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**IHE Laboratory
Technical Framework Supplement**

10

**Laboratory Specimen Barcode Labeling
(LBL)**

15

Trial Implementation

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Please verify you have the most recent version of this document. See [here](#) for Trial Implementation and Final Text versions and [here](#) for Public Comment versions.

Foreword

30 This is a supplement to the IHE Laboratory Technical Framework V6.0. 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 July 14, 2015 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based 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
35 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 addition of large new sections introduced by editor’s instructions to “add new text” or similar,
40 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:

<i>Replace Section X.X by the following:</i>
--

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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: http://ihe.net/IHE_Process and <http://ihe.net/Profiles>.

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

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Introduction to this Supplement

100 This supplement for the Laboratory Technical Framework describes the introduction of a new option to the Laboratory Specimen Barcode Labeling (LBL) Profile, in order to support the labeled containers delivered confirmation event. This additional message is sent by the Label Broker Actor (LB) to the Label Information Provider Actor (LIP) as confirmation that labeled tubes have been effectively produced. This is very important because in real world use cases the Label Broker role is performed by a robotic system, so the new option acts as verification that no error occurred during this process. Currently the Label Broker, for both request and query mode use cases, is able to receive labeling information from the Label Information Provider (and to 105 acknowledge this reception), but no information is sent back to notify the completion of the tube labeling phase.

Open Issues and Questions

NA

Closed Issues

110 NA

Volume 1 – Profiles

1.9 Copyright Permission

115 NA

1.11 Glossary

Add the following term to the Glossary:

120 **[LAB-63] Labels and Containers Delivered:** This transaction contains the messages used by the Label Broker to notify the Label Information Provider of the successfully labeled containers production. These messages include the label information, patient information and specimen information (including containers types).

2 Scope of the Laboratory Technical Framework

125 NA

3.4 Profiles Overview

Replace Section 3.4.5 with the following:

130 3.4.5 Laboratory Specimen Barcode Labeling (LBL)

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

7 Laboratory Specimen Barcode Labeling (LBL)

7.1 Scope

145 *Replace Section 7.1 with the following.*

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

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

155 The Label Broker receives label information, and delivers these labels in appropriate operations, and may notify the status of this process, **sending a confirmation message for labeled containers effectively produced and delivered.**

The Label Information Provider is usually grouped with the Order Filler or the Order Placer from the Laboratory Testing Workflow Integration Profile.

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

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

165 **7.2 Use Cases**

7.2.1 LIP grouped with OP, request mode

Replace Section 7.2.1 with the following:

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

- a) The Order Placer generates a test order and calculates the needed containers and associated barcode labels for this order.
- b) The Order Placer places the order to the Order Filler, and the Order Filler accepts it.
- 175 c) In due time, the Label Information Provider sends the labeling instructions to the Label Broker.
- d) The Label Broker issues the containers with barcode labels. **At the end of the process, the Label Broker may notify the Label Information Provider of successfully labeled containers.**
- 180 e) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.2 LIP grouped with OF, request mode

Replace Section 7.2.2 with the following:

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

- 185 a) A test order is generated either on the Order Placer side or on the Order Filler side.
- b) In both cases, the Order Filler gets this order, and in due time, schedules it and calculates the needed containers and associated barcode labels for this order. Then the Order Filler sends the labeling instructions to the Label Broker.
- 190 c) The Label Broker issues the containers with barcode labels. **At the end of the process, the Label Broker may notify the Label Information Provider of successfully labeled containers.**
- d) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

195 **7.2.3 LIP grouped with OP, informed by OF, request mode**

Replace Section 7.2.3 with the following:

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

- 200 a) A test order is generated either on the Order Placer side or on the Order Filler side.
- b) The Order Filler accepts this order and generates the specimen information, and sends the confirmation back to the Order Placer. This confirmation carries the specimen information.
- 205 c) In due time, the Label Information Provider grouped with the Order Placer sends the labeling instructions to the Label Broker.
- d) The Label Broker issues the containers with barcode labels. **At the end of the process, the Label Broker may notify the Label Information Provider of successfully labeled containers.**
- 210 e) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.4 LIP grouped with OP, query mode

Replace Section 7.2.4 with the following:

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

- a) A test order is generated either on the Order Placer side or on the Order Filler side.
- b) The patient arrives at the specimen collection point. The patient id is entered (scanned) into the Label Broker. This triggers a query from the Label Broker to the Label Information Provider to get labeling instructions for the specimens to be collected from this patient.
- 220 c) The Label Information Provider grouped with the Order Placer responds with the labeling instructions.
- d) The Label Broker issues the containers with barcode labels. **At the end of the process, the Label Broker may notify the Label Information Provider of successfully labeled containers.**
- 225 e) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

7.2.5 LIP grouped with OF, query mode

Replace Section 7.2.5 with the following:

- 230 The Label Broker requests label information from the Label Information Provider grouped with the Order Filler.
- a) A test order is generated either on the Order Placer side or on the Order Filler side.
 - b) In both cases, the Order Filler gets this order, and in due time, schedules it and calculates the needed containers and associated barcode labels for this order.
- 235 c) The patient arrives at the specimen collection point. The patient id is entered into the Label Broker. This triggers a query from the Label Broker to the Label Information Provider to get labeling instructions for the specimens to be collected from this patient.
- d) The Label Information Provider grouped with the Order Filler responds with the labeling instructions.
- 240 e) The Label Broker issues the containers with barcode labels. **At the end of the process, the Label Broker may notify the Label Information Provider of successfully labeled containers.**
- f) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.
- 245

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

Replace Section 7.2.6 content adding the bold text:

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

- a) A test order is generated on the Order Placer side.
- b) The Order Filler gets this order, schedules it and calculates the needed containers and associated barcode labels for this order.
- 255 c) In due time (preparation of the containers for an order group), a query from the Order Placer/Label Broker to the Order Filler/Label Information Provider is issued to get labeling instructions for the specimens to be collected for this order group number.
- d) The Label Information Provider grouped with the Order Filler responds with the labeling instructions.
- 260 e) The Label Broker issues the barcode labels. The labels are attached to the corresponding containers. **At the end of the process, the Label Broker may notify the Label Information Provider of successfully labeled containers.**
- f) The labeled containers are then used for specimen collection and then sent to the laboratory for testing.

265 7.3 Actors/ Transactions

Add the following:

Figure 7.3-1 shows the actors directly involved in the LBL Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in other related profiles, etc. are not necessarily shown.

270

275

Replace Figure 7.3-1 with the following:

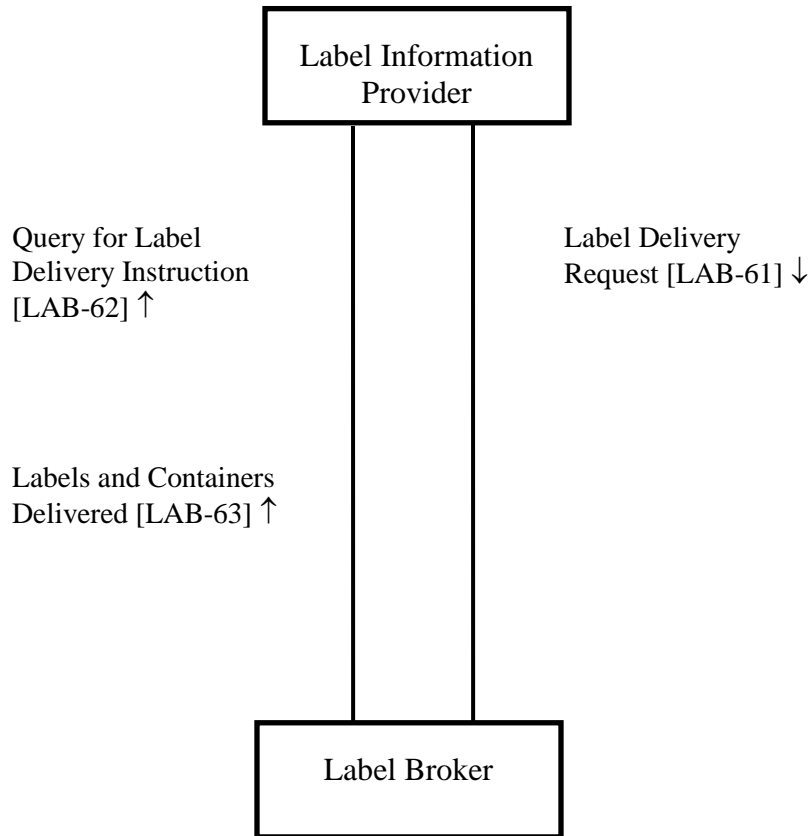


Figure 7.3-1: Laboratory Barcode Labeling Actor Diagram

280

Add the following:

Table 7.3-1 lists the transactions for each actor directly involved in the Laboratory Barcode Labeling Profile. In order to claim support of this Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Profile and that implementations may choose to support is listed in

285

Volume 1, Section 7.2.

290

Replace Table 7.3-1 with the following:

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

Actors	Transactions	Optionality	Section in Vol. 2
Label Information Provider	Transaction LAB-61	R	LAB TF-2:16
	Transaction LAB-62	R	LAB TF-2:17
	<u>Transaction LAB-63</u>	<u>O</u>	<u>LAB TF-2:Y</u>
Label Broker	Transaction LAB-61	R	LAB TF-2:16
	Transaction LAB-62	O	LAB TF-2:17
	<u>Transaction LAB-63</u>	<u>O</u>	<u>LAB TF-2:Y</u>

295

Replace Note 1 with the following:

NOTE: The Label Information Provider SHALL support both request mode and query mode. For the Label Broker the request mode is mandatory, and the query mode is optional. The query mode supported by Transaction LAB-62 corresponds to use cases 4 and 5. **Transaction LAB-63 is optional for both actors and it is applicable in all the use cases.**

300

7.4 LBL Integration Profile Options

Add the following:

Options that may be selected for this Profile are listed in the Table 7.4-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

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Replace Table 7.4-1 with the following:

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

Actor	Options	Volume & Section
<u>Label Information Provider</u>	<u>Labels and Containers Delivered</u>	<u>LAB TF-2:Y</u>
Label Broker	Query for labeling instruction	LAB TF-2:17
	<u>Labels and Containers Delivered</u>	<u>LAB TF-2:Y</u>

310

7.5 Process Flow

7.5.1 LIP grouped with OP, request mode

Replace Figure 7.5.1-1 with the following:

315

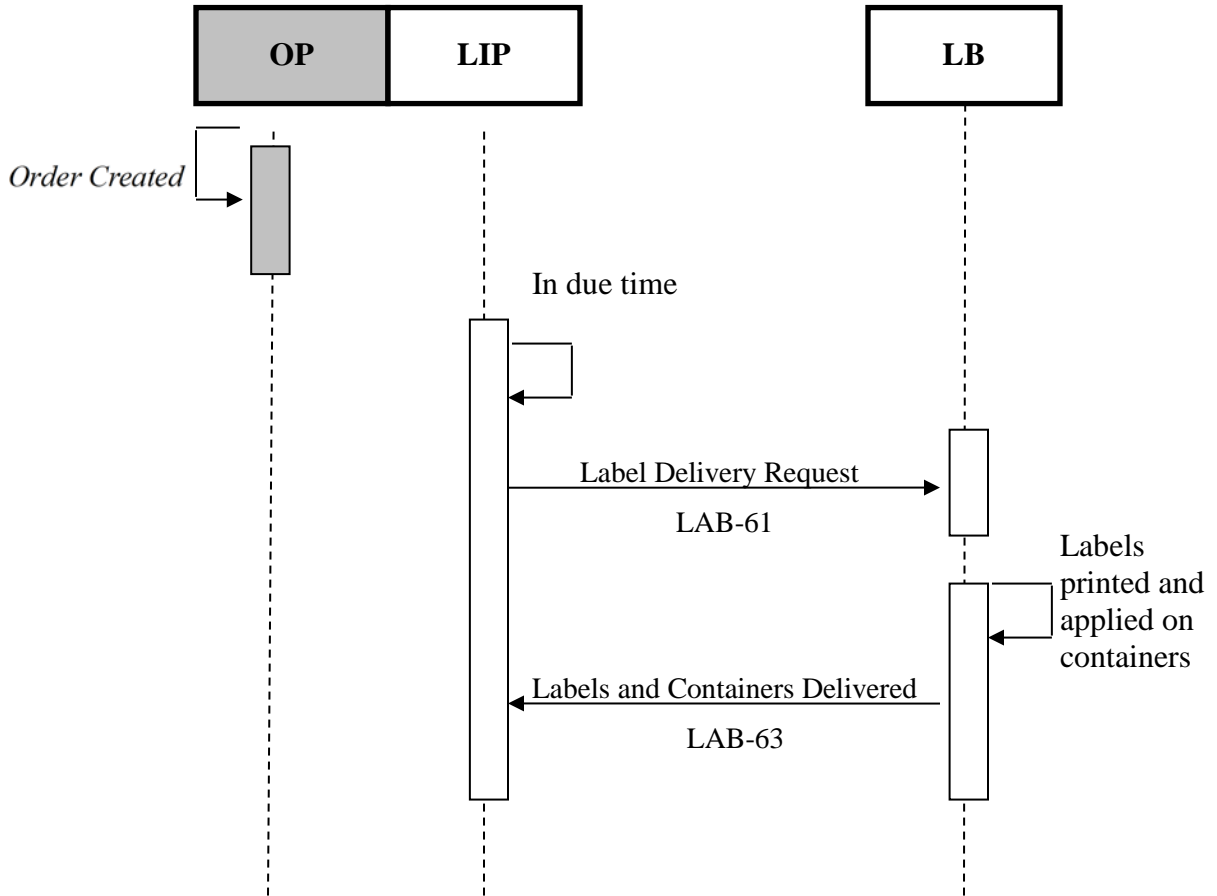
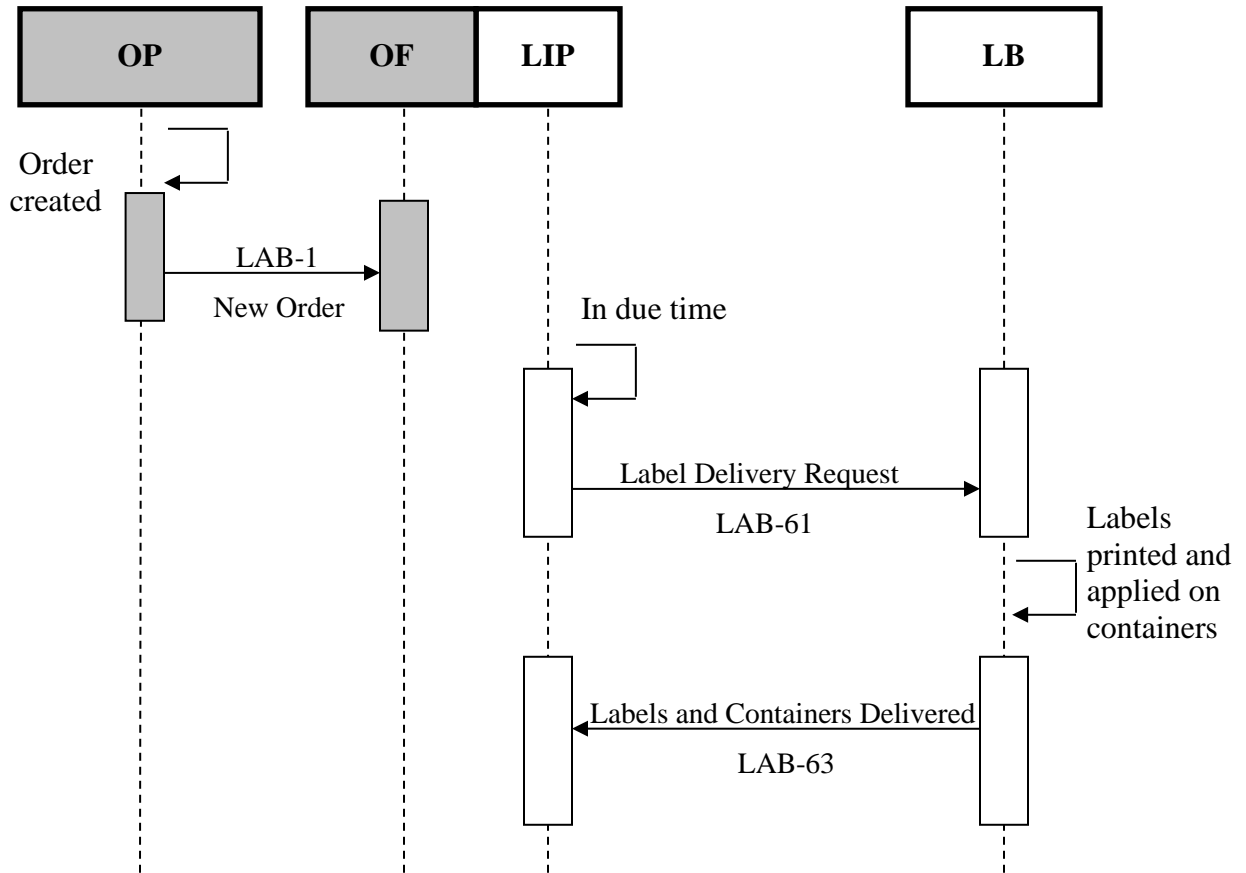


Figure 7.5.1-1: LIP grouped with OP – request mode

320

7.5.2 LIP grouped with OF, request mode

Replace Figure 7.5.2-1 with the following:



325

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

330 **7.5.3 LIP grouped with OP, informed by OF, request mode**

Replace Figure 7.5.3-1 with the following:

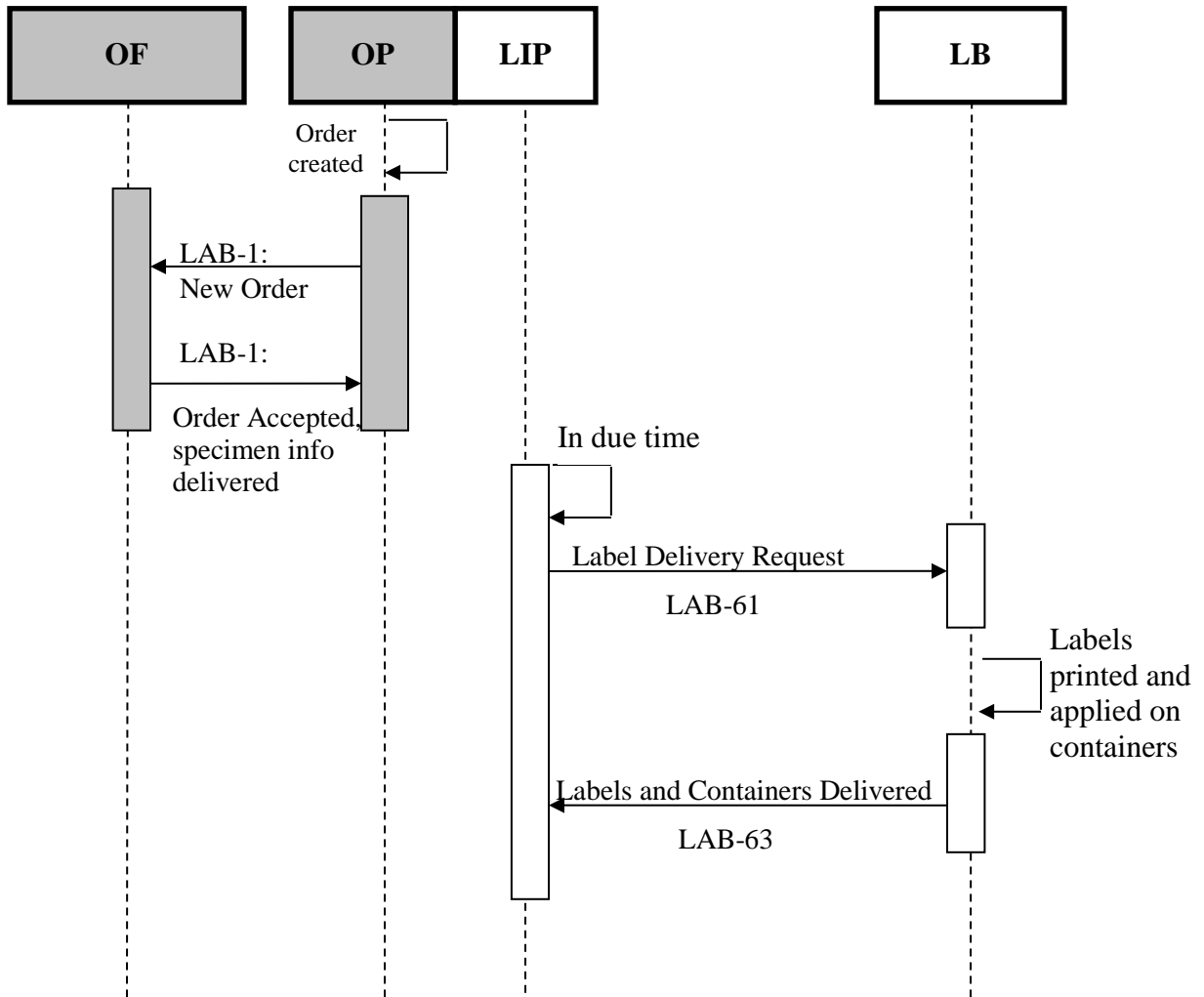
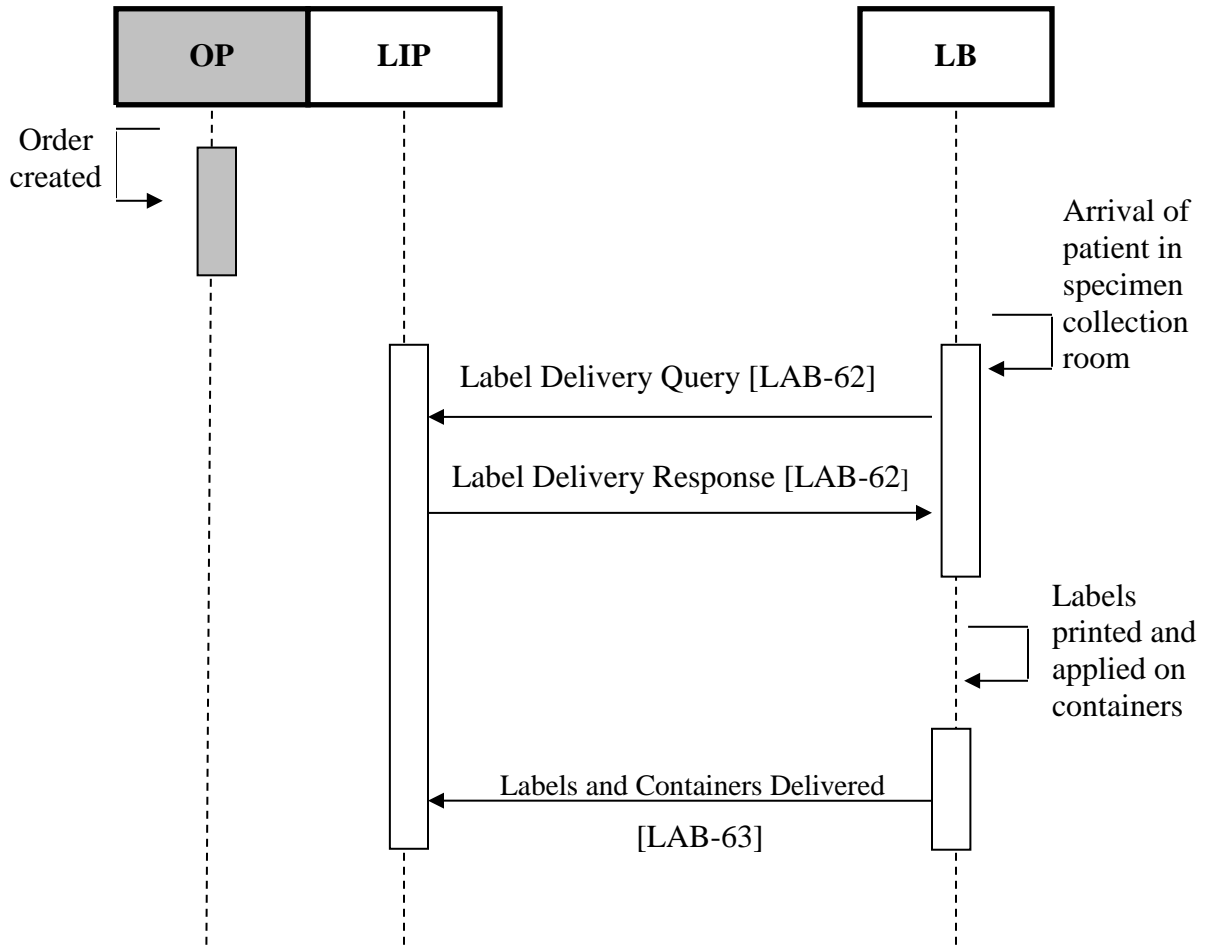


Figure 7.5.3-1: LIP grouped with OP, informed by OF, request mode

335

7.5.4 LIP grouped with OP, query mode

Replace Figure 7.5.4-1 with the following:



340

Figure 7.5.4-1: LIP grouped with OP, query mode

7.5.5 LIP grouped with OF, query mode

345 *Replace Figure 7.5.5-1 with the following:*

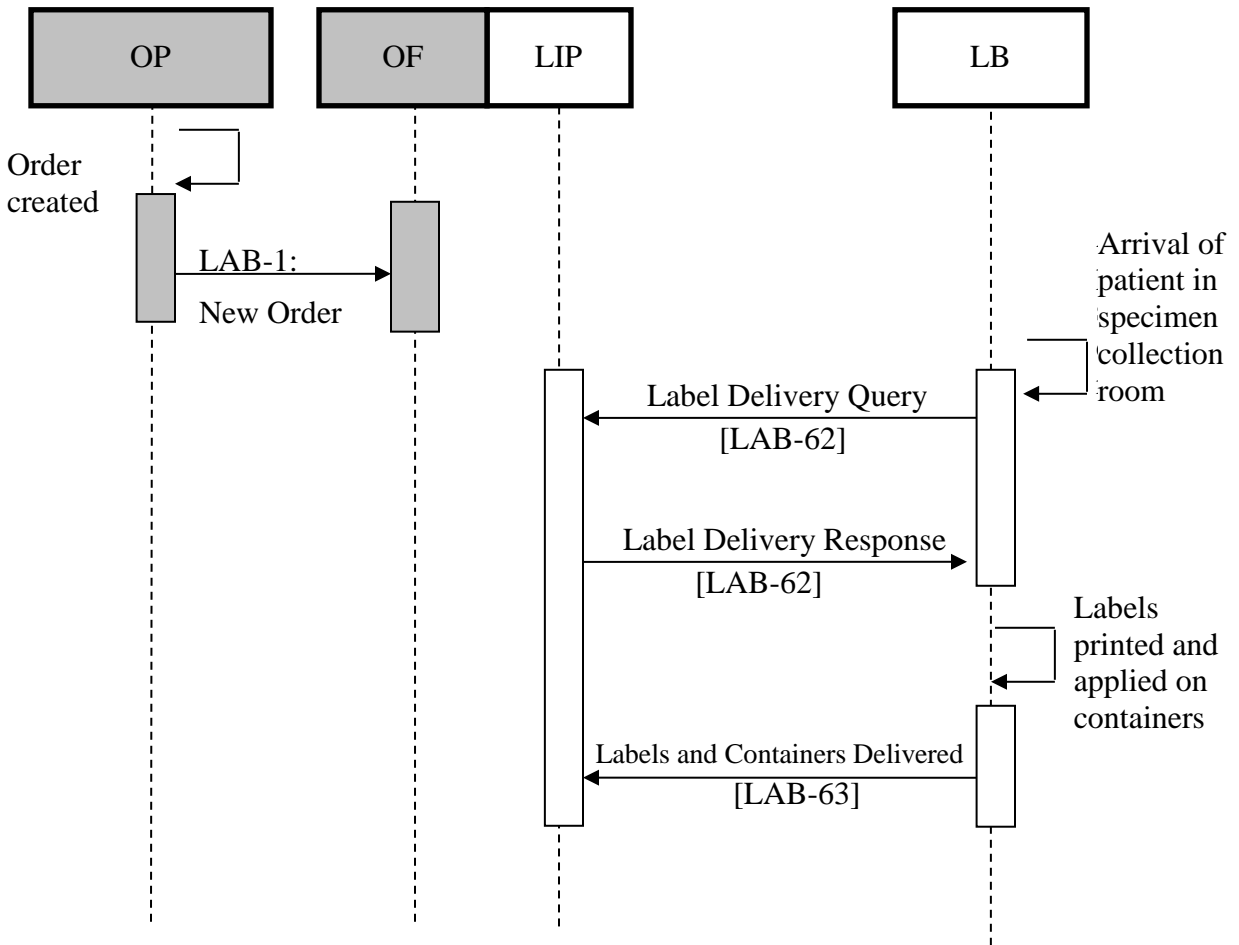


Figure 7.5.5-1: LIP grouped with OF, query mode

350 **7.5.6 LIP grouped with OF, LB grouped with OP, query mode**

Replace Figure 7.5.6-1 with the following:

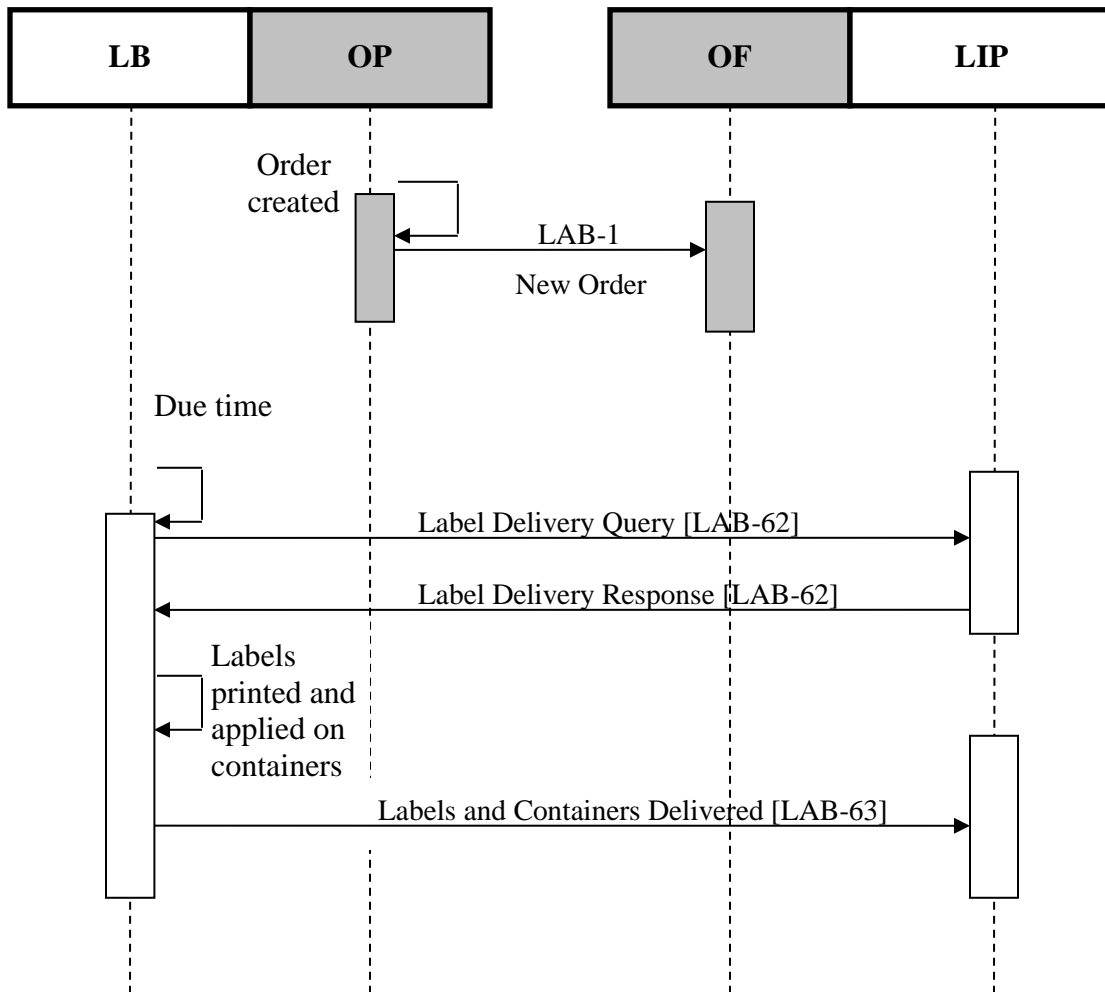


Figure 7.5.6-1: LIP grouped with OF, LB grouped with OP - query mode

355

360 **Appendix B Transaction descriptions**

Add the following to Appendix B

[LAB-63] Labels and Containers Delivered: This transaction contains the messages used by the Label Broker to notify the Label Information Provider of the effectively labeled containers. These messages include the labels' information, patient information and the specimens' information (including containers' types)

365

Volume 2 – Transactions

370 *Add Section 3.Y*

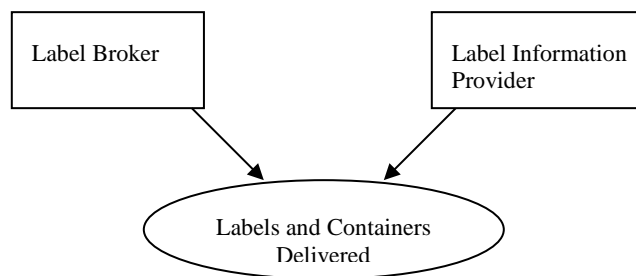
3.Y Labels and Containers Delivered (LAB-63)

3.Y.1 Scope

This transaction is used by the Label Broker to notify the effective labeled containers production to the Label Information Provider.

375

3.Y.2 Use Case Roles



380 **Actor:** Label Broker

Role: The Label Broker sends a notification message to the Label Information Provider for the effective labels printing and labeled containers production

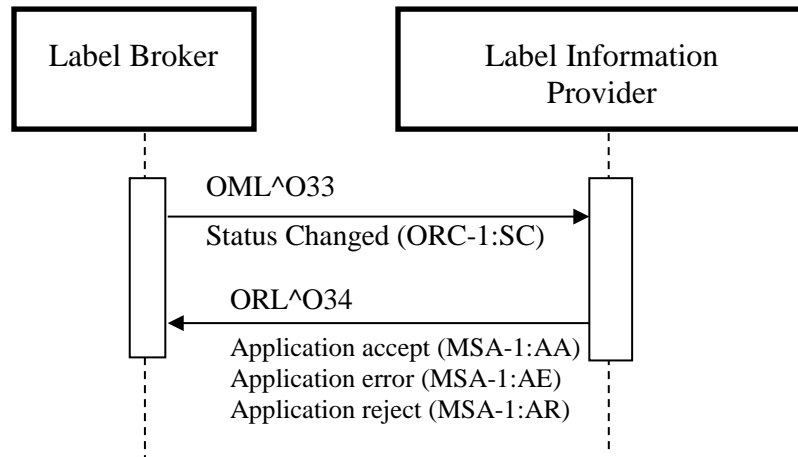
Actor: Label Information Provider

385 **Role:** The Label Information Provider receives the notification message from the Label Broker and may update the status of the process

3.Y.3 Referenced Standard

HL7® V.2.5, Chapter 4

3.Y.4 Interaction Diagram



390

Figure 3.Y.4-1: Interaction Diagram for [LAB-63]

3.Y.5 Message static definitions

This transaction contains the messages used to send labeled containers production notification from the Label Broker to the Label Information Provider.

3.Y.5.1 Trigger Events

395 OML (O33): Status changed information sent by the Label Broker.

ORL (O34): Application acknowledgement of notification information sent by the Label Information Provider.

400 **3.Y.5.2 Message Semantics**

Table 3.Y.5.2-1: OML^O33

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[--- PATIENT begin	R	[1..1]	
PID	Patient Identification	R	[1..1]	3
[PV1]	Patient Visit	RE	[0..1]	3
]	--- PATIENT end			
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[[SAC]]	Specimen Container	O	[0..*]	
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
[[TQ1]]	Timing Quantity	RE	[0..1]	4
[--- OBSERVATION REQUEST begin	O	[0..1]	
OBR	Observation Request	R	[1..1]	4
[TCD]	Test Code Details	O	[0..1]	13
[[O BX]]	Observation Result	O	[0..*]	7
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN end			

405 MSH-9 -Message Type (MSG) shall have its three components respectively valued to "OML", "O33" and "OML_O33".

410 This message carries the production notification of all labeled containers defined in each SPECIMEN segment group, and their related orders. The SPM-27 field is valued with the labeled container type; SPM-2 is the specimen (barcoded) id, SPM-4 the specimen type. Optionally, the SAC segment may be used to deliver additional information on the labeled physical container produced by the Label Broker.

The ORC-1 field SHALL be valued to 'SC' (Status Changed: labels and containers delivered).

The OBR-25 field SHALL be valued to 'S', according to the Correlations of Status between ORC and OBR.

415 Replace the following SPM Segment Descriptions listed in Section 3.7

SPM-2 Specimen ID (EIP), conditional.

This field contains a unique identifier or pair of unique identifiers for the specimen, enterprise-wide.

420 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.

425 This field shall be populated in ORL messages of transaction LAB-1, in the context of the use case "Order placed with specimens identified by a third party" defined in volume 1, when the third party is the Order Filler application itself.

This field shall be populated by the Label Information Provider in RSP messages of transaction LAB-62 and in OML messages of transaction LAB-61, **and by the Label Broker in OML messages of transaction LAB-63.**

430 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. Refer to Section 2.4.6.1 for the details of the data type.

<i>Replace the following SPM Segment Descriptions listed in Section 3.7:</i>
--

435 **SPM-27 Container Type (CWE)**, conditional.

The container(s) on or in which a specimen is transported.

Condition predicate:

440 This field shall be populated in ORL messages of transaction LAB-1, in the context of the use case "Order placed with specimens identified by a third party" defined in volume 1, when the third party is the Order Filler application.

This field shall be populated by the Label Information Provider in RSP messages of transaction LAB-62 and in OML messages of transaction LAB-61, **and by the Label Broker in OML messages of transaction LAB-63.**

445 The IHE Laboratory Technical Framework does not further constrain the usage of this field, nor does it provide any preferred vocabulary for it. This can be done in national extensions of this framework.

Table 3.Y.5.2-2: ORL^O34

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[{ERR}]	Error	C	[0..*]	2
[--- RESPONSE begin	O	[0..1]	
[PID]	Patient Identification	O	[0..1]	3
{	--- SPECIMEN begin	O	[0..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	O	[0..*]	13
[{	--- ORDER begin	O	[0..*]	
ORC	Common Order	R	[1..1]	4
[[TQ1]]	Timing/Quantity	RE	[0..1]	4
[OBR]	Observation Request	R	[1..1]	4
]]	--- ORDER end			
}]	--- SPECIMEN end			
]	--- RESPONSE end			

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

Condition predicate for use of the ERR segment:

The ERR segment SHALL be used whenever the Label Information Provider does not accept the labeled containers production notification (MSA-1 = AE or AR)

455

Table 3.Y.5.2-3: OBR Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	SI	O	[0..1]		00237	Set ID – OBR
2	22	EI	R	[1..1]		00216	Placer Order Number
3	22	EI	RE	[0..1]		00217	Filler Order Number
4	250	CE	R	[1..1]		00238	Universal Service Identifier
5	2	ID	X	[0..0]		00239	Priority – OBR
6	26	TS	X	[0..0]		00240	Requested Date/Time
7	26	TS	X	[0..0]		00241	Observation Date/Time #
8	26	TS	X	[0..0]		00242	Observation End Date/Time #
9	20	CQ	X	[0..0]		00243	Collection Volume *
10	250	XCN	O	[0..*]		00244	Collector Identifier *
11	1	ID	RE	[0..1]	0065	00245	Specimen Action Code *

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SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
12	250	CE	X	[0..0]		00246	Danger Code
13	300	ST	X	[0..0]		00247	Relevant Clinical Information
14	26	TS	X	[0..0]		00248	Specimen Received Date/Time *
15	300	SPS	X	[0..0]		00249	Specimen Source
16	250	XCN	R	[1..1]		00226	Ordering Provider
17	250	XTN	RE	[0..2]		00250	Order Callback Phone Number
18	60	ST	X	[0..0]		00251	Placer Field 1
19	60	ST	X	[0..0]		00252	Placer Field 2
20	60	ST	X	[0..0]		00253	Filler Field 1 +
21	60	ST	X	[0..0]		00254	Filler Field 2 +
22	26	TS	X	[0..0]		00255	Results Rpt/Status Chng - Date/Time +
23	40	MOC	X	[0..0]		00256	Charge to Practice +
24	10	ID	C	[0..1]	0074	00257	Diagnostic Serv Sect ID
25	1	ID	R	[0..0]	0123	00258	Result Status +
26	400	PRL	X	[0..0]		00259	Parent Result +
27	200	TQ	X	[0..0]		00221	Quantity/Timing
28	250	XCN	O	[0..*]		00260	Result Copies To
29	200	EIP	X	[0..0]		00261	Parent
30	20	ID	X	[0..0]	0124	00262	Transportation Mode
31	250	CE	O	[0..1]		00263	Reason for Study
32	200	NDL	O	[0..1]		00264	Principal Result Interpreter +
33	200	NDL	O	[0..1]		00265	Assistant Result Interpreter +
34	200	NDL	O	[0..1]		00266	Technician +
35	200	NDL	O	[0..1]		00267	Transcriptionist +
36	26	TS	O	[0..1]		00268	Scheduled Date/Time +
37	4	NM	O	[0..1]		01028	Number of Sample Containers *
38	250	CE	O	[0..1]		01029	Transport Logistics of Collected Sample *
39	250	CE	O	[0..1]		01030	Collector's Comment *
40	250	CE	X	[0..0]		01031	Transport Arrangement Responsibility
41	30	ID	X	[0..0]	0224	01032	Transport Arranged
42	1	ID	X	[0..0]	0225	01033	Escort Required
43	250	CE	X	[0..0]		01034	Planned Patient Transport Comment
44	250	CE	O	[0..1]	0088	00393	Procedure Code
45	250	CWE	O	[0..1]	0340	01316	Procedure Code Modifier
46	250	CE	O	[0..1]	0411	01474	Placer Supplemental Service Information

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
47	250	CE	O	[0..1]	0411	01475	Filler Supplemental Service Information
48	250	CWE	X	[0..0]	0476	01646	Medically Necessary Duplicate Procedure Reason.
49	2	IS	O	[0..1]	0507	01647	Result Handling

3.Y.5.3 Confirming additional tubes or labels carrying the same specimen ID

460 Some use cases often require that for the same request, more than one tube or label with the same SPECIMEN_ID has to be used to perform request's orders: this situation is due to the Order Filler or Order Placer specimen's collection policy.

465 In order to explain how many labels or tubes with the same SPECIMEN_ID are to be printed, the SAC segment is used for each additional label/tube. The Laboratory Information Provider shall provide, in the OML_O33 message, immediately after the related SPM segment, as many SAC segment as there are additional labels requested. Refer to the Table C.8-1 of TF LAB-2x for details.

3.Y.5.4 Expected Actions

470 The OML message with control code 'SC' sent by the Label Broker to the Label Information Provider contains the information of all produced labeled containers. The Label Information Provider will reply with an ORL^O34 message with either "Accept" (MSA-1 = AA) or "Reject" (MSA-1 = AR) or "Error" (MSA-1=AE)