

IHE International

Integrating the Healthcare Enterprise



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**IHE Laboratory Technical Framework
Supplement year 6**

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**Inter-Laboratory Workflow
(ILW)**

Draft for Trial Implementation

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This is a supplement to the IHE Laboratory Technical Framework 2.1.

25

Details about IHE may be found at: www.ihe.net

Details about the IHE Laboratory domain may be found at:

<http://www.ihe.net/Laboratory/index.cfm>

30

Details about the structure of IHE Technical Frameworks and Supplements may be found at:

<http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>

The current version of the IHE Laboratory Technical Framework may be found at:

35 http://www.ihe.net/Technical_Framework/index.cfm

Editor's Note

40 The in-box italicized instructions hereafter are for the author to indicate to the Volume Editor how to integrate the relevant section(s) into the overall Technical Framework. Below the box instructions, text to be inserted in the Volume is underlined, text to be removed is striped, other text is unchanged.

Example:

In Section X.X update last paragraph as follows:

In this sentence this part is added ~~this part is removed~~. This sentence is unchanged.

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100 **Introduction**

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

- 105 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
- 110 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:

Volume 1:

- 115
- 1.7 Scope of changes introduced in the current year
 - 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
- 120
- 3.4 Integration Profiles Overview: Add the new profile
 - 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
- 125
- Appendix B: Add the two new transactions

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
- 130
- 3.7 SPM segment: Fields 2, 3 in the context of ILW
 - 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

135

Open Issues

<none>

Closed Issues

- 140 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 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
- 145 Requester SHALL rely on its own Order number and Order Group number to record the information received from the Subcontractor.
- 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”.
- 150 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 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
- 155 this choice:
- No need to setup a web server or ftp server to distribute reports as separate files.
 - The sender of the report knows exactly when the whole message (including the report) is received because all data are sent together.
- 160 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 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
- 165 a response [test approved | denied]. See how to deal with that in volume 2 (section Y.4.3).

Volume I – Integration Profiles

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

History of Annual Changes

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

- 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

175 *Add the following terms to the Glossary in section 1.11*

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.
180 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

185 *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 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.

190

195

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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 Synopsis of Usages and Dependencies

205

The synopsis below shows the profiles from the Laboratory Technical Framework, where they are usable, and what their dependencies are.

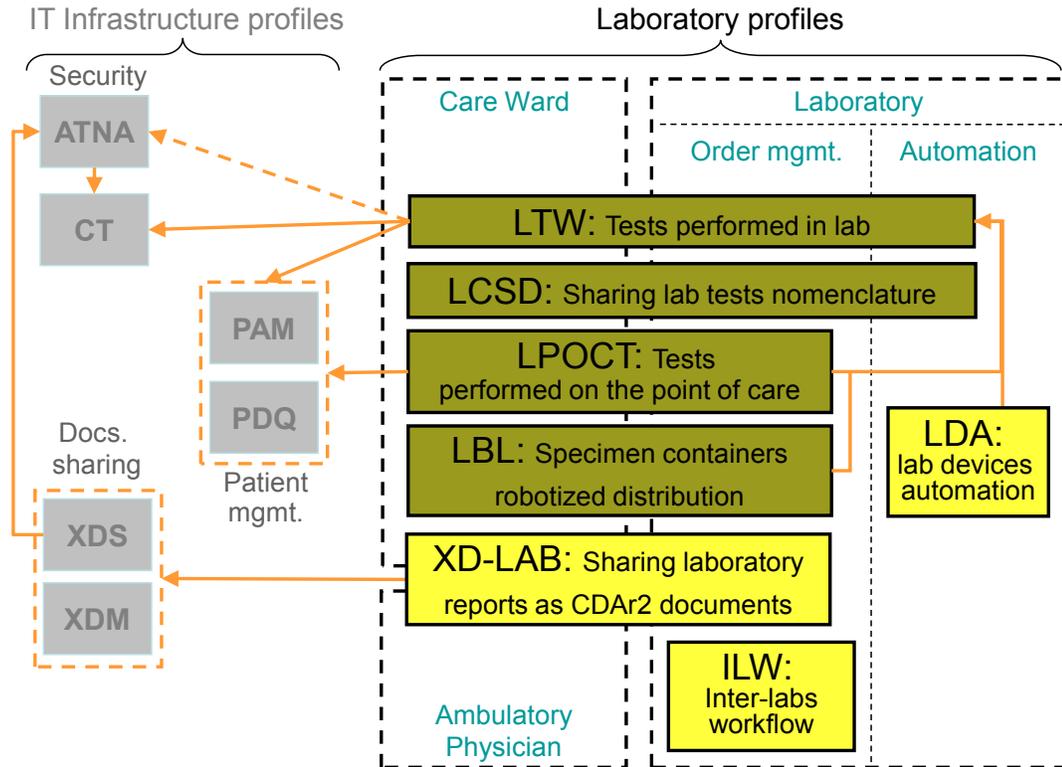


Figure 3-1: Laboratory Profiles Usages and Dependencies

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

210 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 the deployment of any of these three profiles.

215 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.

Dependencies among Integration Profiles

220 *Add the following section to Table 3-1 Integration Profiles Dependencies in section 3.3*

Inter-Laboratory Workflow (ILW)	none		
---------------------------------	------	--	--

Integration Profiles Overview

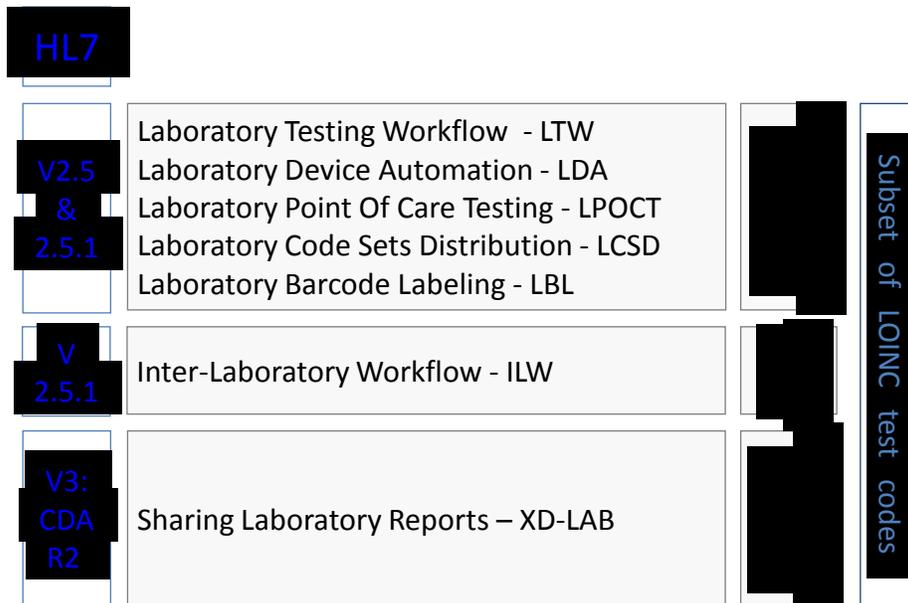
Add the following sub-section to section 3.4

3.4.9 Inter-Laboratory Workflow (ILW)

225 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.

Usage of HL7 standards in LAB TF

Conditioned to the choice of standard: If HL7 V2.x, then In section 3.5.2 replace Figure 3-3 by this one:



230

Figure 3-3: Versions of HL7 in use in the LAB-TF profiles

Relationships between units of work in the LAB TF

Add the following sub-section at the end of section 3.5.3

3.5.3.6 Sub-order

- 235 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 (inability to perform these tests, workload balance ...)
- The Sub-order is uniquely identified by the requesting laboratory with a Placer Group Number.
- 240 Each ordered test or battery composing it is uniquely identified by the requesting laboratory with a Placer Order Number.

Add the following chapter describing the new ILW integration profile:

X Inter-Laboratory Workflow (ILW)

245 X.1 Scope

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

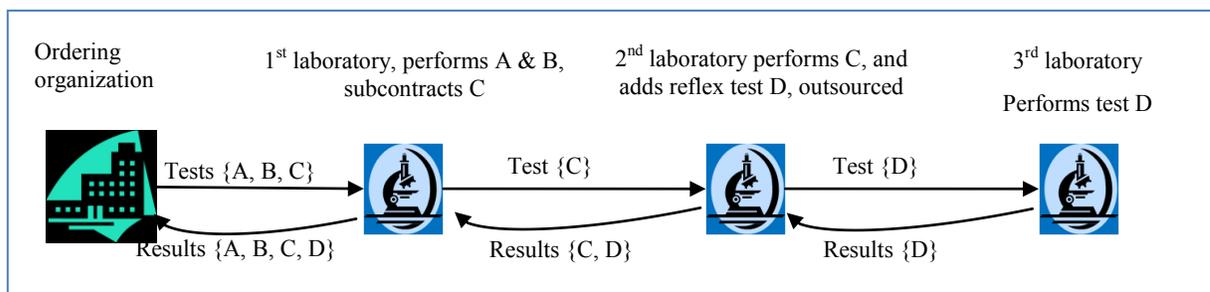
250 Having received a diagnostic tests requisition, the fulfilling laboratory identifies a subset of tests to be subcontracted to a second laboratory for whatever organizational reasons (tests out of specialty scope, mutualization of diagnostic devices and reagent within a cooperative group of laboratories 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 laboratory, which performs the tests and sends the results back to the first laboratory.

255 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 which laboratory performed which test, and which is liable for which observation.

260 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.

265 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 forwarding some tests to a third laboratory.



270 X.2 Out of Scope

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

- 275
- 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:

- 280
- 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.
- 285
- 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.
- 290

295 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 cases characteristics are summarized in Table X.3-1:

Table X.3-1

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.

300

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

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 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, 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.

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.

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 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 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 barcode labeled and processed.

340 The observations on anti-A antibodies are produced and verified by a 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.

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

345 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 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,
350 shared by all the laboratories members of the group.

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

355 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.

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.

360 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.

365 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.

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

370 X.4 Actors/ Transactions

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

- Transaction “Sub-order Management” supports the Sub-order placing and the related specimens provision.

375

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

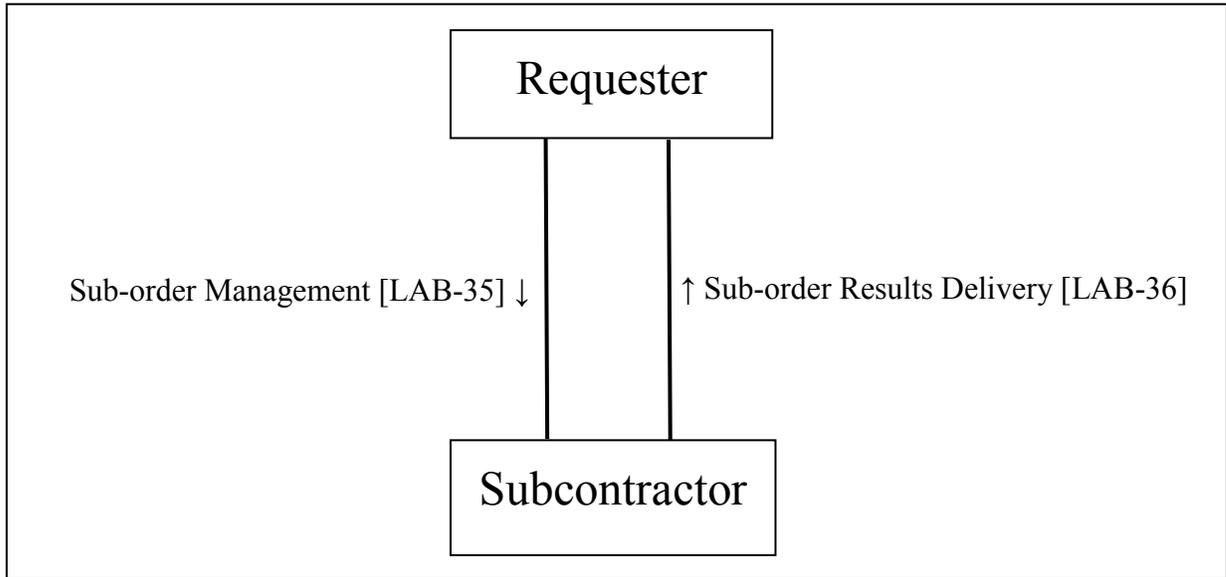


Figure X.4-1: ILW Profile Actor Diagram

380

Table X.4-1 lists the transactions for each actor directly involved in the ILW 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 Volume I, Section X.2.

385

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

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

390

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

Actor	Options	Vol & Section
Requester	<i>Input For Invoicing</i>	Y
	<i>Non-coded orders</i>	Y

Actor	Options	Vol & Section
	<i>Report Fac-Simile For Order Group</i>	Z
	<i>Test addition approval</i>	Y
Subcontractor	<i>Input For Invoicing</i>	Y
	<i>Report Fac-Simile For Order Group</i>	Z
	<i>Non-coded orders</i>	Y
	<i>Test addition approval</i>	Y

Input For Invoicing

395 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.

400 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

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:

405 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.
 - 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.
- 410

Non-coded Orders

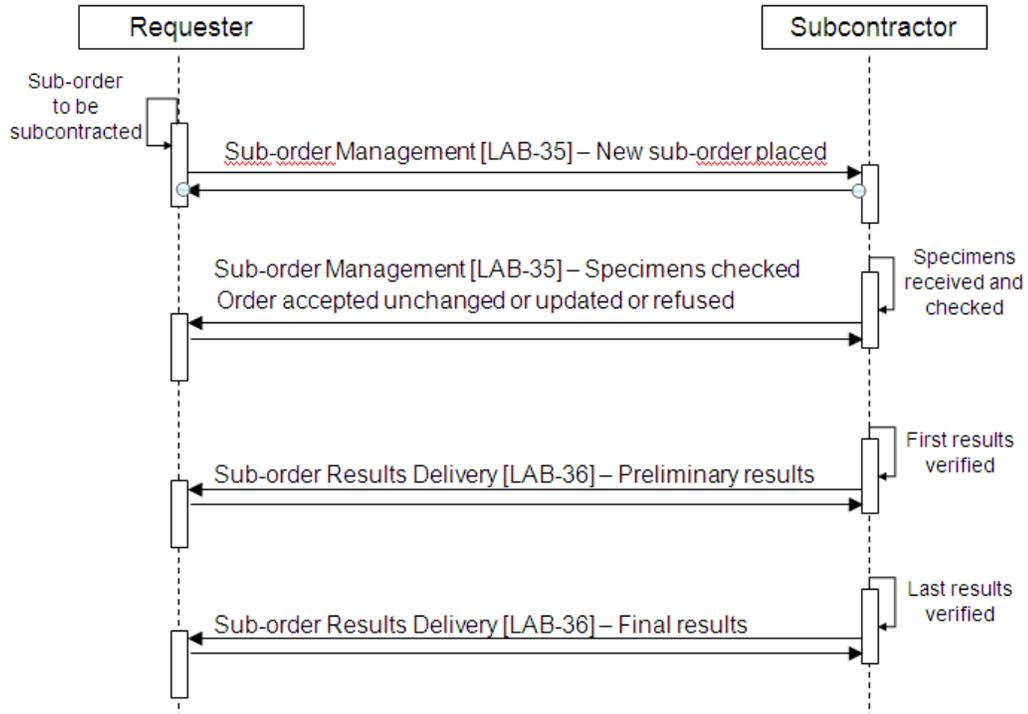
415 This option of Transaction Sub-order Management (LAB-35) enables the Requester to request a test/battery, using a display name which specifies in plain text (copied from the paper requisition) what test is to be performed. The subcontracting laboratory will pick the proper code in its own master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

Test addition approval

420 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.



425

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.

430 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.

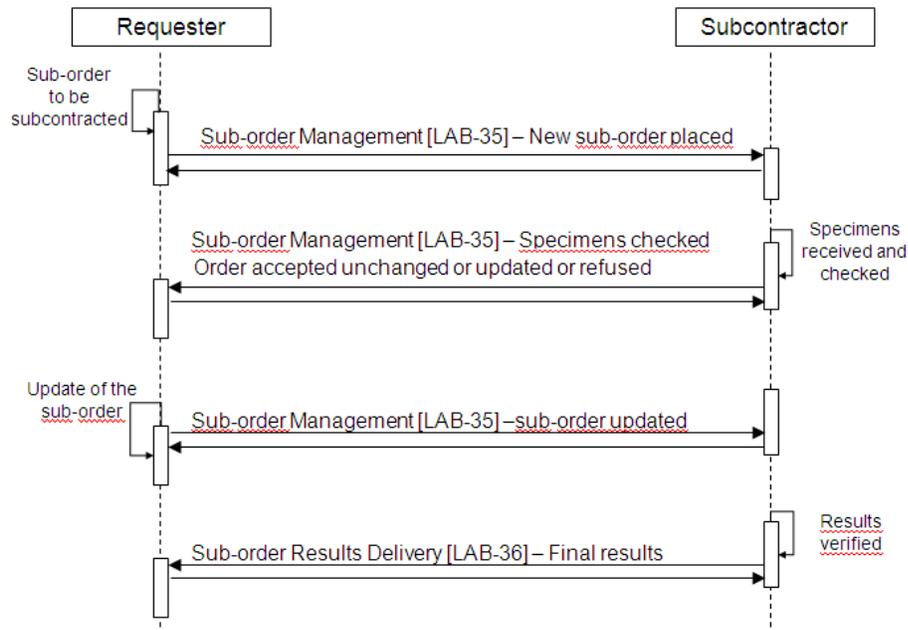


Figure X.6-2. Sub-order updated by Requester during the process

435

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

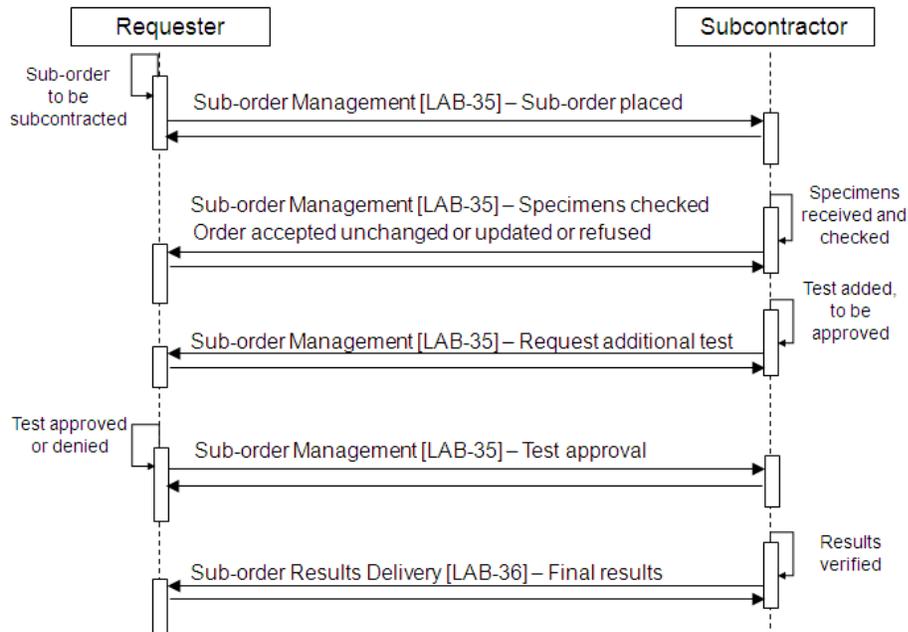


Figure X.6-3. Approval of additional test requested by the Subcontractor

440 **X.7 ILW Integration Profile Security Considerations**

- 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.
- 445 • 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:
 - 450 ○ 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 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.

455

<Appendix A> Actor Summary Definitions

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

460 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 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”.

465 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 and sends results messages.

<Appendix B> Transaction Summary Definitions

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

470 [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 from Subcontractor to Requester.

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

475

Volume 2 - Transactions

Rationale for the choice of the standards

- 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 this profile should leverage the same release of HL7 as the other laboratory profiles, which is V2.5.1.

480

Standard chosen:

485

- 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 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.

490

- 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 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.

495

- 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 of OBX segment instead of being referenced as a separate file.
- Transport layer: The HL7 MLLP protocol is chosen.

500

505

Update section 3 of volume 2 “common HL7 message segment for IHE LAB-TF” with the content below

510 **EIP – Entity Identifier Pair**

<i>Update section 2.4.6.3 “EIP- Entity Identifier Pair” as follows:</i>

HL7 Component Table - EIP – Entity Identifier Pair

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

520 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 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.

525 In the context of transactions LAB-35 and LAB-36 (in ILW profile) the first sub-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.

PID – Patient Identification Segment

545

Section 3.3- PID patient identification segment : add the following paragraph below the segment table

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.

550

SPM – Specimen Segment

Section 3.7- SPM Specimen Segment : add the following sentence in the condition predicate of the SPM-2 description paragraph:

SPM-2 Specimen ID (EIP), conditional

555

Condition predicate: This field shall be populated in OML messages of transaction LAB-1, in the 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.

560

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 the subcontractor laboratory.

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

Section 3.7- SPM Specimen Segment : Update detailed description of SPM-3 as follows:

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

565

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.

Specimen Tracking in a Multi-laboratory Environment:

570

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 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.

575

OBX Observation/Result Segment

Section 3.9- OBX Observation/Result Segment: update the following paragraph

OBX-23 Performing Organization Name (XON), conditional

580 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.

585 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.

590

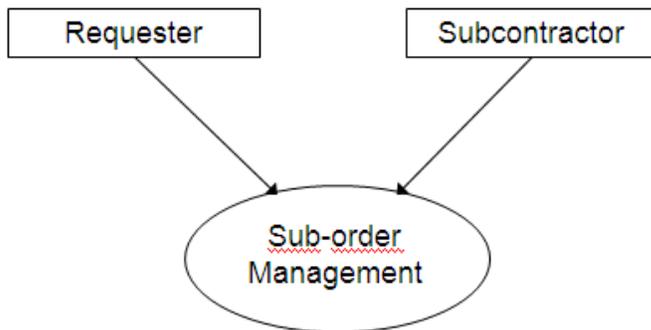
Y Transaction LAB-35: Sub-order Management

Y.1 Scope

595 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
- 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
- 600 • Test addition requested by the Subcontractor and approved or denied by the Requester (if the option “Test addition approval” is in use).
- 605 • The ordered tests/batteries SHALL 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 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 Sub-order placed, with the data necessary to handle the invoicing: “Whom to invoice?”

610 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.

615 **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.

Y.3 Referenced Standards

- 620 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
 - 625 • Chapter 13: "Clinical Laboratory Automation" --> SAC segment

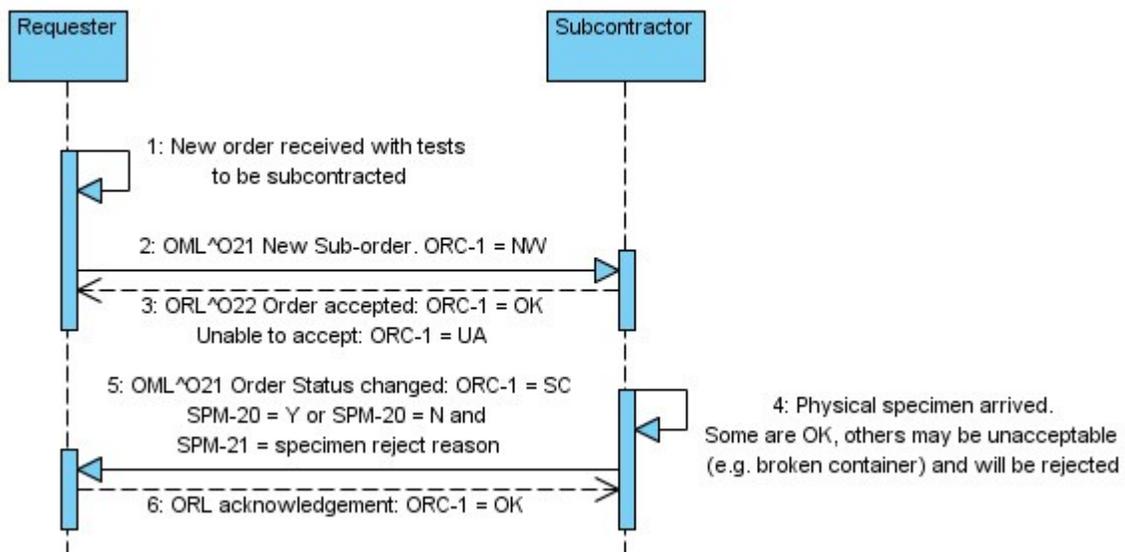
Y.4 Interaction Diagrams

630 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.

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

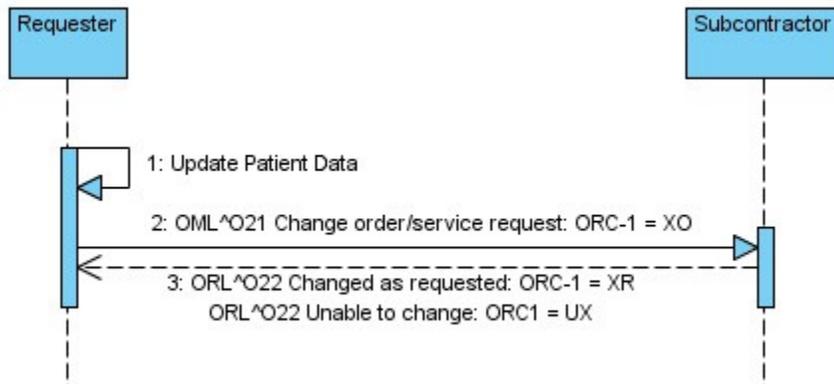
635 A subcontractor may subcontract some or all sub-orders to another subcontractor. In this case it will become the requester for all transactions made with its subcontractor. In this case, it generates a new Placer Order Number and optionally a new Placer Group Number.

Y.4.1 Normal process of a sub-order



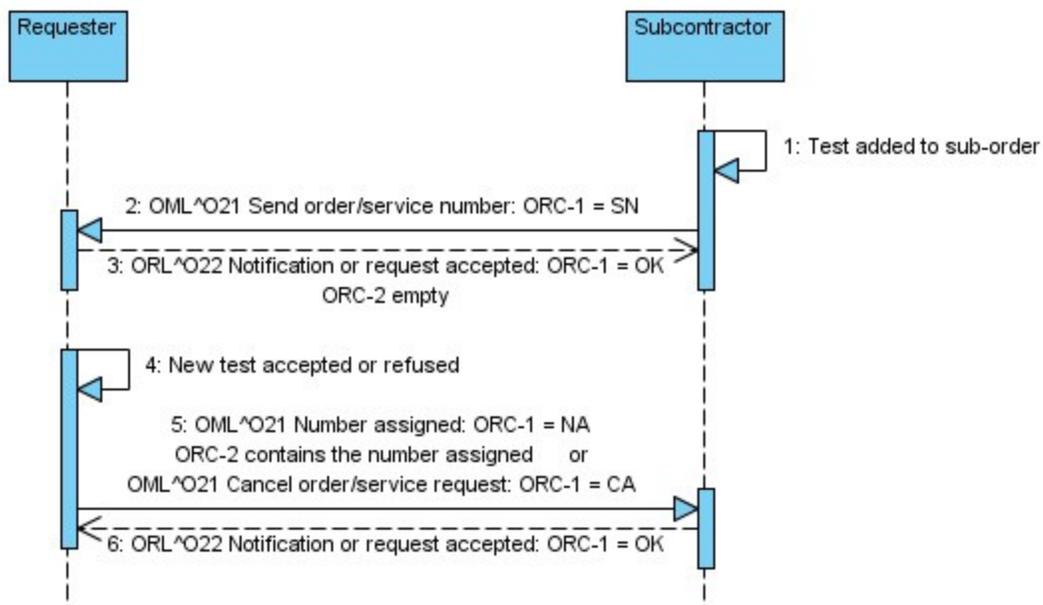
640 The two major events in normal process are the extraction of a Sub-order on the Requester side (tests from a received order, to be outsourced) and then the specimen reception on the Subcontractor side.

Y.4.2 Sub-order updated by the Requester during the process



645 This interaction is mainly used to forward to the subcontractor update of patient data that happens during the process of the sub-order.

Y.4.3 Tests added by the Sub-contractor with need for approval by the Requester



650 In some cases, tests added by the subcontractor need a formal approval by the requester. This interaction needs the use of option “*Test addition approval*”.

Y.5 Messages Static Definition

Y.5.1 OML^O21 Static Definition

Table Y.5-1: 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
[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
[{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			

655 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.

Y.5.2 ORL^O22 Static Definition

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

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

Y.5.3.1 ORC – Common order segment

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

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

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:

HL7 table 0485 - Priority codes

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

670 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

Y.5.3.4 identifying the packaging of specimens

675 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 have a unique identifier.

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

- 680
- SAC-10 Carrier Identifier (EI) represents the box identifier, if any.
 - SAC-13 Tray Identifier (EI) represents the plastic bag identifier, if any.
 - SPM-2 Specimen ID (EIP) carries the specimen ID, bar coded on the specimen container, if any.

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

685 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 service SHALL be identified in this field using this LOINC code exclusively: 11502-2^ LABORATORY REPORT.TOTAL^LN

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

Y.5.3.6 OBR-23 required with option “Input for Invoicing”

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

695 **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 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

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

Z Transaction LAB-36: Sub-order Results Delivery

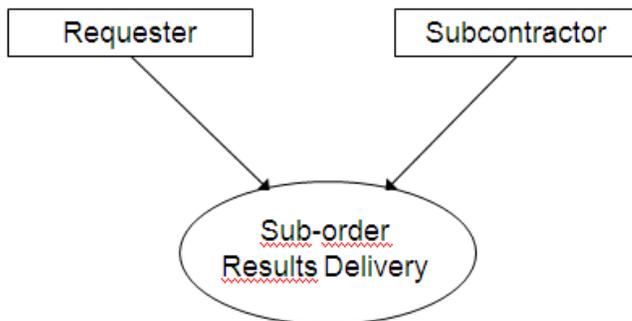
Z.1 Scope

705 This transaction is used by the Subcontractor to:

- 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.
- 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.

710

Z.2 Use Case Roles



715

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.

720

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.

Z.3 Referenced Standards

HL7 version 2.5.1:

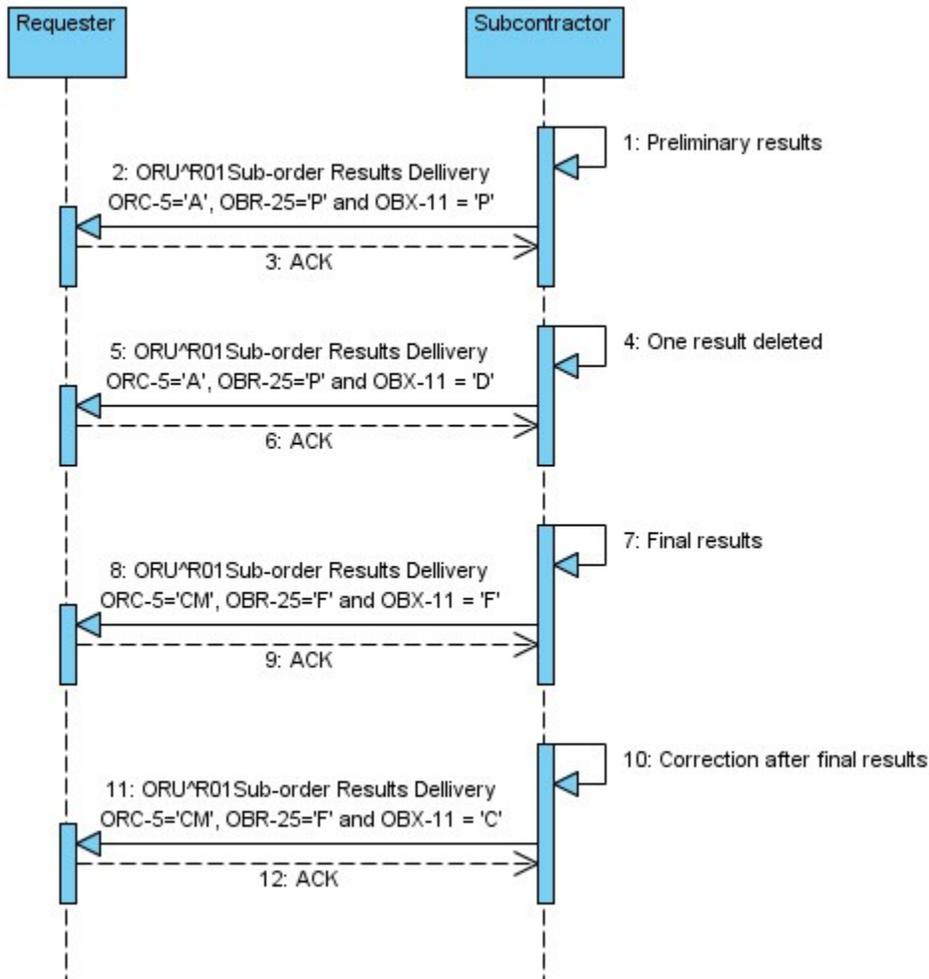
- Chapters 2, 2A: "Control" --> generic segments and data types
- Chapter 3: "ADT" --> PID and PV1 segments
- Chapter 7: "Observation Reporting" --> ORU message

725

Z.4 Interaction Diagrams

730

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.



Z.5 Messages Static Definition

735

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:

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

Z.5.1.1 Pdf Report embedded in series of OBX segments, encoded in base64

740

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 clinically validated and reportable results for this Sub-order.

745 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 SHALL embed this pdf report in the results message.

750 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 3 type of segments: ORC, OBR, OBX.

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

755 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	<i>A results message is always a Status Change.</i>
ORC-4	EI	Placer Group Number	<i>The Order Group number</i>	<i>The identifier assigned by the Order Placer to this Order Group.</i>
ORC-9	TS	Date/Time of Transaction	<i>Date time of the triggering event</i>	<i>Date/time of this release of the laboratory report produced for this Order Group.</i>

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
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	<i>This code announces the laboratory report</i>
OBR-4.2	ST	Text	LABORATORY REPORT.TOTAL	<i>The LOINC name of this code</i>
OBR-4.3	ID	Name of Coding System	LN	<i>Coding system LOINC</i>
OBR-25	ID	Result Status	P, F, C, X	<i>The report is Preliminary, Final, Corrected (after final) or canceled (X). When existing, it contains only verified results (i.e. clinically validated).</i>

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

This segment is populated with these 6 fields:

Field	DT	Element name	Value	comment
OBX-1	SI	Set ID – OBX	1	
OBX-2	ID	Value Type	ED	<i>Encapsulated Data</i>
OBX-3		Observation Identifier		
OBX-3.1	ST	Code	11502-2	<i>The observation is the laboratory report itself</i>
OBX-3.2	ST	Text	LABORATORY REPORT.TOTAL	<i>The LOINC name of this code</i>
OBX-3.3	ID	Name of Coding System	LN	<i>Coding system LOINC</i>
OBX-5	ED	Observation Value		
OBX-5.1	HD	Source Application		<i>A unique designator of the system that stores the data</i>
OBX-5.2	ID	Type of data	AP	<i>Other application data. The report is not to be interpreted by a HL7 parser.</i>
OBX-5.3	ID	Data Subtype	PDF or JPG	<i>The laboratory report is in pdf or jpeg format</i>
OBX-5.4	ID	Encoding	Base64	<i>The laboratory must encode the report in base64</i>
OBX-5.5	TX	Data	String Data	<i>The report fac-simile encoded in base64</i>
OBX-11	ID	Observation Result Status	P, F, C, D	<i>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)</i>
OBX-13	ST	User Defined Access Checks	P or empty	<i>P means this report should be viewed only by privileged users.</i>

760 **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^
765 TWFuIGlzIGRpc3Rpbmd1aXNoZWQs.....|F|P
OBX|2|ED|11502-2^LABORATORY REPORT.TOTAL^LN||HEXALIS&101900^AP^PDF^Base64^
IG5vdCBvbm5IGJ5IGh==.....|F|P
.....
    
```

770 **Z.5.2 Fields usage specific to transaction LAB-36**

Z.5.2.1 ORC – Common order segment

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.