Integrating the Healthcare Enterprise

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IHE Laboratory
Technical Framework Supplement

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Inter-Laboratory Workflow
(ILW)

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Trial Implementation

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Foreword

25 This is a supplement to the IHE Laboratory Technical Framework V5.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published for Trial Implementation on November 08, 2013 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based

30 on the results of testing. Following successful testing it will be incorporated into the Laboratory Technical Framework. Comments are invited and may be submitted at http://ihe.net/Laboratory_Public_Comments.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (**bold strikethrough**), as well as

35 addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

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

40 | *Replace Section X.X by the following:* |
|---|

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

Information about the IHE Laboratory domain can be found at: http://ihe.net/IHE_Domains

Information about the structure of IHE Technical Frameworks and Supplements can be found at:

45 http://ihe.net/IHE_Process and http://ihe.net/Profiles

The current version of the IHE Technical Framework can be found at: http://ihe.net/Technical_Frameworks

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CONTENTS

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Introduction

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This supplement to the Laboratory Technical Framework describes the new integration profile Inter Laboratory Workflow (ILW) supporting the exchanges between laboratories of test orders and observations based on in vitro specimens.

Profile Abstract

125

The Inter-Laboratory Workflow (ILW) Profile supports the exchange of test orders and results related to in vitro specimens between two laboratories: One laboratory is the requester. Its LIS implements the new Actor "Requester" that will place test sub-orders to the second laboratory, referred to as the subcontracting laboratory. The LIS of this second laboratory implements the new Actor "Subcontractor" that will fulfill the sub-orders and send the results back to the

130

Requestor Actor. The requesting laboratory is committed to collect the necessary in vitro specimens related to the order and condition and provide them to the subcontracting laboratory.

Summary of changes brought to LAB TF by this profile

The integration of this supplement shall bring the following changes to the LAB TF-1:

- 1.7 Scope of changes introduced in the current year

135

- 1.11 Glossary: New terms for inter-laboratory workflow

- 2.1 Scope of laboratory testing: Order can come from another laboratory

- 3.1 & 3.2: Merge these two sections and their two figures into one.

- 3.3 Profiles dependencies table: Add the new profile

- 3.4 Integration Profiles Overview: Add the new profile

140

- 3.5.2 Usage of HL7 standard: Figure 3-3 to extend to the new profile

- 3.5.3 Relationship between units of work to extend to the new profile

- Add a new chapter describing ILW profile

- Appendix A: Add the two new actors

- Appendix B: Add the two new transactions

145

Volume 2:

- 1.6 Scope of changes introduced in the current year

- 2.4.6.3 Data type EIP, particularities for ILW

- 3.3 PID segment: Explain PID-3 in the context of ILW

- 3.7 SPM segment: Fields 2, 3 in the context of ILW

150

- 3.9 OBX segment: Field 23

- Before chapter 16, insert two chapters describing transactions 35 & 36
- 19: Add an example of transactions 35 & 36
- Appendix A: Complement the tables

Open Issues

155   None

Closed Issues

ILW-1.   Patient identification: The patient is known from the requester. In case the two laboratories are part of a common affinity domain, with a common patient id, the transactions between them will carry this common patient id. When there is no such

160   common patient id, the transactions will provide only the patient full identity and the Subcontractor will rely only on the patient identity traits to register the patient in the proper patient record in its database, according to its own business rules. In all cases, the Requester SHALL rely on its own Order number and Order Group number to record the information received from the Subcontractor.

165 ILW-2.   Correction of patient identity during the process: The Requester forwards any correction of the patient identity as a change in the sub-order, using Transaction "Sub-order Management".

ILW-3.   The transport protocol will be HL7 MLLP on TCP socket. Other transport protocols (such as web services or secure e-mail) would raise technical or normative issues. For

170   instance, the good practices of IHE limit the usage of web services to the transport of HL7v3 messages rather than v2. Report fac-simile will be encoded in base64 and will be included in LAB36 messages, in multiple OBX segments of ED type. Some benefits of this choice:

- No need to setup a web server or ftp server to distribute reports as separate files.

175   - The sender of the report knows exactly when the whole message (including the report) is received because all data are sent together.

ILW-4.   Tests added by the Subcontractor: in many situations the subcontracting laboratory adds tests, driven by its own procedures and notifies implicitly these additional tests to the requesting laboratory in the results message, which contains additional orders and

180   observations. However, in some situations the subcontracting laboratory needs the approval of the requesting laboratory for the adding of a test, before performing it. These situations need an exchange [test requested] from the Subcontractor to the Requester, and a response [test approved | denied]. See how to deal with that in volume 2 (section 3.Y.4.3).

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Volume 1 – Integration Profiles

This section describes the changes required in Volume 1 of the Technical Framework that result from including this Integration Profile.

History of Annual Changes

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

190
- Added the ILW Profile which covers the exchange of test sub-orders and results between a public or private laboratory playing the role of requester and another one, which is the subcontractor.

Glossary

Add the following terms to the Glossary in section 1.11

195

Requester	The Actor ran by a private or hospital laboratory that subcontracts a part of an Order or of an Order Group to another laboratory. This Actor SHALL send the Sub-order to the Subcontractor and receive the results produced for this Sub-order.
Subcontractor	The Actor ran by a laboratory performing tests upon request from other laboratories. This Actor receives Sub-orders, acknowledges specimen arrival and sends back results fulfilling these Sub-orders.
Sub-order	A part of an Order or of an Order Group, which the current laboratory subcontracts to another laboratory.

Scope of laboratory testing

Add the following paragraph in section 2.1 Laboratory Testing

Some specific tests placed to a laboratory or triggered by the results of other tests, may happen to be out of the specialty field of the laboratory or out of its schedule, or out of its scope. Then the
200 original laboratory refers these tests and related specimens to another laboratory supporting these specific tests. This is a situation in which a laboratory receives test orders and specimens from another laboratory.

205

> *Remove the current sections 3.1 "Intra Institution Integration Profiles" and 3.2 "Content Profiles for a Regional Healthcare Community" and replace by the single section below:*

3.1 Laboratory Profiles Synopsys of Usages and Dependencies

210   The synopsis below shows the profiles from the Laboratory Technical Framework, where they are usable, and what their dependencies are.
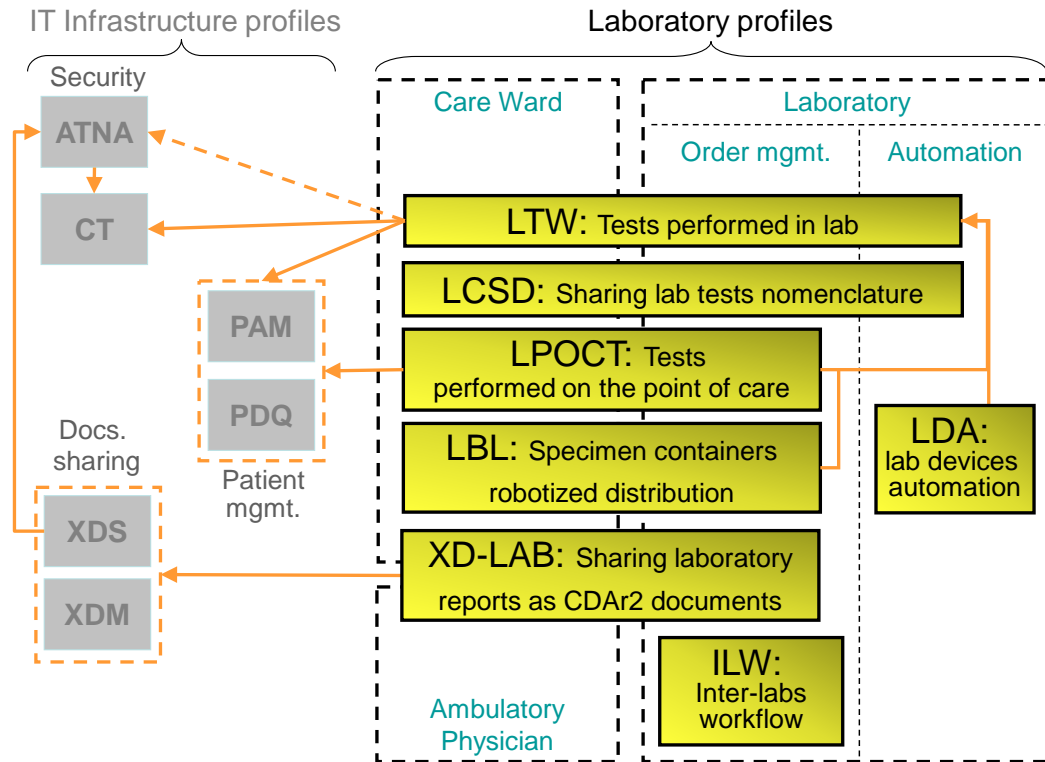
Figure 3.1-1: Laboratory Profiles Usages and Dependencies

215   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. The dependency towards ATNA is not mandatory.

LDA, LBL and LPOCT profiles are articulated on the LTW profile, which is a pre-requisite to
220   the deployment of any of these three profiles.

XD-LAB is a content profile representing a laboratory report and a set of 25 content modules usable within this report. This profile can be used by hospital and commercial laboratories, public health laboratories, ambulatory physicians, as well as acute care settings. It leverages one of the documents sharing profiles from ITI TF: XDS or XDM.

225 ## 3.3 Specification of Dependencies among Integration Profiles

Add the following section to table 3.3-1 Integration Profiles Dependencies in section 3.3

Inter-Laboratory Workflow (ILW)	none		

3.4 Integration Profiles Overview

Add the following sub-section to section 3.4

230 **3.4.X Inter-Laboratory Workflow (ILW)**

The Inter-Laboratory Workflow (ILW) profile covers the placing of test Sub-orders and the provision of the related in-vitro specimens from a requesting laboratory to a subcontracting laboratory, and the return of results and reports produced by the latter.

3.5.2 Usage of HL7 standards in LAB TF

235 | *Conditioned to the choice of standard: If HL7 V2.x, then in section 3.5.2 replace figure 3-3 by this one:* |
| --- |
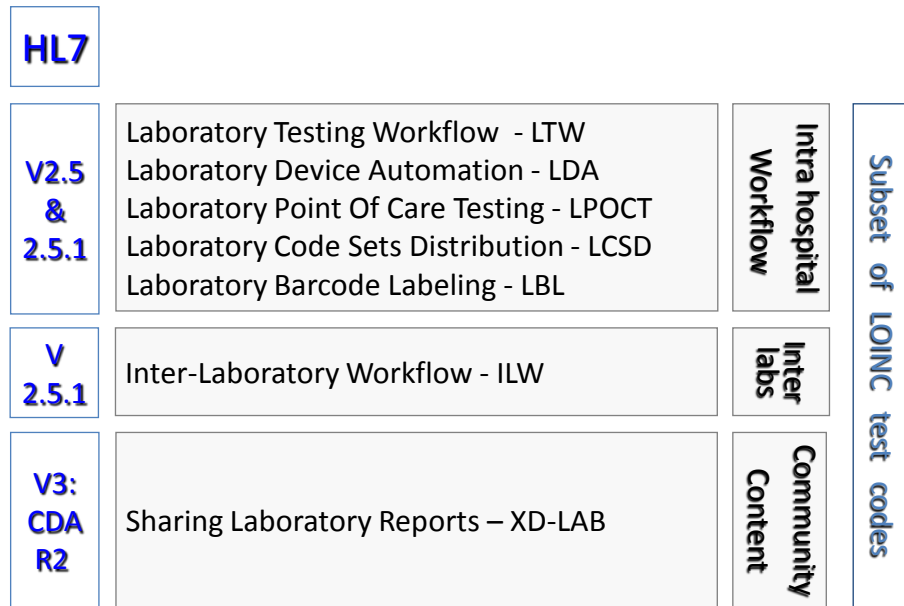
Figure 3-3: Versions of HL7 in use in the LAB-TF profiles

3.5.3 Relationships between units of work in the LAB-TF

240 | *Add the following sub-section at the end of section 3.5.3* |
| --- |

3.5.3.X Sub-order

A Sub-order is a subset of an Order Group or of an Order, which is subcontracted from one laboratory to another: The laboratory committed to fulfill a requisition (Order or Order Group) identifies a subset of tests to be referred to another laboratory, for organizational reasons
245 (inability to perform these tests, workload balance …)

The Sub-order is uniquely identified by the requesting laboratory with a Placer Group Number. Each ordered test or battery composing it is uniquely identified by the requesting laboratory with a Placer Order Number.

250 *Add the following chapter describing the new ILW integration profile:*

X Inter-Laboratory Workflow (ILW)

X.1 Scope

This integration profile supports the workflow between two laboratories when one is subcontracting in vitro diagnostic tests to the other.

255   Having received a diagnostic tests requisition, the fulfilling laboratory identifies a subset of tests to be subcontracted to a second laboratory for whatever organizational reasons (tests out of specialty scope, mutualization of diagnostic devices and reagent within a cooperative group of laboratories and/or healthcare institutions, night shift laboratory…). Then, the first laboratory refers the Sub-order representing this subset with the attached specimens to the second
260   laboratory, which performs the tests and sends the results back to the first laboratory.

Depending upon local regulations and the context of this inter-laboratory cooperation, the results reports produced by the first and second laboratory may be separately addressed to the ordering entity and to the patient, or the first laboratory may consolidate the results it produced together with the results produced by the subcontractor laboratory into a single report clearly identifying
265   which laboratory preformed which test, and which is liable for which observation.

Depending upon context and regulations, the subcontractor laboratory may invoice separately the tests it performed, and obtain the payment directly from the payers (patient, insurance company…), or the first laboratory may consolidate a single invoice grouping its own tests and the tests performed by the subcontractor.

270   This ILW profile focuses on the exchange of Sub-orders and their results between the two laboratories, ensuring that this bi-directional exchange provides each end with the information it needs to handle the operations downstream, such as invoicing, consolidating results and reporting, even if these operations are not directly in the scope of the profile.

In some cases the subcontracting process may be iterated, the subcontracting laboratory
275   forwarding some tests to a third laboratory.
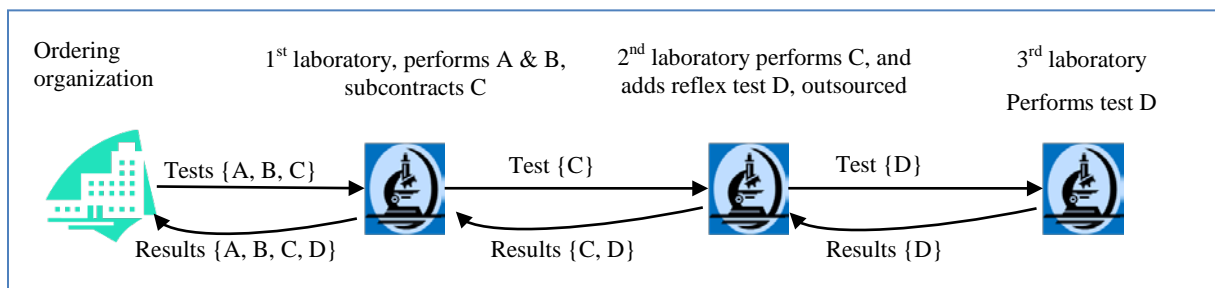
X.2 Out of Scope

- The invoicing itself is not in the scope of this profile, which only provides input data to
280   that process.

- The original order (either on paper or electronically) is usually required to be accessed by every performer. This profile does not handle how this access should happen.

- The publication of the reports coming out of this subcontracting process into a document shared repository is addressed by other IHE profiles, mainly XDS-b and XD-LAB.

X.3 Use cases

This ILW profile solves two major use cases:

- Private or hospital laboratory placing a sub-order to a regional or national reference laboratory. In situations where the specific tests or batteries referred are unknown from the master file of the requesting LIS, these tests or batteries are referred to the subcontracting lab as full text copied from the original paper order. The sub-order message specifies how the invoicing is to be handled by the subcontractor, and provides the information needed by the billing process. Thus the reference laboratory may handle the invoicing and obtain the payment of its acts either directly with the payers or from the requesting laboratory, depending on what was specified in the sub-order message. In this use case, the result reporting is frequently separated, each laboratory reporting its own acts in its own signed report.

- Private or hospital laboratory placing a sub-order to another laboratory, where both belong to an identified and organized cooperative group of laboratories. In this use case the specimens related to the suborder may be conditioned and bar-coded by the requester, with specimen IDs usable directly on the subcontracting laboratory's automated devices. In this use case the requesting laboratory consolidates all results into its own report, and consolidates one bill for both performed acts and subcontracted acts.

In both use cases the results returned by the subcontracting laboratory are clinically validated by the performing laboratory, but in some cases may be validated again by the requesting laboratory, together with the whole set of observations performed locally and remotely.

The two use case characteristics are summarized in table X.3-1:

Table X.3-1: Use Case Characteristics

Characteristics	Specific tests referred to a reference laboratory	Close cooperation between two laboratories
Sub-order	sometimes textual (copied from the original paper order)	always coded
Invoicing	Variable, handled by the subcontractor as requested in the sub-order	Bill consolidated by the requesting laboratory
Specimen identification	Specimens generally re-identified by the subcontractor	The subcontractor may rely on the specimen-id provided by the requester, if any.
Observations reporting	Each laboratory usually builds and signs its own report	The requester consolidates all observations into its own report; each observation is associated with its performer.

X.3.1 Cooperation between a hospital and a specialized private laboratory

310   A hematology laboratory operating in a hospital, having performed a CBC and differential count for a human immunodeficiency virus-positive patient, refers the blood specimen to a private laboratory downtown equipped with the appropriate fluorescence immunoassay method, requesting for count and determination of T4 and T8 lymphocytes.

The LIS of the hospital lab sends a Sub-order message with the specimen uniquely identified, to
315   the LIS of the private laboratory.

An hour later, the blood specimen is carried to the private laboratory and its bar-coded ID is scanned and recognized upon arrival. The LIS of the private laboratory sends a message acknowledging the specimen arrival.

The tests are performed on the device, the laboratory director verifies and comments the results,
320   which are messaged back to the hospital lab LIS.

The hospital laboratory aggregates the T4 & T8 observations to its own report, mentioning the outside performing laboratory and its director. These results are also integrated into the hospital electronic medical record (EMR), as structured data, with among other properties, the performing laboratory.

325   Out of this profile, but enabled by it:

- On patient discharge, the hospital produces the invoice of the encounter, recapitulating all performed acts, including subcontracted acts.

- Monthly, the subcontractor lab issues an invoice recapitulating the acts performed during the month for the hospital, and addresses it to the hospital for payment.

330   ### X.3.2 Specific test subcontracted to a national reference laboratory

A laboratory fulfills a blood group panel order upon a request from a surgeon in a clinic, for a planned surgery. Beside identifying the group ABO and Rhesus factor "A+" and detailed phenotypes, the laboratory detects the presence of atypical irregular agglutinins.

The LIS of the laboratory builds a Sub-order requesting the identification and titration of each
335   anti-A antibody to a national reference laboratory. The Sub-order is documented with the identification, mail and telecom address of the orderer (clinic surgeon), the patient full demographics and insurance data. The Sub-order is attached to a 5ml serum specimen and a 5 ml whole blood on anticoagulant specimen, both labeled with the patient full identification and the Sub-order ID. The two specimens, a photocopy of the original order from the surgeon and a
340   hardcopy of the Sub-order are stored together in a standardized container provided by the reference laboratory. The Sub-order is sent as a message to the system of the reference laboratory.

A daily truck courier brings the containers from the referring labs to the reference lab. Upon arrival, each container is checked with the Sub-orders previously received. The specimens are
345   barcode labeled and processed.

13

The observations on anti-A antibodies are produced and verified by an immuno-hematologist of the reference laboratory. The reference lab system builds the report and addresses it to the ordering physician (the surgeon). The results are sent back to the referring laboratory, together with a PDF copy of the report.

350   The reference laboratory produces its own invoice for the Sub-order and sends it directly to the various payers (patient and/or insurance companies).

X.3.3 Distributed process in a cooperative group of laboratories

A number of laboratories spread in a big city and its suburb, have built a close cooperation in order to mutualize their investments in diagnostic devices and reagent, and to streamline their
355   processes. Each laboratory belonging to the group performs itself its short time tests (e.g., chemistry, blood gas), and subcontracts longer time tests (e.g., immunology, serology, microbiology) to a central technical facility equipped with state-of -the-art automated devices, shared by all the laboratories members of the group.

The group has globally defined a scheme of identification for specimens, which ensures that each
360   member laboratory will produce a unique identifier for each of the specimens it refers to the central technical facility.

Whenever a member laboratory receives a request containing microbiology this laboratory builds a Sub-order with this microbiology, uniquely identifies the microbiology specimen, and sticks this id bar-coded on the container.

365   The Sub-order is messaged to the management system of the central facility. The specimen together with a hardcopy of the Sub-order is sent to the central facility.

Upon recognition of the barcode specimen ID the system of the central facility acknowledges specimen arrival to the LIS of the referring lab, and launches the microbiology process on the selected device, which will match the Sub-order associated with the barcode specimen ID.

370   The results verified on the central facility are messaged back to the referring LIS and integrated with the other results produced locally in fulfillment of the same request. Each observation is recorded with, among other properties, the identification of the laboratory (local lab or central facility) that performed it, the identification of the person assuming full liability for this observation.

375   The members laboratories assume the complete invoicing and reporting of their requests no matter whether they contain centralized tests or not.

X.3.4 Telepathology

A pathology laboratory requests a telepathology procedure to a secondary pathology laboratory, based on a set of whole slide images representing the virtual specimen. The sub-order addressed
380   to the secondary structure carries a reference pointer to the image set representing the virtual specimen.

X.4 Actors/ Transactions

This profile involves a pair of Actors (Requester and Subcontractor) and a set of two Transactions between them:

385
- Transaction "Sub-order Management" supports the Sub-order placing and the related specimens provision.

- Transaction "Sub-order Results Delivery" supports the delivery of results from Subcontractor to Requester.

Table X.4-1 lists the transactions for each actor directly involved in the ILW Profile. In order to
390 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 Volume 1, Section X.2.

395
Table X.4-1: ILW Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Requester	Sub-order Management [LAB-35]	R	3.Y
	Sub-order Results Delivery [LAB-36]	R	3.Z
Subcontractor	Sub-order Management [LAB-35]	R	3.Y
	Sub-order Results Delivery [LAB-36]	R	3.Z

X.5 ILW Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table X.4-1 along with the Actors to which they apply.

400

Table X.5-1: Evidence Documents - Actors and Options

Actor	Options	Vol. & Section
Requester	*Input For Invoicing*	3.Y
	Non-coded orders	3.Y
	Report Fac-Simile For Order Group	3.Z
	Test addition approval	3.Y
Subcontractor	*Input For Invoicing*	3.Y
	Report Fac-Simile For Order Group	3.Z
	Non-coded orders	3.Y
	Test addition approval	3.Y

15

Input For Invoicing

405   This option of Transaction Sub-order Management (LAB-35) mandates the Requester to include in its Sub-order message the set of data that will instruct the Subcontractor how to handle the invoicing of this Sub-order. This set of data includes the identification of the various payors, such as: the patient, the ordering clinic, one or more insurance company, the guarantor, or the requesting laboratory itself. It also provides rules indicating how to split the bill between the payers.

410   To claim support of this option a system implementing the Requester Actor must be able to provide this set of data input for invoicing. To claim support of this option a system implementing the Subcontractor Actor must be able to integrate this set of data.

Report Fac-Simile For Order Group

415   This option is associated with Transactions Sub-order Management (LAB-35) and Sub-order Results Delivery (LAB-36), and follows almost the same process as in the LTW profile:

When this option is activated:

- The Requester referring an Order Group to the Subcontractor (using Transaction LAB-35) MAY request an additional service requesting the Subcontractor to provide the fac-simile of the report in every result message sent back to the Requestor.

420   - The Subcontractor having received an Order Group including the request for provision of the report fac-simile SHALL provide this report fac-simile as a PDF file embedded encoded in base64 in the result message of transaction LAB36.

Non-coded Orders

425   This option of Transaction Sub-order Management (LAB-35) enables the Requester to request a test/battery, using a display name which specifies in plain text (copied from the paper requisition) what test is to be performed. The subcontracting laboratory will pick the proper code in its own master file, from the text displayed.

Test addition approval

430   In most cases the subcontractor does not need requester's approval for adding a test. But in some cases, tests added by the subcontractor need a formal approval by the requester. This case is supported by this option.

X.6 ILW Integration Profile Process Flow

Figure X.6-1 covers the basic process workflow for the use cases presented in section X.2.
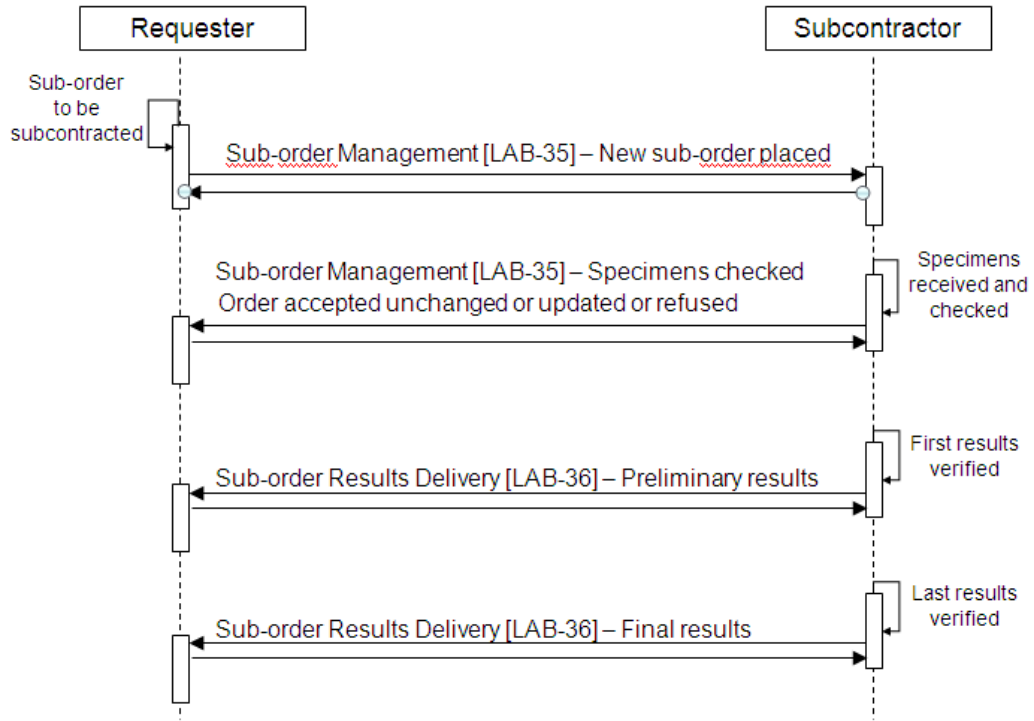
435 **Figure X.6-1: Basic Process Flow in ILW Profile**

Note 1: The cancellation of a test by the Subcontractor can be notified at any stage: In the "Specimens checked" message or in any of the "results" messages.

Note 2: Specimens checking includes checking with the electronic order received as well as with the paper sub-order accompanying the specimens.

440   Figure X.6-2 covers the case of correction of the sub-order by the Requester during the process: new test or battery placed on the existing specimen, correction of patient data (including patient identity), test or battery cancelled.
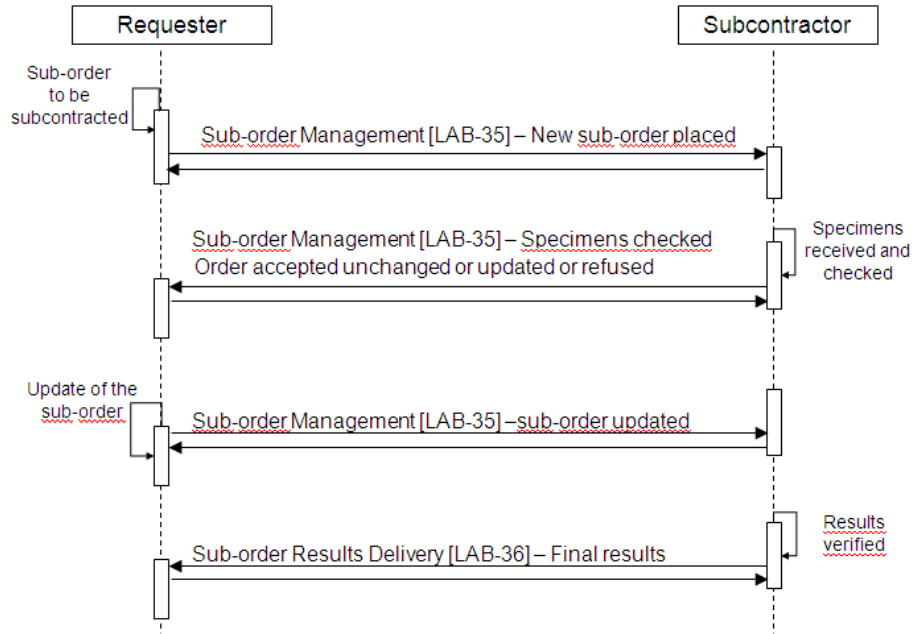

Figure X.6-2: Sub-order updated by Requester during the process

445

Figure X.6-3 covers the case of test added by the Subcontractor, waiting for approval of the Requester.
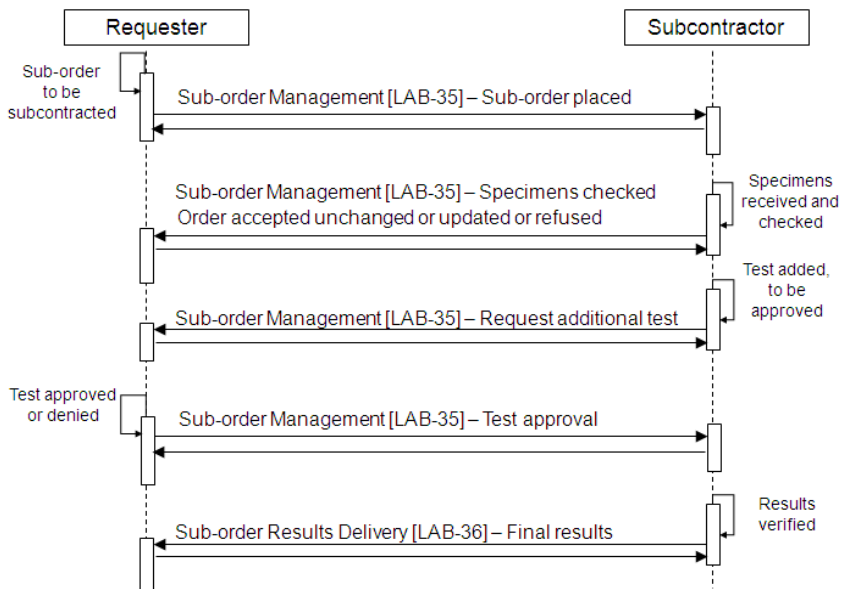

Figure X.6-3: Approval of additional test requested by the Subcontractor

X.7 ILW Integration Profile Security Considerations

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- Privacy: Tracking the patient consent for reporting the observations to the various physicians. When the patient does not give his or her consent regarding one particular subcontracted test, both labs should register the fact that this specific test is not allowed to be disclosed to any other recipient than the ordering physician and the patient.

455

- This is the first integration profile of LAB that implements message exchanges outside of the hospital, and of its protected network. This implies the need to:

  - Protect each of the LIS involved in the transactions against intrusions and attacks from the internet. This risk may be addressed by the constitution of a VPN between the set of laboratories working together, or by implementing and appropriately tuning
460   firewalls on both ends.

  - Protect the patient clinical data that are exchanged from disclosure to any external parties. This risk may be addressed by the constitution of a VPN, or by the implementation of the ATNA profile and its Encryption option. However this will not be mandated by the profile.

Appendix A – Actor Summary Definitions

465

Add the following paragraphs (in alphabetical order of Actors) to that section

Requester: An application used by a laboratory to fulfill the upcoming test Orders or Order Groups, and deliver the results thereof to the orderers and to the intended recipients. When necessary, this application is able to extract Sub-orders out of these Orders or Order Groups, to
470 message these Sub-orders to the system of a subcontracting laboratory and to receive and integrate the results returned by this system as well as the Sub-order status changes such as "specimen accepted".

Subcontractor: An application used by a laboratory to fulfill the upcoming Sub-orders placed by other laboratories. This application receives Sub-order messages, acknowledges specimen arrival
475 and sends results messages.

Appendix B – Transaction Summary Definitions

Add the following paragraphs (in ordinal order of Transactions) to that section

[LAB-35] Sub-order Management. This transaction provides the message flow placing Sub-orders from Requester to Subcontractor and the message flow acknowledging specimen arrival
480 from Subcontractor to Requester.

[LAB-36] Sub-order Results Delivery. This transaction provides the results message flow from Subcontractor to Requester.

Volume 2b - Transactions

Rationale for the choice of the standards

485
- This profile is a workflow, more real time oriented, with fine grained changes to be tracked, therefore it needs messages more than documents.

- V3 LAB messages are not finalized yet. Moreover, the switching to V3 and xml technology should be made for all profiles of this technical framework, to avoid a LIS having to support both technologies depending on the system it is talking to. Therefore
490 this profile should leverage the same release of HL7 as the other laboratory profiles, which is V2.5.1.

Standard chosen:

- Transactions LAB-35 and LAB-36 leverage HL7 v2.5.1, which was issued precisely to manage accurately subcontracted lab orders and observations, in conformance with an US
495 CLIA amendment. (extra fields added to OBX segment for that purpose).

- Transaction LAB-35 (Sub-order Management) will use a pair of (OML^O21, ORL^O22) messages.

- The option "Input For Invoicing" will mandate the capacity to manage the repeatable INSURANCE segment group [IN1, IN2, IN3, ROL] as well as the Guarantor segment
500 GT1 and the diagnosis segment DG1, in LAB-35.

- Transaction LAB-36 (Sub-order Results Delivery) will use a pair of (ORU^R01, ACK) messages.

- The implementation of Report Fac simile option in LAB-36 is similar to what it is in Transaction LAB-3, except that in LAB-36 the report Fac simile is embedded in a series
505 of OBX segment instead of being referenced as a separate file.

- Transport layer: The HL7 MLLP protocol is chosen.

> *Update section 2.4.6.3 "EIP- Entity Identifier Pair" as follows:*

2.4.6.3 EIP – Entity Identifier Pair

510

HL7 Component Table - EIP – Entity Identifier Pair

SEQ	LEN	DT	Usage	CARD	TBL#	COMPONENT NAME
1	427	EI	C	[0..1]		Placer Assigned Identifier

SEQ	LEN	DT	Usage	CARD	TBL#	COMPONENT NAME
2	427	EI	C	[0..1]		Filler Assigned Identifier

The IHE LAB-TF uses this data type for identifying specimens (see SPM-2 "Specimen ID" and SPM-3 "Specimen Parent IDs" in SPM segment static definition).

515   Condition predicate for EIP-1:

In the context of transactions LAB-1, LAB-2, LAB-3, the first sub-component is populated with the specimen ID assigned by the Order Placer Actor, if available.

In the context of transactions LAB-4 and LAB-5, the first sub-component is populated with the specimen ID assigned by an Actor preceding the Automation Manager in the
520   workflow, if available.

In the context of transactions LAB-21, LAB-22, LAB-23, LAB-26 (in LDA profile), the first sub-component is populated with the specimen ID assigned by an Actor preceding the Laboratory Device, if available.

In the context of transactions LAB-35 and LAB-36 (in ILW profile) the first sub-
525   component is populated with the specimen ID assigned by an Actor preceding the Subcontractor, if available.

In the context of transactions LAB-61 and LAB-62, the first sub-component is populated with the specimen ID assigned by the Label Information Provider Actor.

Condition predicate for EIP-2:

530   In the context of transactions LAB-1, LAB-2, LAB-3, the second sub-component is populated with the specimen ID assigned by the Order Filler Actor, if available.

In the context of transactions LAB-4 and LAB-5, the second sub-component is populated with the specimen ID assigned by the Automation Manager or by a Laboratory Device, if available.

535   In the context of transactions LAB-21, LAB-22, LAB-23, LAB-26 (in LDA profile), the second sub-component is populated with the specimen ID assigned by a Laboratory Device, if available.

In the context of transactions LAB-35 and LAB-36 (in ILW profile) the second sub-component is populated with the specimen ID assigned by the Subcontractor, if available.

540   In the context of transactions LAB-61 and LAB-62, the second sub-component is never populated.

> *Add sections 3.Y and 3.Z*

21

3.Y Transaction LAB-35: Sub-order Management

545 **3.Y.1 Scope**

This transaction is used by the Requester to place a Sub-order to the Subcontractor. The transaction enables both Requester and Subcontractor to notify all subsequent changes of status and/or content of the Sub-order:

- Tests added by the Requester, to be performed on the existing specimen

550 - Specimens checked with ordered tests, and accepted or rejected by the Subcontractor

- Update of the Sub-order by the Requester, including correction of patient data

- Test cancelled by the Requester

- Test addition requested by the Subcontractor and approved or denied by the Requester (if the option "Test addition approval" is in use).

555 - The ordered tests/batteries SHAL be coded in the Sub-order messages sent by the Requester, unless the option "Non-coded orders" is in use, in which case some tests/batteries MAY be carried as plain text, with the Subcontractor having the responsibility to map this text to the appropriate item in its own dictionary.

- If the "Report Fac-simile For Order Group" option is in use, this transaction MAY
560   include into an Order Group placed, the request for the fac-simile of the report related to that Order Group.

- If the "Input for Invoicing" option is activated, the Requester SHALL accompany every new Su-order placed, with the data necessary to handle the invoicing: "Whom to invoice?"

565 **3.Y.2 Use Case Roles**
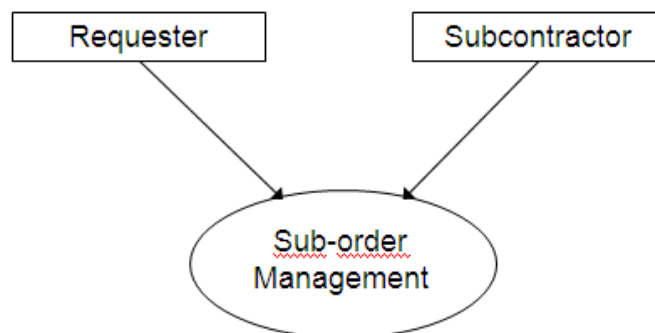
Actor: Requester

Roles: Places sub-orders. Updates sub-orders. Receives acceptance or rejection from the Subcontractor. Receives requests for approval of additional tests from the Subcontractor.

570 **Actor**: Subcontractor

Roles: Receives sub-orders. Notifies the Requester of acceptance or refusal. Receives sub-order updates from the Requester. Notifies acceptance or rejection of tests and specimens to the Requester. Requests approval of additional tests from the Requester.

3.Y.3 Referenced Standards

575   HL7 version 2.5.1:

- Chapters 2, 2A: "Control" --> generic segments and data types

- Chapter 3: "ADT" --> PID and PV1 segments

- Chapter 4: "Order Entry" --> OML and ORL messages

- Chapter 7: "Observation Reporting" --> SPM segment

580   - Chapter 13: "Clinical Laboratory Automation" --> SAC segment

3.Y.4 Interaction Diagrams

Trigger events: In all interactions below, the initiator uses OML^O21 message structure. The responder SHALL respond with the related ORL^O22 message structure, as an applicative acknowledgement. An OML message shall be responded to with exactly one ORL message.

585   The requester will send the Placer Order Number and optionally the Placer Group Number in corresponding ORC fields.

A subcontractor may subcontract some or all sub-orders to another subcontractor. In this case it will become the requester for all transactions made with its subcontractor. In this case, it generates a new Placer Order Number and optionally a new Placer Group Number.

590

3.Y.4.1 Normal process of a sub-order
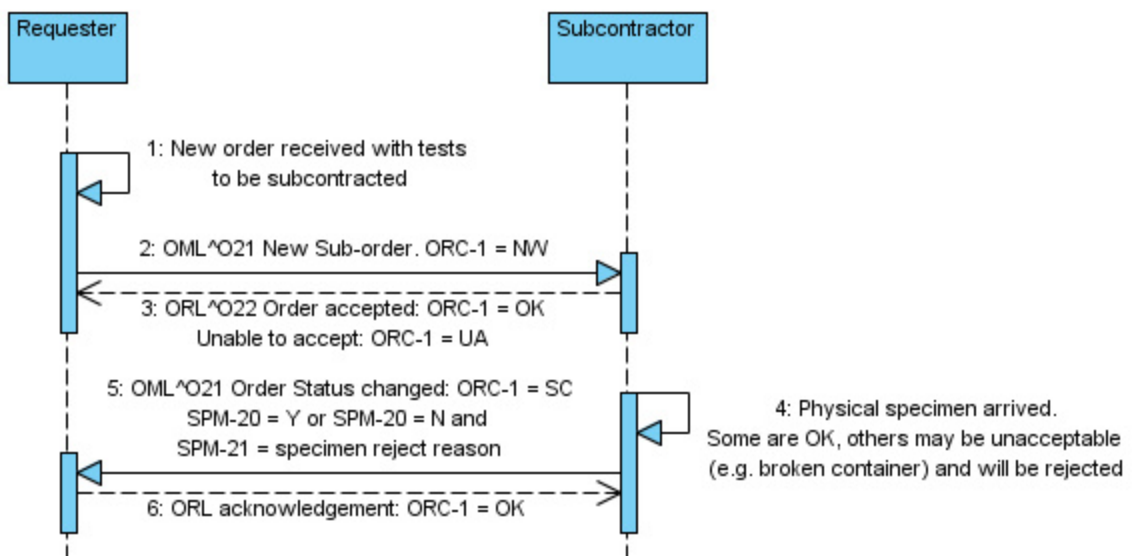
The two major events in normal process are the extraction of a Sub-order on the Requester side (tests from a received order, to be outsourced) and then the specimen reception on the
595   Subcontractor side.

3.Y.4.2 Sub-order updated by the Requester during the process
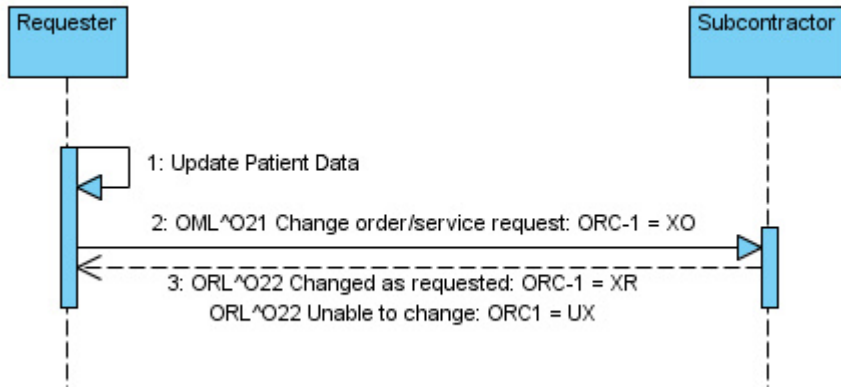
This interaction is mainly used to forward to the subcontractor update of patient data that happens during the process of the sub-order.

600

3.Y.4.3 Tests added by the Sub-contractor with need for approval by the Requester
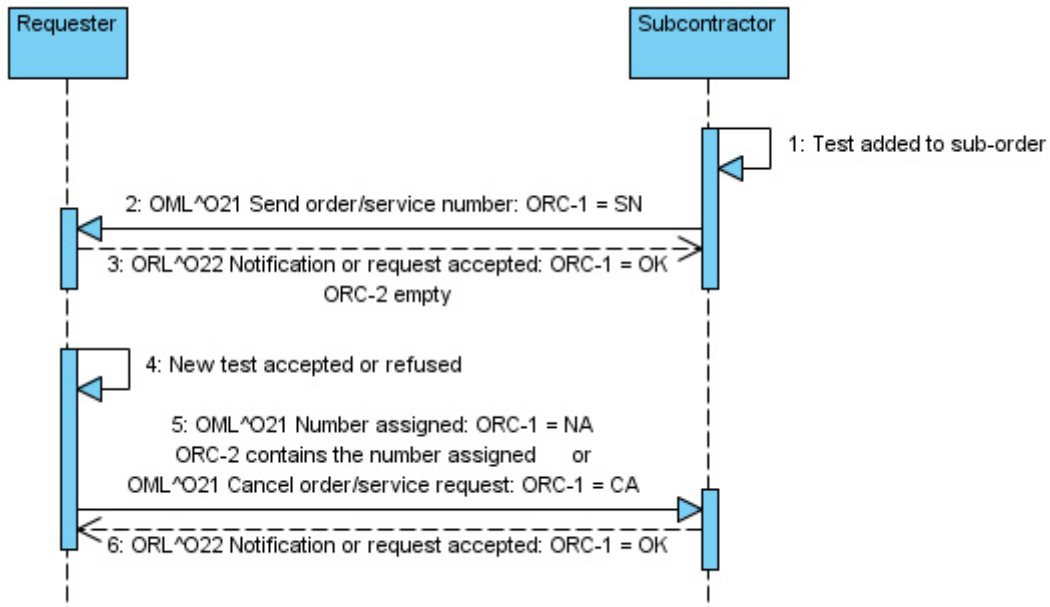
In some cases, tests added by the subcontractor need a formal approval by the requester. This
605   interaction needs the use of option *"Test addition approval"*.

3.Y.4.4 Sub-order for interpretation of digital evidence
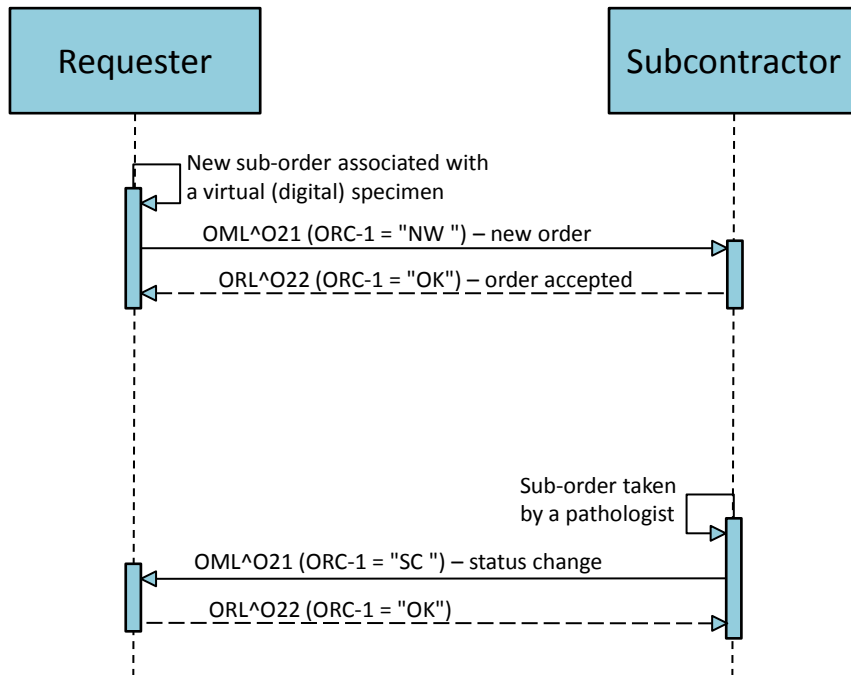
The sub-order is for the interpretation of a virtual specimen, for instance a whole slide image set.
610   The schedule of the order on the subcontractor side is triggered by a pathologist assignment to
this sub-order.

3.Y.5 Messages Static Definition

3.Y.5.1 OML^O21 Static Definition

615   **Table 3.Y.5.1-1: OML^O21 static definition for transaction LAB-35**

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[	--- PATIENT begin	RE	[0..1]	
PID	Patient Identification	R	[1..1]	3
[PV1]	Patient Visit	RE	[0..1]	3
]	--- PATIENT end			
[{	--- INSURANCE begin	O	[0..1]	6
IN1	Insurance	R	[1..1]	6

Segment	Meaning	Usage	Card.	HL7 chapter
[IN2]	Insurance Additional Info	O	[0..1]	6
[IN3]	Insurance Add'l Info - Cert.	O	[0..1]	6
[GT1]	Guarantor	O	[0..1]	6
}]	--- Insurance end			
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
[TQ1]	Timing Quantity	RE	[0..1]	4
	--- OBSERVATION REQUEST begin	R	[1..1]	
OBR	Observation Request	R	[1..1]	4
{[NTE]}	Notes and Comments	O	[0..*]	2
[{	--- OBSERVATION begin	O	[0..*]	
OBX	Observation Result	R	[1..1]	7
[{NTE}]	Comment of the result	C	[0..*]	2
}]	--- OBSERVATION end			
[{	--- SPECIMEN begin	O	[0..*]	
SPM	Specimen	R	[1..1]	7
[{OBX}]	Observation related to Specimen	C	[0..*]	7
[{SAC}]	Container	C	[0..*]	13
}]	--- SPECIMEN end			
[{	--- PRIOR_RESULT begin	O	[0..*]	
PV1	Patient Visit – previous result	R	[1..1]	3
{	--- ORDER_PRIOR begin	R	[1..*]	
ORC	Common Order - previous result	R	[1..1]	4
OBR	Order Detail - previous result	R	[1..1]	4
{[NTE]}	Notes and Comments - previous result	O	[0..*]	2
{	--- OBSERVATION_PRIOR begin	R	[1..*]	
OBX	Observation/Result - previous result	R	[1..1]	7
{[NTE]}	Notes and Comments - previous result	O	[0..*]	2
}	--- OBSERVATION_PRIOR end			
}	--- ORDER_PRIOR end			
]}	--- PRIOR_RESULT end			
	--- OBSERVATION REQUEST end			
}	--- ORDER end			

In the context of the option "input for invoicing", the message can carry the insurance (segments IN1, IN2 and IN3) and guarantor (segment GT1) data. IHE does not constraint the usage of these segments at the international level. This is left up to national extensions of this profile.

620 **3.Y.5.2 ORL^O22 Static Definition**

This message is the same as the ORL^O22 of transaction LAB-1 specified in LAB TF-2:4.5.4.

3.Y.5.3 Segments and fields usage specialized for LAB-35

3.Y.5.3.1 ORC – Common order segment

ORC-2 – Placer Order Number: identifies a subcontracted test or battery.

625 ORC-4 – Placer Group Number: identifies a group of test and batteries subcontracted together.

3.Y.5.3.2 TQ1-9 Priority (CWE), required in the TQ1 segment

This field defines the priority of the order. The values authorized in LAB-35 are this subset of HL7 table 0485 - Priority codes:

630

HL7 table 0485 - Priority codes

Value	Description	Comment
A	ASAP	Fill before S orders
R	Routine	Default

3.Y.5.3.3 SPM-11   Specimen Role (CWE), required in the SPM segment

In LAB-35, this field is restricted to this value set:

HL7 User-defined Table 0369 – Specimen Role

Value	Description	Comment
P	Patient (human or other species)	
PSN	Human patient	added by IHE LAB TF, taken from HL7 V3 vocab
ANM	Animal	added by IHE LAB TF, taken from HL7 V3 vocab
MIC	Microorganism	added by IHE LAB TF, taken from HL7 V3 vocab
PLNT	Plant	added by IHE LAB TF, taken from HL7 V3 vocab
MAT	Material, non-living subject	added by IHE LAB TF, taken from HL7 V3 vocab

635 ### 3.Y.5.3.4 identifying the packaging of specimens

The requesting laboratory usually groups the specimens addressed to the subcontracting laboratory in a box. Moreover, these specimens may be sorted in a number of plastic bags within the box.

Each specimen is uniquely identified. Each plastic bag may be identified. And the box may also
640 have a unique identifier.

Transaction LAB-35 is able to carry these 3 levels of identifiers:

- SAC-10 Carrier Identifier (EI) represents the box identifier, if any.

- SAC-13 Tray Identifier (EI) represents the plastic bag identifier, if any.

645
- SPM-2 Specimen ID (EIP) carries the specimen ID, bar coded on the specimen container, if any.

3.Y.5.3.5 OBR-4 Universal Service Identifier (CE), required

This field contains one battery/test of the sub-order.

Additionally, when the "Report Fac-simile For Order Group" option is activated, the requester MAY request this service in an extra (ORC/OBR) segment group. In that case this requested
650   service SHALL be identified in this field using this LOINC code exclusively: `11502-2^ LABORATORY REPORT.TOTAL^LN`

In the context of the option "Non-coded Orders", the requester may provide the text expressing the requested battery or test, living the code empty as well as the code system name.

3.Y.5.3.6 OBR-23 required with option "Input for Invoicing"

655   In case the option "Input for Invoicing" is in use, field OBR-23 "Charge to Practice" is required and SHALL be populated as follows:

OBR-23 "Charge to Practice" (MOC)

HL7 definition: Components: <Monetary Amount (MO)> ^ <Charge Code (CE)>

IHE usage: This field is required with option "Input for Invoicing". The Requester Actor SHALL
660   populate only the second component "Charge Code", to indicate how this sub-order is to be charged, using one of the following values:

Code	Text	Coding system name
TOLAB	Charge to requesting laboratory	IHE_LAB_CHARGE
TOORD	Charge to ordering healthcare facility	IHE_LAB_CHARGE
TOPAT	Charge to patient	IHE_LAB_CHARGE
TOPAY	Charge to payers described	IHE_LAB_CHARGE
NOCHG	No charge on this order	IHE_LAB_CHARGE

The value "TOPAY" implies that the requester provide the description of the payers in the
665   message, using the guarantor (GT1) segment and/or the INSURANCE segment group.

3.Y.5.3.7 OBR-46 required for interpretation of digital evidence

In case the sub-order is for interpretation of digital evidence (e.g., referenced images) and no physical specimen is sent, field OBR-46 "Placer Supplemental Service Information" is required and SHALL be populated as follows:

670   OBR-46 "Placer Supplemental Service Information" (CWE)

Code	Text	Coding system name

Code	Text	Coding system name
DIGITAL	Interpretation of referenced digital evidence	IHE_LAB_SUPSVC

3.Y.5.3.8 OBX required for referenced digital evidence

OBX following SPM may reference digital evidence to be interpreted.

675

- The data type (OBX-2) is valued "RP" (Reference Pointer), or possibly ED (Encapsulated Data).

- The observation value in OBX-5 is a pointer to the digital evidence.

3.Z Transaction LAB-36: Sub-order Results Delivery

3.Z.1 Scope

This transaction is used by the Subcontractor to:

680

- Notify results to the Requester, including corrections of results and cancellation of results, and including sub-order status changes.

- Notify tests added or replaced by the Subcontractor to an existing sub-order, together with the results they produced, when there is no need for prior approval by the Requester for such addition, which is the most common use case.

685

- If the "Report Fac-simile For Order Group" option is activated, and this service was requested by the Requester in the Sub-order, the Subcontractor SHALL provide the fac-simile of the report related to the Order Group.

3.Z.2 Use Case Roles
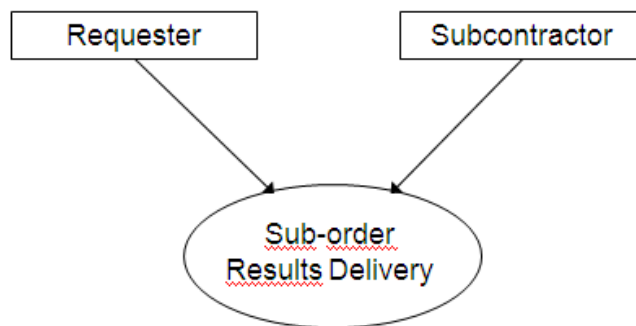
690 **Actor**: Requester

Roles: Receives notifications regarding a sub-order and its results from the Subcontractor.

Actor: Subcontractor

Roles: Sends notifications regarding a sub-order and its results to the Requester.

695

Some of the tests reported may be new tests added or replaced in lieu of some of the ordered tests, upon the subcontractor lab's initiative.

3.Z.3 Referenced Standards

HL7 version 2.5.1:

- Chapters 2, 2A: "Control" --> generic segments and data types

- Chapter 3: "ADT" --> PID and PV1 segments

700

- Chapter 7: "Observation Reporting" --> ORU message

3.Z.4 Interaction Diagrams

Trigger events: In all interactions below, the Subcontractor sends an ORU^R01 message. The Requester responds with an ACK message. An ORU message shall be responded to with exactly one ACK message.
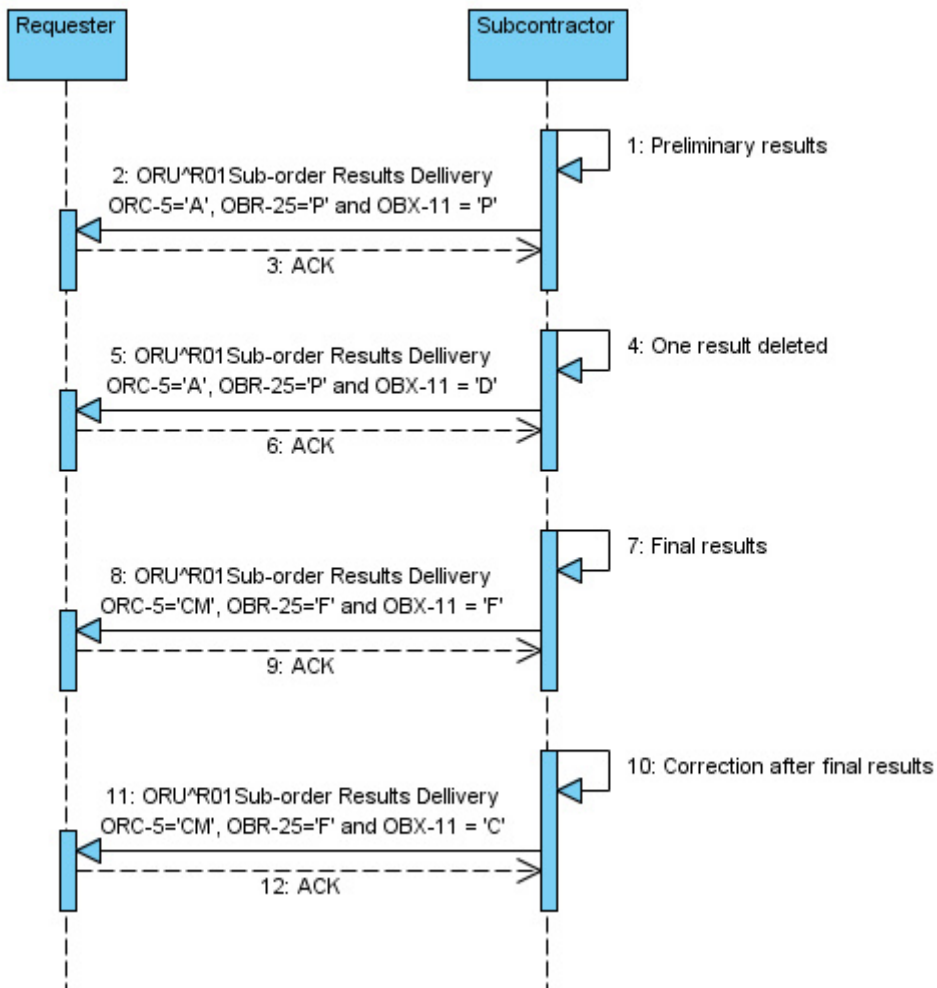
705

3.Z.5 Messages Static Definition

The ORU^R01 message profile is the same as in LAB-3 transaction as described in LAB TF-2:6.5.2, with the exceptions below:

3.Z.5.1 Use of the Option Report Fac-simile For Order Group in LAB-36

710 **3.Z.5.1.1 PDF Report embedded in series of OBX segments, encoded in base64**

When this option is activated, if the Requester requested this fac-simile report service with a Sub-order, then messages ORU^R01 carrying clinically validated results related to a Sub-order SHALL encode the PDF file in base64 and embed it in a series of OBX segments, each of them having the OBX-2 Value Type (ID) set to ED. This PDF file is the report recapitulating all
715 clinically validated and reportable results for this Sub-order.

3.Z.5.1.2 Subcontractor Actor Sending Responsibilities Extended for this Option

If the Requester requested the fac-simile of the report in a Sub-order, when the Subcontractor prepares a message containing some clinically validated results for this Sub-order, it SHALL construct the PDF report recapitulating all results validated and releasable for this Sub-order and
720 SHALL embed this PDF report in the results message.

3.Z.5.1.3 Segment Group Dedicated to the Report Fac-simile

Message ORU^R01 provides this link in a dedicated ORDER_OBSERVATION segment group, appearing at the bottom of the message. This last ORDER_OBSERVATION segment group, which was requested by the Order Placer when the Order Group was placed, is composed of only
725 3 type of segments: ORC, OBR, OBX.

This message structures the 3 segments introducing the PDF report are populated as follows:

3.Z.5.1.4 ORC Segment Introducing the Laboratory Report for the Order Group

This segment is populated with at least these 3 fields:

Field	DT	Element name	Value	Comment
ORC-1	ID	Order Control	SC	A results message is always a Status Change.
ORC-4	EI	Placer Group Number	The Order Group number	The identifier assigned by the Order Placer to this Order Group.
ORC-9	TS	Date/Time of Transaction	Date time of the triggering event	Date/time of this release of the laboratory report produced for this Order Group.

730 **3.Z.5.1.5 OBR Segment Introducing the Laboratory Report for the Order Group**

This segment is populated with at least these 4 fields:

Field	DT	Element name	Value	Comment

Field	DT	Element name	Value	Comment
OBR-2	EI	Placer Order Number	As assigned by Requester	
OBR-3	EI	Filler Order Number	As assigned by Subcontractor	
OBR-4	CE	Universal Service Identifier		
OBR-4.1	ST	Code	11502-2	This code announces the laboratory report
OBR-4.2	ST	Text	LABORATORY REPORT.TOTAL	The LOINC name of this code
OBR-4.3	ID	Name of Coding System	LN	Coding system LOINC
OBR-25	ID	Result Status	P, F, C, X	The report is Preliminary, Final, Corrected (after final) or canceled (X). When existing, it contains only verified results (i.e., clinically validated).

3.Z.5.1.6 OBX Segment Carrying the Laboratory Report Fac-simile

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This segment is populated with these 6 fields:

Field	DT	Element name	Value	Ccomment
OBX-1	SI	Set ID – OBX	1	
OBX-2	ID	Value Type	ED	Encapsulated Data
OBX-3		Observation Identifier		
OBX-3.1	ST	Code	11502-2	The observation is the laboratory report itself
OBX-3.2	ST	Text	LABORATORY REPORT.TOTAL	The LOINC name of this code
OBX-3.3	ID	Name of Coding System	LN	Coding system LOINC
OBX-5	ED	Observation Value		
OBX-5.1	HD	Source Application		A unique designator of the system that stores the data
OBX-5.2	ID	Type of data	AP	Other application data. The report is not to be interpreted by a HL7 parser.
OBX-5.3	ID	Data Subtype	PDF or JPG	The laboratory report is in PDF or JPEG format
OBX-5.4	ID	Encoding	Base64	The laboratory must encode the report in base64
OBX-5.5	TX	Data	String Data	The report fac-simile encoded in base64
OBX-11	ID	Observation Result Status	P, F, C, D	The report is Preliminary, Final, Corrected, Deleted, or cannot be produced (X). In the two latter cases (D or X) OBX-5.1 SHALL be nullified (i.e., populated with two double quotes)
OBX-13	ST	User Defined Access Checks	P *or empty*	P means this report should be viewed only by privileged users.

3.Z.5.1.7 Example of ORDER_OBSERVATION Segment Group in an ORU Message

```
…
ORC|SC|||777^Nephro|||||200805191100

OBR||||11502-2^LABORATORY REPORT.TOTAL^LN|||||||||||||||||||||||F

OBX|1|ED|11502-2^LABORATORY REPORT.TOTAL^LN||HEXALIS&101900^AP^PDF^Base64^
TWFuIGlzIGRpc3Rpbmd1aXNoZWQs……||||||F||P

OBX|2|ED|11502-2^LABORATORY REPORT.TOTAL^LN||HEXALIS&101900^AP^PDF^Base64^
IG5vdCBvbmx5IGJ5IGh==……||||||F||P
……
```

740

745

3.Z.5.2 Fields usage specific to transaction LAB-36

3.Z.5.2.1 ORC – Common order segment

750   ORC-2 – Placer Order Number: identifies a subcontracted test or battery.

ORC-4 – Placer Group Number: identifies a group of test and batteries subcontracted together.

Volume 2x- Appendices

Update Appendix C of volume 2x "Common HL7 message segment for IHE LAB-TF" with the content below

755

C.3 PID – Patient Identification Segment

Section C.3- PID patient Identification Segment: add the following paragraph below the segment table

760 **PID-3 Patient identifier list, required**

This field contains one or more patient identifier. Each identifier is formatted with the CX data type, providing at least the type of identifier and the assigning authority with the identifier itself.

C.7 SPM – Specimen Segment

765 *Section C.7- SPM Specimen Segment: add the following sentence in the condition predicate of the SPM-2 description paragraph:*

SPM-2 Specimen ID (EIP), conditional

Condition predicate: This field shall be populated in OML messages of transaction LAB-1, in the
770 context of the use case "Externally placed order with identified specimens" defined in volume 1. This field is required in OML messages of the LAB-2 transaction. It may also be used in transaction LAB-3. This field is required if known (RE) in transactions LAB-4 and LAB-5.

This field is populated in transaction LAB-35 in situations where the requesting laboratory is providing pre-identified specimens with barcode stickers on the specimen container addressed to
775 the subcontractor laboratory.

Refer to section 2.4.6.1 for the details of the data type.

Section C.7- SPM Specimen Segment: Update detailed description of SPM-3 as follows:

SPM-3 Specimen Parent ID (EIP), required if available

780 This field contains the identifiers for the parent specimen, from which the specimen described by the segment instance has been extracted. ~~Please~~ Refer to section 2.4.6.1 for the details of the data type.

The IHE Laboratory Technical Framework does not admit pooling of specimens; therefore the maximum cardinality for the parent specimen is 1.

785 **Specimen Tracking in a Multi-laboratory Environment:**

In case a specimen is aliquoted and transmitted for outsourced testing from laboratory to laboratory, all the Actors crossed by the end-to-end workflow (i.e., Order Filler, Requester, Subcontractor) SHOULD populate the first component "Placer Assigned Identifier" of SPM-3 "Specimen Parent ID" with the original ID of the specimen upmost ancestor, in every message
790 they produce. Thus the ID of the original collected specimen will be passed by unchanged from laboratory to laboratory, enabling every child of this specimen to be tracked back to its common ancestor, whatever laboratory used it.

C.9 OBX Observation/Result Segment

Section C.9- OBX Observation/Result Segment: *update the following paragraph*

795

OBX-23 Performing Organization Name (XON), conditional

This field has been added by release 2.5.1 of HL7. It specifies the laboratory that produced the test result described in this OBX segment. When this field is null, the receiving system assumes that the observations were produced by the sending organization.

800 Condition predicate: This field shall be valued in transaction LAB-3 when the test result carried by this OBX is produced by an outside laboratory, subcontracting a part of the order. In that case, this field shall be populated with the name of the subcontractor laboratory. This field shall be valued in transaction LAB-36 when the result carried by this OBX has been produced by another subcontracting laboratory, different from the one sending the message.

805