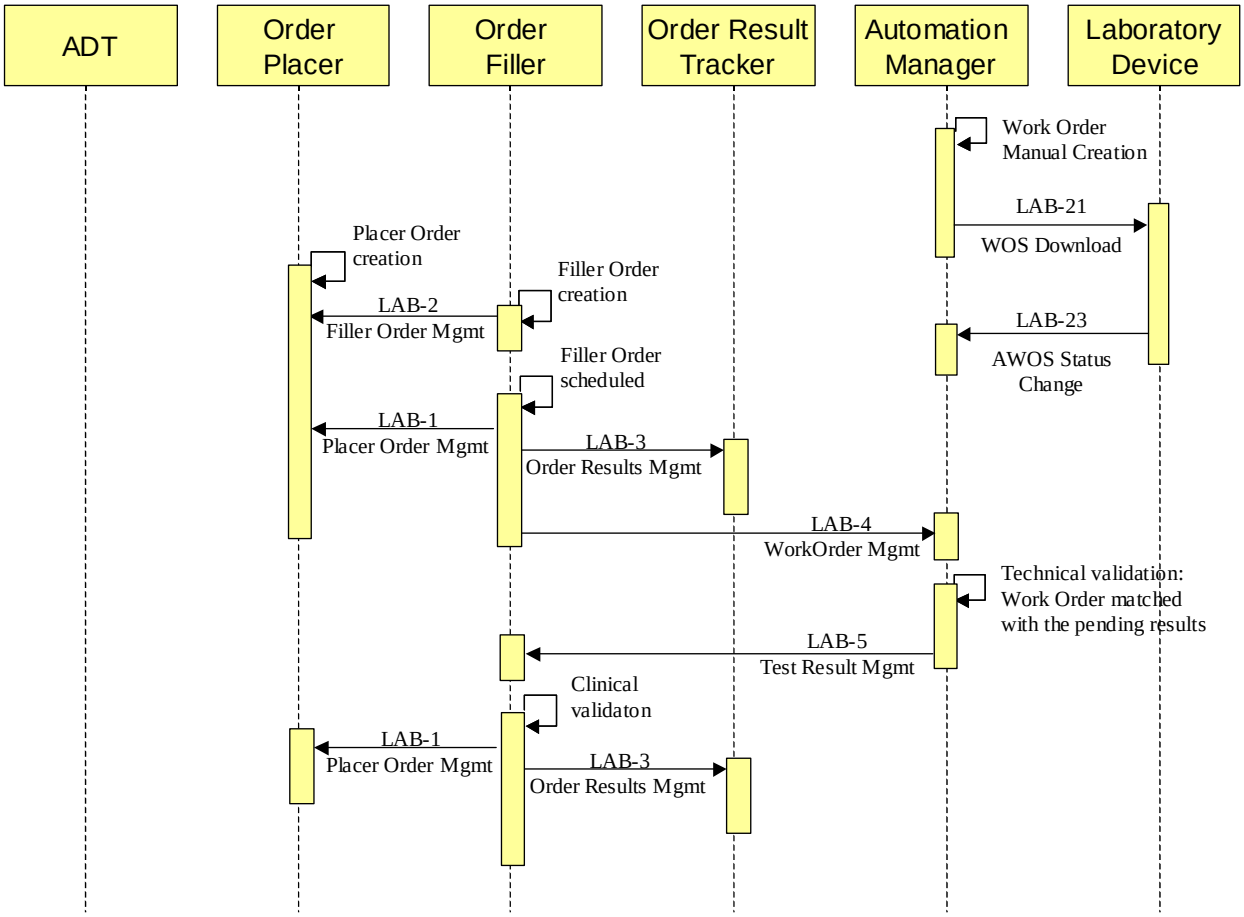

Figure X.4-6. LIR Profile : process started on AM and reconciliation at AM

As the Work Order exists in the AM, the laboratory device can perform a Query for WOS (LAB-22) if it does not know what action to perform on the loaded specimen.

In this case the Filler Order is produced by the OF (see X.1.3.3 option 1 Note 1). This process does not change the initial part of the scenario defined at chapter X.1.3.2 but just gives further options for creating the Filler Order.

X.4.5.2 Second final part of the scenario

Use case in chapter X.1.3.2 and 2nd option in chapter X.1.3.3.

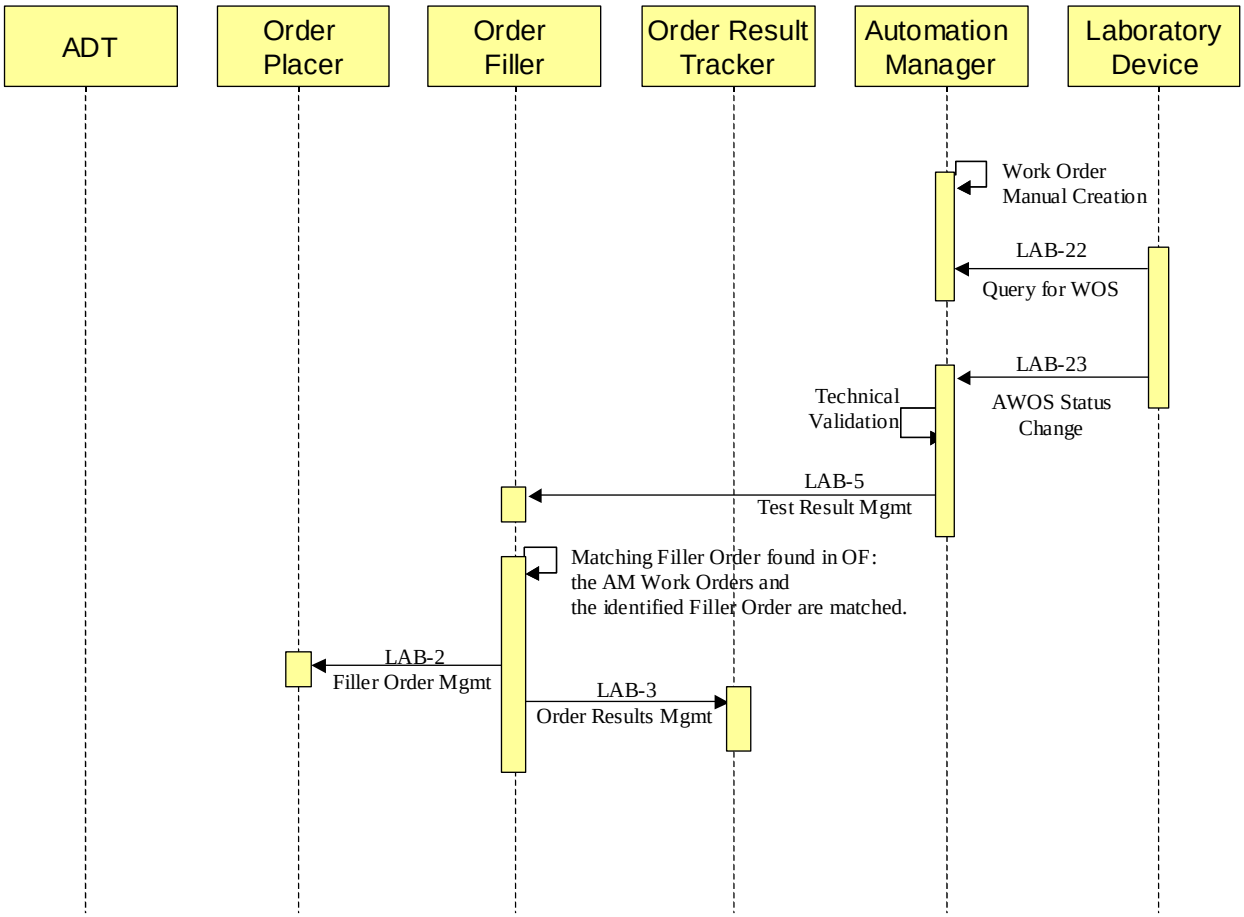

Figure X.4-7. LIR Profile: process started on AM and reconciliation at OF

As a consequence of the Work Order manual creation in AM, the specimen can be placed on a laboratory device that can query the AM for the suitable operation sequence to perfom on it.

Once the results are sent, the OF can find an existing Order to match the results and so no new Filler Order is created (see X.1.3.3 option 2 Note 2).

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