Integrating the Healthcare Enterprise



IHE Laboratory (LAB) Technical Framework

Volume 2b (LAB TF-2b) Transactions Part B

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125 **1** Introduction

1.1 Overview of IHE

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established interoperability standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework, organizes educational sessions, exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is to support the use of existing standards, e.g., HL7, ASTM, DICOM, ISO, IETF, OASIS, CLSI and others as appropriate, rather than to define new standards. IHE profiles further constrain configuration choices where necessary in these standards to ensure that they can be used in their respective domains in an integrated manner between different extern. When clarifications or extensions to existing standards are necessary.

140 between different actors. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

1.2 Overview of the Laboratory Technical Framework

1.2.1 Production

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

This document is updated annually, following a period of public review, and maintained regularly through the identification and correction of errata. The current version, rev. 4.0 Final

150 Text, specifies the IHE transactions defined and implemented as of May 2012. The latest version of the document is always available via the Internet at http://www.ihe.net/Technical_Framework/index.cfm.

It has been produced with the help of the following organizations:

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

1.2.2 How the Laboratory Technical Framework is organized

The IHE Laboratory Technical Framework identifies a subset of the functional components of the healthcare enterprise or healthcare community, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth, and is organized in volumes:

- Volume 1 of the Laboratory Technical Framework (LAB TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called integration profiles that highlight their capacity to address specific integration requirements for clinical purposes.
- Volumes 2a, 2b, and 2x of the Laboratory Technical Framework (LAB TF-2a, Lab TF-2b, LAB TF-2x) provide a detailed technical description of each message-based transaction and of its messages.
- Volume 3 of the Laboratory Technical Framework (LAB TF-3) provides a detailed technical description of each document-based transaction, its persistent content and binding.
- Volume 4 of the Laboratory Technical Framework (LAB TF-4) has been deprecated

1.3 Audience

The intended audience of this document is:

- Technical staff of vendors participating in the IHE initiative
- IT managers of healthcare institutions and healthcare communities
 - Experts involved in standards development
 - Anyone interested in the technical aspects of integrating healthcare information systems

1.4 Relationship to Standards

The IHE Laboratory Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their 185 interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on HL7, IETF, ISO, CLSI, OASIS and W3C standards. As the scope of the IHE initiative expands, transactions based on other international standards may be included as required.

- 190 In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.
- 195 IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration

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

1.5 Relationship to Real-world architectures

The IHE Actors and transactions are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g., Hospital Information System, Electronic Patient Record, Clinical Information System, Laboratory Information System, Laboratory Automation System, analyzer, robotic transportation system and other pre and post-analytic process equipment), the IHE Laboratory Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Laboratory Technical Framework defines only those

210 functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

1.6 History of Annual Changes

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

1.6.1 Scope of Changes Introduced in the Current Year (2012)

This revision 4.0 incorporates a number of Change Proposals resulting from the Connectathons of years 2011 - 2012. It will be the basis for 2013 Connectathons.

220 **1.6.2 Scope of Changes Introduced in Year 2011**

This revision 3.0 incorporates a number of Change Proposals resulting from the Connectathons of years 2008 - 2010. It will be the basis for Connectathons 2011 (in Europe, Japan and other regions) and 2012 (in North-America).

The major enhancements are:

- Batch option and various refinements added to transaction LAB-51 (LCSD profile)
 - Fixes and refinements on some field definitions in various transactions.

1.6.3 Scope of Changes Introduced in Year 2008

The main changes introduced by revision 2.1 were the following:

- Refined descriptions of segments ORC, SAC, TQ1, OBX, SPM (see sections 3.5 to 3.9)
- Microbiology reporting rules (see section 3.11 and example in section 19.5)
 - Option "Report Facsimile For Order Group" (see sections 4, 6 and example in section 19.4)
 - HL7 Ack, and MSA, ERR segments descriptions externalized to ITI TF-2: Appendix C
 - Support of HL7 v2.5.1 (see OBX segment description in section 3.9)
 - Cleanup of all examples messages in section 19

235 **1.7 Comments**

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

1.8 Copyright Permissions

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IHE grants permission to CLSI to reproduce either parts of this document or the document in its entirety.

1.9 IHE Technical Framework Development and Maintenance Process

- 250 The IHE Laboratory Technical Framework is being continuously extended and maintained by the IHE Laboratory Technical committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.
- 255 The first of these principles is that any extensions, clarifications and corrections to the Technical Framework must maintain backward compatibility with previous versions of the framework in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there.

1.10 Glossary

260 See Glossary section in Volume 1: LAB TF-1:1.11

2 Conventions

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2.1 Technical Framework Cross-references

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

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

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

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

270 <section number> is the applicable section number.

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

When references are made to Transaction numbers in the Technical Framework, the following format is used:

[<domain designator>-<transaction number>], where

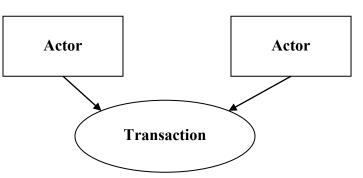
275 <transaction number> is the transaction number within the specified domain. For example: [LAB-1] refers to Transaction 1 from the IHE Laboratory Technical Framework, [ITI-30] refers to Transaction 30 from the IT Infrastructure Technical Framework.

2.2 The generic IHE Transaction Model

Transaction descriptions are provided in Section 3. In each transaction description, the actors, the roles they play, and the transactions between them are presented as use cases.

The generic IHE transaction description includes the following components:

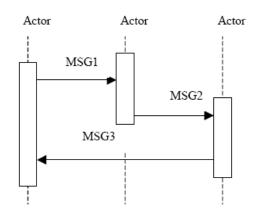
- Scope: a brief description of the transaction.
- Use case roles: textual definitions of the actors and their roles, with a simple diagram relating them, e.g.,:



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• *Referenced Standards*: the standards (stating the specific parts, chapters or sections thereof) to be used for the transaction.

• *Interaction Diagram*: a graphical depiction of the actors and messages that support the transaction, with related processing within an Actor shown as a rectangle and time progressing downward, similar to:



The interaction diagrams used in the IHE Laboratory Technical Framework are modeled after those described in Grady Booch, James Rumbaugh, and Ivar Jacobson, *The Unified Modeling Language User Guide*, ISBN 0-201-57168-4. Simple acknowledgment messages are often omitted from the diagrams for brevity. One or more messages may be required to satisfy a transaction. Each message is represented as an arrow starting from the Actor initiating the message.

• *Message definitions*: descriptions of each message involved in the transaction, the events that trigger the message, its semantics, and the actions that the message triggers in the receiver.

300 2.3 HL7 Profiling Conventions

The messages used by each transaction are described in this document using static definitions of "HL7 constrainable message profiles". Refer to HL7 v2.5 section 2.12.6. The static definition of each message is represented within tables. At the message level, a table represents the message structure and its definition in terms of segments. At the segment level, a table details one segment and its definition in terms of fields.

2.3.1 Static Definition - Message Level

The table describing a message contains 5 columns:

- *Segment*: gives the segment name, and places the segment within the hierarchy of the HL7message structure. Segments or segment groups not required appear between square brackets. Repeatable segments or segment groups appear between braces.
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- *Meaning*: Meaning of the segment as defined by HL7
- *Usage*: Coded usage of the segment, as defined by this static definition built for the context of this particular transaction within IHE Laboratory Technical Framework. The coded values used in this document are:
- **R**: Required: A compliant sending application shall populate all "R" elements with a nonempty value. A compliant receiving application shall process (save/print/archive/etc.) or ignore the information conveyed by required elements. A compliant receiving

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| | application shall not raise an error due to the presence of a required element, but may raise an error due to the absence of a required element. |
|-----|--|
| 320 | RE : Required if available. The element may be missing from the message, but shall be sent by the sending application if there is relevant data. A conformant sending application shall be capable of providing all "RE" elements. If the conformant sending application knows the required values for the element, then it shall send that element. If the conformant sending application does not know the required values, |
| 325 | then that element may be omitted. Receiving applications will be expected to process (save/print/archive/etc.) or ignore data contained in the element, but shall be able to successfully process the message if the element is omitted (no error message should be generated if the element is missing). |
| 330 | O: Optional. The usage for this field within IHE Laboratory Technical Framework has not been defined yet |
| | C: Conditional. This usage has an associated condition predicate. (See HL7 v2.5 section 2.12.6.6 "Condition Predicate"). |
| 335 | If the predicate is satisfied: A compliant sending application shall always send the element. A compliant receiving application shall process or ignore data in the element. It may raise an error if the element is not present. If the predicate is NOT satisfied: A compliant sending application shall NOT send the element. A compliant receiving application shall NOT raise an error if the condition |
| 340 | predicate is false and the element is not present, though it may raise an error if the element IS present. |
| | X: Not supported. For conformant sending applications, the element will not be sent. Conformant receiving applications may ignore the element if it is sent, or may raise an application error. |
| • | Cardinality: Within square brackets, minimum and maximum number of occurrences authorized for this segment, in this static definition of the message, built for the context of this particular transaction within IHE Laboratory Technical Framework. |

• HL7 chapter: Reference of the HL7 v2.5 chapter that describes this segment.

Simplification:

For a better readability of the table, the usage "X" is not shown at the message level: if a segment is "not supported" by an IHE profile, it simply doesn't appear in the table representing the message structure.

| 2 | 5 | Δ |
|---|---|---|
| J | J | υ |

Table 2.3.1-1: Example - Initial segments of a message description

| Segment | Meaning | Usage | Card. | HL7 chapter |
|---------|------------------------|-------|-------|-------------|
| MSH | Message Header | R | [11] | 2 |
| [| PATIENT begin | 0 | [01] | |
| PID | Patient Identification | R | [11] | 3 |

| Segment | Meaning | Usage | Card. | HL7 chapter |
|---------|---------------------|-------|-------|-------------|
| [| PATIENT VISIT begin | RE | [01] | |
| PV1 | Patient Visit | R | [11] | 3 |

2.3.2 Static Definition - Segment Level

The table describing a segment and its definition in terms of fields contains 7 columns:

- **SEQ**: Position (sequence) of the field within the segment.
- LEN: Maximum length of the field
- **DT**: Field Data Type
 - Usage: Usage of the field in this particular context of IHE Laboratory Technical Framework. Same coded values as in the message level: R, RE, C, O, X
 - **Cardinality**: Minimum and maximum number of occurrences for the field in this particular context of IHE Laboratory Technical Framework. Same meaning as in the message level.
- **TBL#**: Table reference (for fields using a set of defined values)
 - **ITEM#**: HL7 unique reference for this field
 - Element Name: Name of the field.

Simplification :

For a better readability of the table, the usage "O" is not shown <u>at the segment level</u>: Optional fields do not appear in the tables. The number in the first column SEQ is the only item of information that provides the exact position of a field within this segment.

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Table 2.3.2-1: Example - The MSH segment description

| SEQ | LEN | DT | Usage | Card. | TBL # | ITEM# | Element name |
|-----|-----|----|-------|-------|----------|-------|---------------------|
| 1 | 1 | ST | R | [11] | | 00001 | Field Separator |
| 2 | 4 | ST | R | [11] | | 00002 | Encoding characters |
| 3 | 227 | HD | R | [11] | 0361 | 00003 | Sending Application |
| | | | | | | | |

2.4 HL7 Implementation Notes

2.4.1 Network Guidelines

The IHE Laboratory Technical Framework makes these recommendations:

Applications shall use the Minimal Lower Layer Protocol (MLLP) defined in appendix C of the HL7 Implementation Guide.

An application that wants to send a message (initiate a transaction) will initiate a network connection (if one does not already exist) to start the transaction. The receiver application will respond with an acknowledgement or response to query but will not initiate new transactions on this network connection.

375 **2.4.2 Message Granularity**

A message is generated from one trigger event in the real world. Therefore a message is related to one single business object:

A LAB-1, LAB-2 or LAB-3 message is related to one Order or to one Order Group.

A LAB-4 or LAB-5 message is related to one Work Order.

380 A LAB-21, LAB-22, LAB-23 or LAB-26 message is related to one Work Order Step.

2.4.3 Empty and Nullified Fields

According to HL7 standard, if the value of a field is not present, the receiver shall not change corresponding data in its database. However, if the sender defines the field value to be the explicit NULL value (i.e., two double quotes ""), it shall cause removal of any values for that

385 field in the receiver's database. This convention is fully applied by the IHE Laboratory Technical Framework.

2.4.4 Acknowledgement Modes

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The Laboratory Technical Framework applies thoroughly the acknowledgement rules and syntax as defined in **ITI TF-2: C.2.3**. Implementers are referred to this **section C.2.3 in Appendix C of ITI TF volume 2** for all details regarding the usage of the MSA segment in acknowledgement messages (that is ACK, ORL and RSP messages), as well as the usage of the ERR segment.

For the IHE Laboratory Technical Framework, applications that receive HL7 messages shall send acknowledgements using the HL7 original acknowledgement mode as defined in HL7 v2.5 chapter 2, 2.9.2. The enhanced acknowledgement rules are not supported.

395 An OML message shall be acknowledged by one single ORL message. An OUL or an ORU message shall be acknowledged by one single ACK message. These acknowledgements are application-level acknowledgements (i.e., not transport acknowledgements) and must be generated by the receiving application after it has parsed the message and processed its content.

400 The receiving application shall automatically generate the application-level acknowledgement 400 messages without waiting for human approval of the contents of the message that was received.

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2.4.5 IHE Laboratory Technical Framework Acknowledgement Policies

From a transactional viewpoint a MLLP (Minimal Lower Layer Protocol) network connection is *unidirectional*. Event-triggered messages flow in one direction and acknowledgement messages related to those event-triggered messages flow in the other direction.

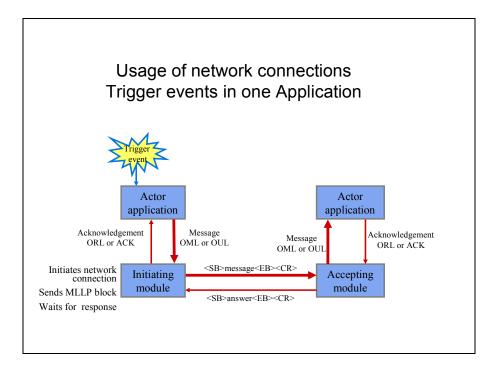
405 The acknowledgement message to an event-triggered message shall be sent *immediately* to the sender on the same MLLP connection that carried the event-triggered message. The receiver of an event-triggered message should assume that the sending application is blocking and send an application-level acknowledgement as soon as possible.

It may take the receiving system a while (seconds, minutes) to acknowledge a message. If the

410 MLLP connection is broken whilst the sending application is still waiting for an acknowledgement, the sending application shall initiate a new MLLP connection and resend the message.

The acknowledgement message is an application-level acknowledgement. (Note: HL7 commit/accept acknowledgement messages shall not be used). The application acknowledgement

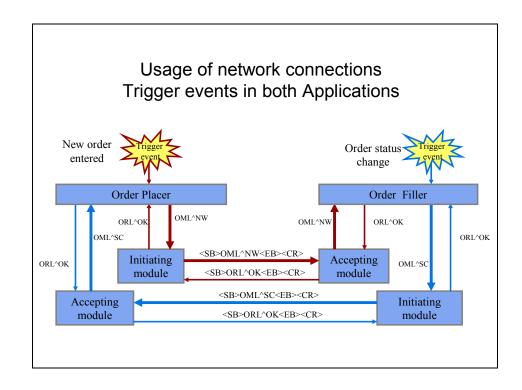
415 shall only be created by an application that is able to examine a message at the semantic / business-process level. Intermediate message brokers do not have this capacity and therefore shall not be used to generate the contents of application acknowledgements.



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Transactions between 2 applications which contain trigger events on both sides (such as LAB-1) require at least two network connections between the Actors, one for each direction:

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2.4.6 HL7 Data Types

This section describes the IHE constraints on some HL7 data types.

430 2.4.6.1 CX – Extended Composite ID with Check Digit

The constraints below particularly apply to the Patient Identifiers (PID segment).

| SEQ | LEN | DT | Usage | CARD | TBL# | COMPONENT NAME |
|-----|-----|-----|-------|------|------|-----------------------------------|
| 1 | 15 | ST | R | [11] | | ID Number |
| 2 | 1 | ST | 0 | [01] | | Check Digit |
| 3 | 3 | ID | 0 | [01] | 0061 | Check Digit Scheme |
| 4 | 227 | HD | R | [11] | 0363 | Assigning Authority |
| 5 | 5 | ID | RE | [01] | 0203 | Identifier Type Code |
| 6 | 227 | HD | 0 | [01] | | Assigning Facility |
| 7 | 8 | DT | 0 | [01] | | Effective Date |
| 8 | 8 | DT | 0 | [01] | | Expiration Date |
| 9 | 705 | CWE | 0 | [01] | | Assigning Jurisdiction |
| 10 | 705 | CWE | 0 | [01] | | Assigning Agency or Department |

The data type has been constrained because the IHE Framework regards the Assigning Authority and the Identifier Type Code as essential components.

435 **2.4.6.2 El – Entity Identifier**

The constraints below particularly apply to the following fields: placer group number, placer order number, filler order number and specimen number.

| SEQ | LEN | DT | Usage | CARD | TBL# | COMPONENT NAME |
|-----|-----|----|-------|------|------|-------------------|
| 1 | 16 | ST | R | [11] | | Entity Identifier |
| 2 | 20 | IS | С | [01] | 0363 | Namespace ID |
| 3 | 199 | ST | С | [01] | | Universal ID |
| 4 | 6 | ID | С | [01] | 0301 | Universal ID Type |

440 Component 1 is required. Either component 2 or both components 3 and 4 are required. Components 2, 3 and 4 may be all present.

The EI is appropriate for machine or software generated identifiers. The generated identifier goes in the first component. The remaining components, 2 through 4, are known as the assigning authority; they can also identify the machine/system responsible for generating the identifier in component 1.

445 component 1

Example 1: AB12345[^]RiversideHospital

Example 2: AB12345^^1.2.840.45.67^ISO

Example 3: AB12345^RiversideHospital^1.2.840.45.67^ISO

IHE restrains the length of the first component to 16 characters. National extensions can extendthis length up to a maximum of 199.

IHE recommends to fill component 2 "Namespace ID" in all cases. Particularly when there are several concurrent assigning authorities within the healthcare enterprise, this Namespace ID will indicate which assigning authority provided this number.

This happens for instance, when there are several Order Placer actors within the enterprise, each one assigning placer order numbers and placer group numbers.

Example 4: Placer order number and placer group number assigned by two different Order Placer actors.

In message 1: ORC|NW|9876543^Nephro||777^Nephro|... In message 2: ORC|SC|9876543^Urology||555^Urology|...

460 This also commonly happens when there are several Order Filler actors within the enterprise, each one assigning its own filler order numbers and specimen numbers.

Example 6: Filler order number and specimen number assigned by the Order Filler actor operated by the clinical laboratory of cytology. SPM | 1 | 45611^Cytology | . . .

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... OBR|1|<mark>456^Cytology</mark>|...

2.4.6.3 EIP – Entity Identifier Pair

HL7 Component Table - EIP – Entity Identifier Pair

| SEQ | LEN | DT | Usage | CARD | TBL # | COMPONENT NAME |
|-----|-----|----|-------|------|----------|----------------------------|
| 1 | 427 | EI | С | [01] | | Placer Assigned Identifier |
| 2 | 427 | EI | С | [01] | | Filler Assigned Identifier |

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

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.

475 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.

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:

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485 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.

490 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-61 and LAB-62, the second sub-component is never populated.

2.4.6.4 HD – Hierarchic Designator

| SEQ | LEN | DT | Usage | CARD | TBL # | COMPONENT NAME |
|-----|-----|----|-------|------|----------|-------------------|
| 1 | 20 | IS | R | [11] | 0300 | Namespace ID |
| 2 | 199 | ST | С | | | Universal ID |
| 3 | 6 | ID | С | | 0301 | Universal ID Type |

495 This Integration Profile requires that a field of Data Type HD be populated with:

- Either the first component "Namespace ID" alone, which in this case contains a local identifier of the object.
- Or with all three components, "Namespace ID" containing the name of the object, "Universal ID" containing its universal OID, and "Universal ID Type" containing the value **ISO**.
- 500 This data type is particularly used in this technical framework to identify facilities, applications and assigning authorities: sending and receiving applications, sending and receiving facilities, last update facility, assigning authority of an identifier, etc.

3 IHE Transactions

505 **3.30 Initiate POCT on a patient specimen (LAB-30)**

This transaction is used on a persistently connected POCRG. It implements option *Patient Identity Checking* of the LPOCT integration profile.

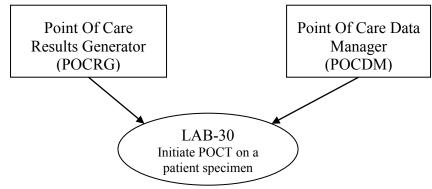
3.30.1 Scope

The point of care devices often work with a patient (or visit) identifier scanned or typed on their user interface. The purpose of this transaction is to provide a real-time control of this patient/visit identifier, and to avoid any risks of mistyping.

This transaction is used by a POCRG in a ward to inform the POCDM that a new point of care set of tests is about to start on a patient specimen. The POCRG delivers the relevant information related to the testing, including a patient/visit identifier. The POCDM checks the information

515 received, and particularly verifies that the patient/visit identifier is associated with this ward. It then sends back an acknowledgement carrying either the patient's name or a textual error (e.g., "Patient unknown"). The POCRG displays the information received in the acknowledgement, enabling the operator to check that he is testing on the right patient.

3.30.2 Use Case Roles



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Figure 3.30.2-1: Use case for LAB-30

Actor: POCRG

Role: Informs the POCDM that a new set of tests is starting, giving all relevant information related to this point of care testing. Waits for the patient identity in the acknowledgement, and displays this identity on its user interface.

Actor: POCDM

Role: Checks the information received related to the point of care testing, searches for the patient data related to the patient identifier received, and sends an acknowledgement back to the POCRG. The acknowledgement carries either the patient's name, or an error (e.g., "Test

530 unauthorized on this device")

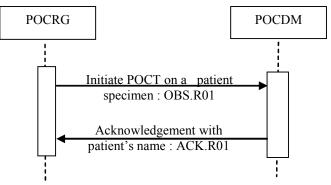
3.30.3 Referenced Standard

POCT1-A: Device Message Layer (DML) defined in Appendix B of POCT1-A standard.

In the POCT1-A standard, the POCRG actor of IHE is called the *Device* and the POCDM actor of IHE is called the *Observation Reviewer*.

535 This transaction LAB-30 uses the *Continuous Mode* defined in section 4.2 of Appendix B of POCT1-A. This continuous mode is usable if the POCRG has a persistent link with the POCDM, which is the prerequisite for using transaction LAB-30.

3.30.4 Interaction Diagram



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Figure 3.30.4-1: Interaction Diagram [LAB-30]

3.30.4.1 Patient Identity Checking

The POCT1-A standard currently does not describe this interaction for real-time patient identity checking. Transaction LAB-30 of this IHE profile will use as initial message a "patient-related observation message" OBS.R01 as defined in POCT1-A Appendix B. The status of the Service abient will be valued to "INII" (as "initiate a point of area testing") and no results will be

545 object will be valued to "INI" (as "initiate a point of care testing"), and no results will be provided in the message. This value "INI" is added by IHE to the table of service status defined in POCT1-A.

The Acknowledgement message ACK.R01 from the POCDM to the POCRG, will carry the patient's name as a note related to the acknowledgement, within the note_txt field of the Acknowledgement object.

The two messages are exchanged within an "*Observations*" *Topic* within the *Continuous Mode* of POCT1-A Device Messaging Level.

3.30.5 Trigger Events

An operator (caregiver or patient) sets a patient specimen on the point of care device (the 555 POCRG actor supporting the option "Patient identity checking"), and enters relevant information including the operator's ID and the patient's ID. This triggers the initial message of Transaction LAB30: "Initiate POCT on a patient specimen".

3.30.6 Message Semantics

3.30.6.1 Initiate POCT on a patient specimen – Message OBS.R01, status_cd = 'INI'

560 The figure below describes the use of message OBS.R01 in Transaction LAB-30. It respects the formalism of POCT1-A, Annex B.

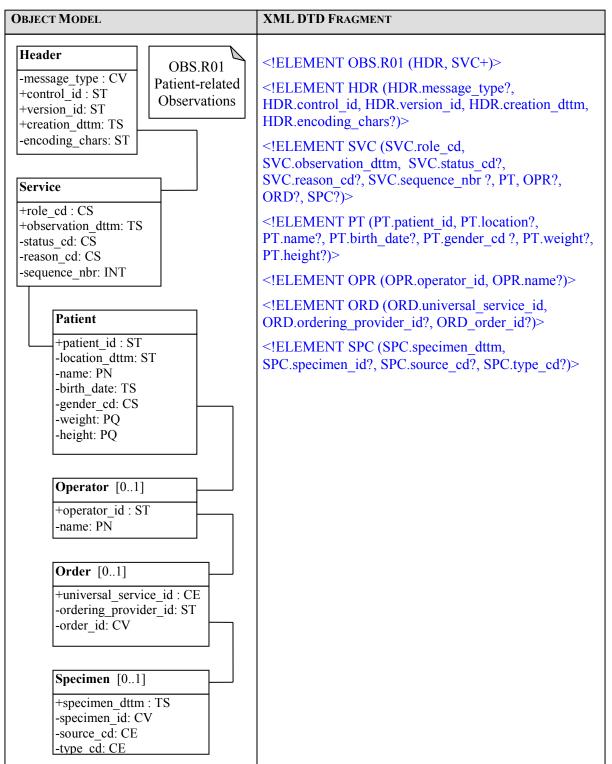


Figure 3.30.6.1-1: Message OBS.R01 in Transaction LAB-30

565 3.30.6.1.1 Use of the Service Object

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|------------------|--------------|--------------|----------------------|---|
| role_cd | CS | R | [11] | Value "OBS": Patient test observation |
| observation_dttm | TS | R | [11] | Starting date/time of the test |
| status_cd | ST | R | [11] | Value "INI": The point of care test is about to start. No observation produced yet. |
| reason_cd | ST | Х | [00] | This code is not used in the context of LAB-30. |
| sequence_nbr | ST | Х | [00] | This number is not used in the context of LAB-30. |

One and only one occurrence of this object must appear in the context of Transaction LAB-30.

Table 48 of POCT1-A: Service Status code Field Values

| Code | Meaning | Description |
|------|---------------|--|
| NRM | Normal | This test was performed under normal conditions |
| OVR | Override | This test was performed in an 'override' or 'stat' circumstance. Some normal procedures (e.g., QC) may not have been followed. |
| UNK | Unknown | It is not known under what circumstances this test was performed. |
| INI | Test starting | This test is going to start for this patient. Value added by IHE to this table |

The last value "INI" is added by this LPOCT IHE profile, for the unique purpose of this Transaction LAB-30.

3.30.6.1.2 Use of the Patient Object

570

One and only one occurrence of this object must appear in the context of Transaction LAB-30.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|------------|--------------|--------------|----------------------|--|
| patient_id | ST | R | [11] | A unique identifier for the patient, supposed to be known from the POCDM actor |
| location | ST | RE | [01] | Location of the patient |
| name | PN | Х | [00] | Patient name. Not used in the context of LAB-30. |
| birth_date | TS | Х | [00] | Patient date of birth. Not used in the context of LAB-30. |
| gender_cd | CS | Х | [00] | Patient gender. Not used in the context of LAB-30. |
| weight | PQ | Х | [00] | Patient weight. Not used in the context of LAB-30. |
| height | PQ | Х | [00] | Patient height. Not used in the context of LAB-30. |

3.30.6.1.3 Use of the Operator Object

One and only one occurrence of this object must appear in the context of Transaction LAB-30.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-------------|--------------|--------------|----------------------|--|
| operator_id | ST | R | [11] | A unique identifier for the operator |
| name | PN | RE | [01] | Operator's name. Required if available on the POCRG. |

575 **3.30.6.1.4** Use of the Order Object

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------------|--------------|--------------|----------------------|---|
| universal_service_id | CE | R | [11] | Identifies the service provided by these observations. LOINC is the preferred encoding scheme. The CE data type allows transmission of two encodings, if appropriate. |
| ordering_provider_id | ST | RE | [01] | An identifier that uniquely identifies the provider who ordered this service. |
| order_id | CV | 0 | [01] | An identifier that uniquely identifies this service instance. This field may contain an order id, accession number, or other such identifier. |

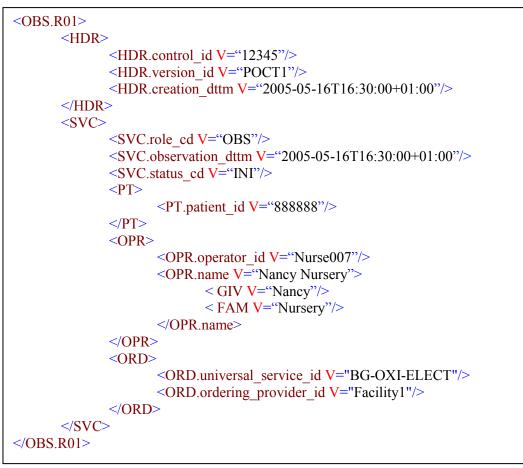
Zero or one occurrence of this object may appear in the context of Transaction LAB-30.

3.30.6.1.5 Use of the Specimen object

Zero or one occurrence of this object may appear in the context of Transaction LAB-30.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|---------------|--------------|--------------|----------------------|--|
| specimen_dttm | TS | R | [11] | Time the specimen was drawn. |
| specimen_id | CV | 0 | [01] | Code identifying the specimen |
| source_cd | CE | 0 | [01] | Location of the specimen. Coded in table 51 of POCT1-A |
| type_cd | CE | 0 | [01] | Type of the specimen. Coded in table 52 of POCT1-A |

3.30.6.1.6 Example Message OBS.R01: Initiate POCT on a Patient Specimen



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In this example, the operator Nancy Nursery wants to start a blood gas test on a patient specimen for a patient whose enterprise id is « 888888 ». The device is in a hospital in Palermo one hour ahead GMT.

3.30.6.2 Acknowledgement with Patient Name – Message ACK.R01

585 The figure below is extracted from POCT1-A, Annex B.

| Object Model | XML DTD FRAGMENT |
|--|---|
| Header -message_type : CV +control_id : ST +version_id : ST +creation_dttm : TS -encoding_chars : ST Acknowledgement +type_cd : CS +ack_control_id : ST -note_txt : ST -error_detail_cd : CV | ELEMENT ACK.R01 (HDR, ACK) ELEMENT HDR (HDR.message_type?, HDR.control_id, HDR.version_id,<br HDR.creation_dttm, HDR.encoding_chars?)> ELEMENT ACK (ACK.type_cd, ACK.ack_control_id, ACK.note_txt?,<br ACK.error_detail_cd?)> |

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|---------------|--------------|--------------|----------------------|---|
| message_type | CV | Х | [00] | Not used: Redundant with the root element of the message |
| control_id | ST | R | [11] | unique identifier of the instance of this acknowledgement message |
| version_id | ST | R | [11] | "POCT1" |
| creation_dttm | TS | С | [01] | date/time of creation of this acknowledgement |

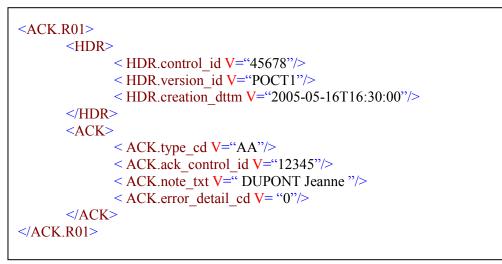
3.30.6.2.1 Use of the Header Object

| 3.30.6.2.2 | Use of the Acknowledgement Object |
|------------|-----------------------------------|
|------------|-----------------------------------|

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------------|--------------|--------------|----------------------|---|
| type_cd | CS | R | [11] | AA: Application Accept AE: Application Error |
| ack_control_id | ST | R | [11] | The unique identifier of the acknowledged message |
| note_txt | ST | R | [11] | This field is required in the context of IHE Transaction LAB-30. It contains either the patient's name in case of Application Accept or a text describing the error condition in case of Application Error. |
| error_detail_cd | CV | R | [11] | A code detailing the error. Described in Table 14 of Annex B of POCT1-A. |

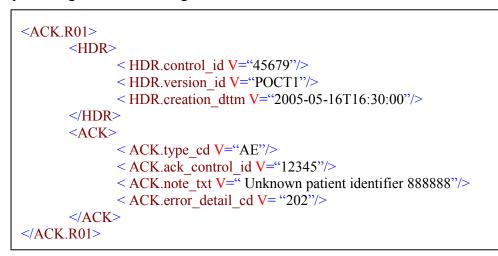
Condition predicate for the field **note_txt**:

- 590 If the POCDM has matched an existing patient, and has controlled that the information received within the OBS.R01 message is consistent with this patient and that the test for this patient on this device by this operator is authorized, then the POCDM sends back a positive acknowledgement (type_cd = "AA", error_detail_cd = "0"). In this case, the note_txt is required and shall be valued with the patient's name, using any display oriented string format.
- 595 Example of positive acknowledgement for patient Jeanne DUPONT:



If the POCDM has failed to match a patient from the patient identifier received within the OBS.R01 message, then it sends back a negative acknowledgement (type_cd = "AA", error detail cd = "202"), with the field note txt containing a text explaining the error condition.

Example of negative acknowledgement:



3.30.7 Expected Actions

605 When receiving the message "Initiate POCT on a patient specimen", the POCDM must search for the patient using the patient ID, and must check the information related to the testing. Then the POCDM builds its Acknowledgement message and sends it to the POCRG.

When receiving the message "Acknowledgement with patient identity", the POCRG must display as much of the patient identity as possible, to allow the operator to verify this identity.

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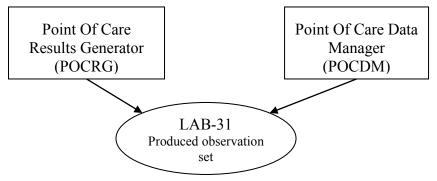
3.31 Produced Observation Set (LAB-31)

3.31.1 Scope

The POCRG sends a set of observations to the POCDM. The POCDM checks the content of this set of results. If it is acceptable, the POCDM stores it and acknowledges it to the POCRG; otherwise the POCDM rejects the set of results and sends a negative acknowledgement back to the POCRG that will display it to its user.

The set of observations may be obtained on a patient specimen or on a QC specimen.

3.31.2 Use Case Roles



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Actor: POCRG

Role: Sends to the POCDM a new set of observations obtained on a patient specimen or a QC specimen. Waits for the acknowledgement of this set of observations

Actor: POCDM

625 **Role:** Checks the information received with this set of observations, controls the results against its own business rules, accepts them or rejects them, stores the accepted results, and acknowledges them to the POCRG.

3.31.3 Referenced Standard

POCT1-A: Device Message Layer (DML) defined in Appendix B.

630 This LPOCT profile describes the upper-layer messaging protocol (DML) of POCT1-A. The POCRG actor of IHE is called the "*Device*" in POCT1-A. The POCDM actor of IHE is called "*Observation Reviewer*" in POCT1-A.

This transaction LAB-31 can be used on the *Basic Profile* defined in section 4.1 of Appendix B of POCT1-A, or on the *Continuous Mode* defined in section 4.2 of the same document.

635 3.31.4 Interaction Diagram

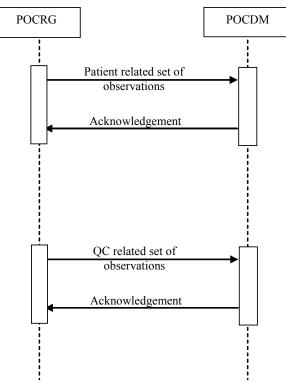


Figure 3.31.4-1: Interaction Diagram for [LAB-31]

The message "Patient related set of observations" of the diagram above uses the Observations message **OBS.R01** defined in Appendix B – section 6.10 of POCT1-A.

640 The message "QC related set of observations" uses the Observations message **OBS.R02** defined in the same section of POCT1-A.

3.31.5 Trigger Events

650

- 1. The "Patient related set of observations" message is triggered by any new patient observations obtained on the POCRG actor.
- 645 2. The "QC related set of observations" message is triggered by any new non-patient observations (internal or external QC, calibration) obtained on the POCRG actor.

When using the "*Continuous Mode*" of POCT1-A the above events trigger the Observations messages at once.

When using the "*Basic Profile*" of POCT1-A the sending of these Observation messages requires these prior conditions:

- 3. Establishment of a *Conversation* between POCRG and POCDM. (*Topic Hello*)
- 4. The sending of the message "Device status" by the POCRG actor and its acknowledgement by the POCDM actor. (*Topic Device Status*)
- 5. The sending of the message "Request Observations" by the POCDM to the POCRG (if the 655 Conversation is not in continuous mode).

3.31.6 Message Semantics

3.31.6.1 Message OBS.R01: Patient-Related Set of Observations

The figure below is extracted from POCT1-A, Annex B.

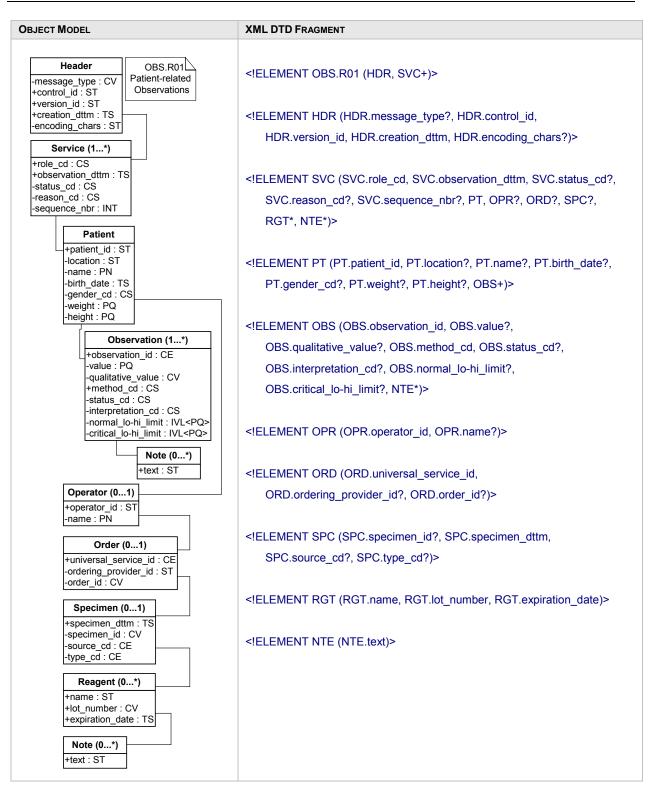


Figure 3.31.6.1-1: Patient-Related Observation Message Model, POCT1-A – Appendix B

660

| Attribute | Data | IHE | IHE | Description |
|------------------|------|-------|---------------|--|
| | Туре | Usage | Cardinalities | |
| role_cd | CS | R | [11] | Value "OBS": Patient test observation |
| observation_dttm | TS | R | [11] | production date/time of this set of observations |
| status_cd | ST | R | [11] | One of the values listed in table 48 of POCT1-A, Annex B |
| reason_cd | ST | R | [11] | One of the values listed in table 49 of POCT1-A, Annex B |
| sequence_nbr | ST | 0 | [O1] | An optional number to indicate the position of this service in a historical list of services performed by this Device. This number is unique only across a single Device, and may wrap (e.g., a 'use counter'). |

3.31.6.1.1 Use of the Service Object

Table 48 of POCT1-A: Service Status code Field Values

| Code | Meaning | Description |
|------|----------|--|
| NRM | Normal | This test was performed under normal conditions |
| OVR | Override | This test was performed in an 'override' or 'stat' circumstance. Some normal procedures (e.g., QC) may not have been followed. |
| UNK | Unknown | It is not known under what circumstances this test was performed. |

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Table 49 of POCT1-A: Service Reason Code Field Values

| Code | Meaning | Description | | | |
|------|---------|--|--|--|--|
| NEW | New | Default. This is a new set of observations. | | | |
| RES | Resent | This set of observations is being resent. | | | |
| EDT | Edited | Some fields of this set of observations have been edited since last transmission | | | |

3.31.6.1.2 Use of the Patient Object

One and only one occurrence of Patient per Service:

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|------------|--------------|--------------|----------------------|--|
| patient_id | ST | R | [11] | A unique identifier for the patient, supposed to be known from the POCDM actor |
| location | ST | RE | [01] | Location of the patient. Required if known. |
| name | PN | RE | [01] | Patient name. Required if known. |
| birth_date | TS | RE | [01] | Patient date of birth. Required if known. |
| gender_cd | CS | RE | [01] | Patient gender. Required if known. |
| weight | PQ | С | [01] | Patient weight. Required if known and relevant for the test. |
| height | PQ | С | [01] | Patient height. Required if known and relevant for the test. |

3.31.6.1.3 Use of the Observation Object

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------------|---------------|--------------|----------------------|--|
| observation_id | CE | R | [11] | The test identifier, preferably coded with LOINC |
| value | PQ | С | [01] | The observation result, if expressed quantitatively (i.e., a numerical value with units). |
| qualitative_value | CV | С | [01] | The observation result, if expressed qualitatively. POCT1-A, Annex B provides a list of codes in table 35. This list is extensible. |
| method_cd | CS | R | [11] | Origin of the result. Coded in table 36 of POCT1-A, Annex B. This LPOCT profile authorizes only these values: C = Calculated (The value was calculated) D = Default (The value is a default value) E = Estimated I = Input (The value was externally input to the POCRG) M = Measured (The value was measured on the POCRG) |
| status_cd | CS | R | [11] | Status of the result. Coded in table 37 of POCT1-A, Anne: B. This IHE LPOCT profile authorizes only this value for patient-related results: A = Accepted |
| interpretation_cd | CS | С | [01] | Interpretation of the result (abnormal flags). Coded in tabl 38 of POCT1-A, Annex B: L = below low normal H = above high normal LL = below lower panic limits HH = above upper panic limits < = below absolute low-off instrument scale > = above absolute high-off instrument scale N = normal A = abnormal (applies to nonnumeric results) AA = very abnormal (applies to nonnumeric results) null = no range defined or normal ranges don't apply U = significant change up D = significant change down B = better (use when direction not relevant) W = worse (use when direction not relevant) |
| normal_lo-hi_limit | IVL <pq></pq> | R | [11] | The low and high limit range for a normal result |
| critical_lo-hi_limit | IVL <pq></pq> | R | [11] | The low and high limit range outside which clinical review is required |

One or more occurrences of Observation per Patient:

670 Condition predicate for fields *value*, *qualitative_value* and *interpretation_cd*:

Every Observation object instance must contain either a value or a qualitative_value field. The interpretation_cd field may be used to provide additional information about the quantitative or qualitative value.

3.31.6.1.4 Use of the Note Object Related to the Observation Object

675 Zero or one occurrence of this object may appear below an observation. The note is a comment related to the observation.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------|--------------|--------------|----------------------|----------------------------|
| text | ST | R | [11] | Comment of the observation |

3.31.6.1.5 Use of the Operator Object

One and only one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-------------|--------------|--------------|----------------------|--|
| operator_id | ST | R | [11] | A unique identifier for the operator |
| name | PN | RE | [01] | Operator's name. Required if available on the POCRG. |

3.31.6.1.6 Use of the Order Object

680 One and only one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------------|--------------|--------------|----------------------|---|
| universal_service_id | CE | R | [11] | Identifies the service provided by these observations. LOINC is the preferred encoding scheme. The CE data type allows transmission of two encodings, if appropriate. |
| ordering_provider_id | ST | RE | [01] | An identifier that uniquely identifies the provider who ordered this service. |
| order_id | CV | 0 | [01] | An identifier that uniquely identifies this service instance. This field may contain an order id, accession number, or other such identifier. |

3.31.6.1.7 Use of the Specimen Object

Zero or one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|---------------|--------------|--------------|----------------------|--|
| specimen_dttm | TS | R | [11] | Time the specimen was drawn. |
| specimen_id | CV | 0 | [01] | Code identifying the specimen |
| source_cd | CE | 0 | [01] | Location of the specimen. Coded in table 51 of POCT1-A, Annex B |
| type_cd | CE | R | [11] | Type of the specimen. Coded in table 52 of POCT1-A, Annex B |

3.31.6.1.8 Use of the Reagent Object

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------------|--------------|--------------|----------------------|--|
| name | ST | RE | [01] | The manufacturer's name for the reagent |
| lot_number | CV | R | [11] | The lot number of reagent used |
| expiration_date | TS | RE | [01] | The date past which the reagent should not be used |

Zero or one occurrence.

685 **3.31.6.1.9 Use of the Note Object**

Zero or more occurrences of this object may appear below the Service object. The note is a comment related to the service (i.e., the set of observations).

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------|--------------|--------------|----------------------|----------------------------|
| text | ST | R | [11] | Comment of the observation |

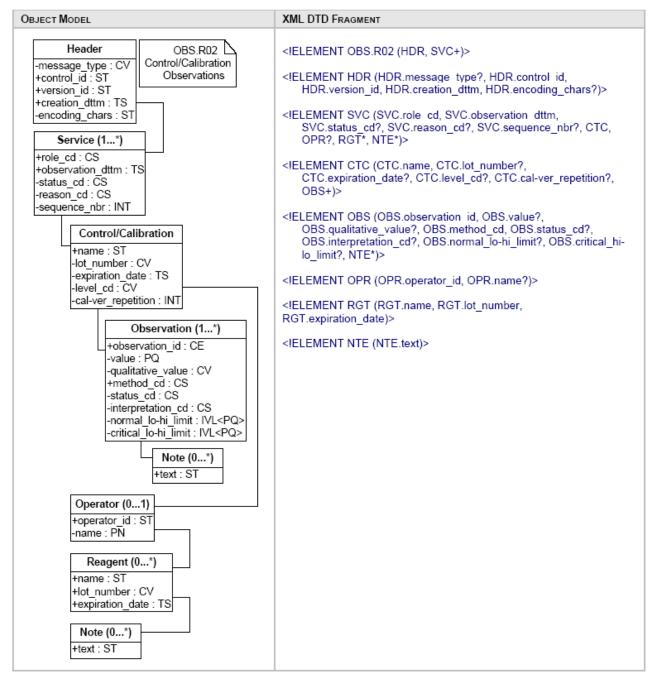
3.31.6.1.10 Example Message of Patient Observations

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```
<OBS.R01>
         <HDR>
                   <HDR.control id V="12345"/>
                   <HDR.version_id V="POCT1"/>
                   <HDR.creation dttm V="2005-05-16T16:30:00+1:00"/>
         </HDR>
         <SVC>
                   <SVC.role cd V="OBS"/>
                   <SVC.observation dttm V="2005-05-16T16:30:00+1:00"/>
                   <SVC.status_cd V="NRM"/>
                   <SVC.reason_cd V="NEW"/>
                   \langle PT \rangle
                             <PT.patient id V="8888888"/>
                             <PT.location V="ICU-Bed3"/>
                             <PT.name V="Pat Patient"?
                                       <GIV V="Patrick">
                                      <FAM V="Patient">
                             </ PT.name >
                             <PT.birth_date V="1958-10-31"/>
                             <PT.gender_cd V="M"/>
                             <OBS>
                                       < OBS.observation_id V="2703-7" SN="LN" DN="Oxygen"/>
                                       <OBS.value V="110" U="mmHg"/>
                                       <OBS.method cd V="M"/>
                                       <OBS.status_cd V="A"/>
                                       <OBS.interpretation_cd V="H"/>
                                       <OBS.normal lo-hi limit V="[83;108]" V="mmHg"/>
                                       <OBS.critical_lo-hi_limit V="[40;130]" V="mmHg"/>
                             </OBS>
                             <OBS>
                                       < OBS.observation_id V="11557-6" SN="LN" DN="Carbon Dioxyd"/>
                                       <OBS.value V="33.2" U="mmHg"/>
                                       <OBS.method_cd V="M"/>
                                       <OBS.status_cd V="A"/>
                                       <OBS.interpretation_cd V="L"/>
                                       <OBS.normal lo-hi limit V="[35.0;48.0]" V="mmHg"/>
                                       <OBS.critical_lo-hi_limit V="[20.0;60.0]" V="mmHg"/>
                             </OBS>
                             <NTE>
                                       <NTE.text V="result below reference ranges, within critical ranges"/>
                             </NTE>
                             <OBS>
                                       < OBS.observation id V="11558-4" SN="LN" DN="pH"/>
                                       <OBS.value V="7.47"/>
                                       <OBS.method_cd V="M"/>
                                       <OBS.status cd V="A"/>
                                       <OBS.interpretation_ cd V="H"/>
                                       <OBS.normal lo-hi limit V="[7.35;7.45]" V="mmHg"/>
                                       <OBS.critical lo-hi limit V="[7.00;7.60]" V="mmHg"/>
                             </OBS>
                   </PT>
                   <OPR>
                             <OPR.operator_id V="Nurse007"/>
                             <OPR.name V="Nancy Nursery">
                                       < GIV V="Nancy"/>
                                       < FAM V="Nursery"/>
                             </OPR.name>
                   </OPR>
                   <ORD>
                             <ORD.universal_service_id V="BG-OXI-ELECT"/>
                             <ORD.ordering_provider_id V="Facility1"/>
                   </ORD>
                   <SPC>
                             <SPC.specimen_dttm V="2005-05-19T10:20:00-1.00"/>
                             <SPC.source cd V="LLFA"/>
                             <SPC.type_cd V="BLDA"/>
                   </SPC>
                   <NTE>
                             <NTE.text V="Battery approved by Dr Esclapios"/>
                   </NTE>
         </SVC>
</OBS.R01>
```

690 **3.31.6.1.11** Message OBS.R02: QC Related Set of Observations

The figure below is extracted from POCT1-A, Annex B.





| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description | | | |
|------------------|--------------|--------------|----------------------|---|--|--|--|
| role_cd | CS | R | [11] | The following values are authorized within OBS.R02 message, taken from table 47 in POCT1-A, Annex B: | | | |
| | | | | LQC = Liquid QC (observation from a liquid QC test) | | | |
| | | | | EQC = Electronic QC (observation from an electronic QC test) | | | |
| | | | | CVR = Calibration verification | | | |
| | | | | CAL = Calibration | | | |
| | | | | $\mathbf{PRF} = \mathbf{Proficiency test}$ | | | |
| observation_dttm | TS | R | [11] | production date/time of this set of observations | | | |
| status_cd | ST | R | [11] | One of the values listed in table 48 of POCT1-A, Annex B (see section Y.6.1.1 in this document) | | | |
| reason_cd | ST | R | [11] | One of the values listed in table 49 of POCT1-A, Annex B (see section Y.6.1.1 in this document) | | | |
| sequence_nbr | ST | 0 | [01] | An optional number to indicate the position of this service in a historical list of services performed by this Device. This numbe is unique only across a single Device, and may wrap (e.g., a 'us counter'). | | | |

695 **3.31.6.1.12** Use of the Service Object

3.31.6.1.13 Use of the Control/Calibration Object

| One and only one o | occurrence of Control/Calibration | per Service: |
|--------------------|-----------------------------------|--------------|
| | | |

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|--------------------|--------------|--------------|---|--|
| name | ST | RE | [01] | The manufacturer's name for the QC/Calibration material |
| lot_number | CV | R | [11] The vendor-specific lot number of the QC/Calibration n | |
| expiration_date | TS | RE | [01] | The date past which the reagent should not be used |
| level_cd | CV | С | [01] The level for the QC test or for the calibration verificat. Not applicable to proficiency tests nor to calibration test | |
| cal-ver_repetition | INT | С | [01] | Only applicable to calibration verification: If tests within a linearity sequence are repeated at a given level, this field indicates the repetition count for this particular test. |

3.31.6.1.14 Use of the Observation Object

At least one occurrence of Observation below Control/Calibration:

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-------------------|--------------|--------------|---|---|
| observation_id | CE | R | [11] | The test identifier, preferably coded with LOINC |
| value | PQ | С | [01] The observation result, if expressed quantitatively numerical value with units). | |
| qualitative_value | CV | С | [01] | The observation result, if expressed qualitatively. |
| method_cd | CS | R | [11] | Origin of the result. Coded in table 36 of POCT1-A, Annex B. This LPOCT profile authorizes only these values: |
| | | | | C = Calculated (The value was calculated)D = Default (The value is a default value) |
| | | | | $\mathbf{E} = \text{Estimated}$ |
| | | | | I = Input (The value was externally input to the POCRG) |

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------------|---------------|--------------|----------------------|--|
| | | | | \mathbf{M} = Measured (The value was measured on the POCRG) |
| status_cd | CS | R | [11] | Status of the result. Coded in table 36 of POCT1-A, Annex B. This LPOCT profile authorizes only these values for patient-related results: A = Accepted D = Discarded R = Rejected |
| interpretation_cd | CS | С | [01] | Interpretation of the result (abnormal flags). Coded in table 38 of POCT1-A, Annex B (See section Y.6.1.3 above) |
| normal_lo-hi_limit | IVL <pq></pq> | RE | [01] | The low and high limit range for a normal result |
| critical_lo-hi_limit | IVL <pq></pq> | RE | [01] | The low and high limit range outside which clinical review is required |

700 Condition predicate for fields *value*, *qualitative_value* and *interpretation_cd*: Same as in section Y.6.1.3 above.

3.31.6.1.15 Use of the Note Object Related to the Observation Object

Zero or one occurrence of this object may appear below an observation. The note is a comment related to the observation.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description | |
|-----------|--------------|--------------|----------------------|----------------------------|--|
| text | ST | R | [11] | Comment of the observation | |

705 **3.31.6.1.16** Use of the Operator Object

One and only one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description | |
|-------------|--------------|--------------|----------------------|--|--|
| operator_id | ST | R | [11] | A unique identifier for the operator | |
| name | PN | RE | [01] | Operator's name. Required if available on the POCRG. | |

3.31.6.1.17 Use of the Reagent Object

Zero or one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------------|--------------|--------------|----------------------|--|
| name | ST | RE | [01] | The manufacturer's name for the reagent |
| lot_number | CV | R | [11] | The lot number of reagent used |
| expiration_date | TS | RE | [01] | The date past which the reagent should not be used |

3.31.6.1.18 Use of the Note Object

710 Zero or more occurrences of this object may appear below the Service object. The note is a comment related to the service (i.e., the set of observations).

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description | |
|-----------|--------------|--------------|----------------------|----------------------------|--|
| text | ST | R | [11] | Comment of the observation | |

3.31.7 Expected Actions

The POCDM receiving a message OBS.R01 (patient related observations) must check this set of observations against its own configuration rules (comparison with normal ranges, QC performed and OK, operator allowed to proceed, patient known in this point of care ...). It then accepts or rejects this set of observations, and sends its reply in an Acknowledgement message. If the set of observations was accepted, the POCDM stores it in its data base. If the option "Supervision by laboratory" is supported, the POCDM initiates a Transaction LAB-32 with the Order Filler to forward this accepted set of observations.

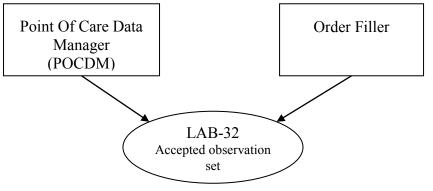
720 The POCDM receiving a message OBS.R02 (non-patient related observations) must check this set of observations against its own configuration rules. It then accepts or rejects this set of observations, and sends its reply in an Acknowledgement message. If the set of observations (QC or calibration results) was accepted, the POCDM stores it in its data base.

725 3.32 Accepted Observation Set (LAB-32)

3.32.1 Scope

This transaction is used within LPOCT profile with the option "Supervision by laboratory": The POCDM forwards all accepted sets of patient observations to the Order Filler.

3.32.2 Use Case Roles



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Actor: POCDM

Role: Forwards to the Order Filler each set of observations accepted for a patient specimen. Waits for the acknowledgement of this set of observations and stores the filler order number that it contains.

735 Actor: Order Filler

Role: Receives the set of patient observations, and according to the trigger event, either stores this set in an existing order, or generates a new order for it. In either case it will return the filler order number in the associated acknowledgement sent back to the POCDM.

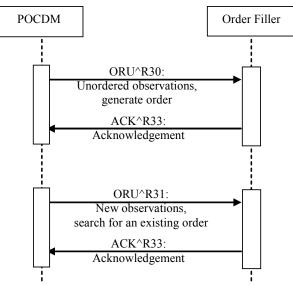
3.32.3 Referenced Standard

740 POCT1-A : Observation Reporting Interface (ORI) defined in Appendix C of this standard. The POCT1-A standard names "*Observation Reviewer*" the IHE **POCDM** actor, and names "*Observation Recipient*" the IHE **Order Filler** actor.

HL7 v2.5: The ORI of POCT1-A relies on HL7 v2.5 messages structures ORU defined in chapter 7 of the HL7 standard.

- All implementation rules and notes specified in the present Volume 2 of the IHE Laboratory Technical Framework fully apply to the messages of this transaction LAB-32. More precisely:
 - Section 2.2 "HL7 profiling conventions"
 - Section 2.3 "HL7 implementation notes"
 - Section 3 "Common message segments for Laboratory Technical Framework". This section
- 750 provides the common description of segments MSH, MSA, NTE, ERR, PID, that are also applicable to this transaction LAB-32.

3.32.4 Interaction Diagram



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Figure 3.32.4-1: Interaction diagram for [LAB-32]

Transaction LAB-32 offers two distinct message structures to support the various use cases described in Volume 1:

• ORU^R30 (Unordered observations) is used in part 4 of scenarios 5.5.1 and 5.5.3, as well as in part 2 of scenario 5.5.4. The Order Filler SHALL generate a new order when receiving this message.

760 me

• ORU^R31 is used in part 4 of scenario 5.5.2: The POCDM instructs the Order Filler to match an existing order to store the observations.

The acknowledgement to both message structures is ACK^AR33. This acknowledgement is an application acknowledgement that sends back the filler order number of the order generated or matched by the Order Filler, to store this set of POCT results.

Note 5: The trigger event ORU^R32 "preordered observations" described in POCT1-A's ORI, is not part of the IHE LPOCT profile. As explained in Volume 1 of this profile, section 1.4 "Relationship to real world architectures, and in Volume 2a, section 3.2.5.2, Note 1, this event corresponds to the normal scheduled workflow and is supported by the two IHE profiles LSWF and LDA.

770 3.32.5 Trigger Events

The POCDM integrates a set of point of care observations for a patient, received from a POCRG on LAB-31. The option "Supervision by laboratory" being supported, this event triggers a message of LAB-32 that sends these observations to the Order Filler.

If the indication "existing order" is present in the set of observations, the message is ORU^R31, otherwise the message is ORU^R30.

3.32.6 Message Semantics

3.32.6.1 Common Static Definition for ORU^R30 and ORU^R31 Table3.32.6.1-1: Static Definition for ORU^R30 and ORU^R31

| Segment | Meaning | Usage | Card. | HL7 chapter | | | | | |
|---------|------------------------------------|-------|-------|-------------|--|--|--|--|--|
| MSH | Message Header | R | [11] | 2 | | | | | |
| PID | Patient Identification | R | [11] | 3 | | | | | |
| ORC | Common Order information | R | [11] | 4 | | | | | |
| OBR | Observation Request | R | [11] | 4 | | | | | |
| [{NTE}] | Notes or Comments for order/Result | RE | [01] | 4 | | | | | |
| [{ | RESULT begin | 0 | [0*] | | | | | | |
| OBX | Observation related to OBR | R | [1*] | 7 | | | | | |
| [{NTE}] | Comment of the result | С | [01] | 2 | | | | | |
| }] | RESULT end | | | | | | | | |

3.32.6.1.1 Usage of MSH segment

780 MSH-9 – Message Type, shall have its three components valued as follows:

- ORU^R30^ORU_R30 for the unordered point of care observations
- ORU^R31^ORU_R30 for the point of care observations to match with a possibly existing order

3.32.6.1.2 Usage of ORC Segment

785 The common definition of segment ORC in Volume 2 – section 3.7, does not apply to this LPOCT Integration Profile: The ORU^R30 message structure instructs the recipient to generate the order, and the ORU^R31 message instructs to match an existing order, without identifying it.

Hence, the usage definition of ORC segment within this LPOCT profile, below:

| SEQ | LE N | DT | Usage | Card. | TBL # | ITEM# | Element name |
|-----------------|------------------|-----|-----------------|-------|----------|--------------------|----------------------------------|
| 1 | 2 | ID | R | [11] | 0119 | 00215 | Order Control |
| 2 | 22 | EI | Х | [00] | | 00216 | Placer Order Number |
| 3 | 22 | EI | С | [00] | | 00217 | Filler Order Number |
| 4 | 22 | EI | Х | [00] | | 00218 | Placer Group Number |
| 5 | 2 | ID | Х | [00] | 0038 | 00219 | Order Status |
| 7 | 200 | TQ | Х | [00] | | 00221 | Quantity/Timing |
| 8 | 200 | EIP | Х | [00] | | 00222 | Parent |
| 9 | 26 | TS | Х | [00] | | 00223 | Date/Time of Transaction |
| 10 | 250 | XCN | Х | [00] | | 00224 | Entered By |
| 11 | 250 | XCN | Х | [00] | | 00225 | Verified By |
| 17 | 250 | CE | Х | [00] | | 00231 | Entering Organization |
| 20 | 250 | CE | Х | [00] | 0339 | 01310 | Advanced Beneficiary Notice Code |
| <mark>21</mark> | <mark>250</mark> | XON | <mark>RE</mark> | [01] | | <mark>01311</mark> | Ordering Facility Name |

Table 3.32.6.1.2-1: ORC Segment

| SEQ | LE N | DT | Usage | Card. | TBL # | ITEM# | Element name |
|-----|---------|-----|-------|-------|----------|-------|--|
| 25 | 250 | CWE | Х | [00] | | 01473 | Order Status Modifier |
| 26 | 60 | CWE | Х | [00] | 0552 | 01641 | Advanced Beneficiary Notice Override Reason |
| 27 | 26 | TS | Х | [00] | | 01642 | Filler's Expected Availability Date/Time |

790 **ORC-1 Order Control (ID)**, required. This field shall be valued to "NW" (new order) both in ORU^R30 and ORU^R31 message structures.

ORC-3 Filler Order Number (EI): This LPOCT profile applies the condition predicate specified by POCT1-A: *"The POCDM may supply an external identifier in this field that other systems can use to reference this result set. This specification places no restrictions on the*

795 format or content of this field's value. For example, some POCDM might expose a database key in this field while others might use a combination of Device name, serial number and the timestamp of the result as the unique external identifier".

ORC-21 Ordering Facility Name (XON), required but may be empty (RE).

For this LPOCT profile, this field contains the facility (ward) where this point of care observation set has been performed. These three components shall be valued:

- 1st = Organization name.
- 7th = Identifier Type Code with the value "FI", which means "Facility ID" as stated by HL7 table n° 0203.
- 10th = Organization Identifier.
- 805 Example: Urology^^^^FI^^UR01

3.32.6.1.3 Usage of OBR Segment

Table3.32.6.1.3-1: OBR Segment

| | | | | | | | - | | | |
|-----|---------|-----|-------|-------|----------|-------|--------------------------------|--|--|--|
| SEQ | LE N | DT | Usage | Card. | TBL # | ITEM# | Element name | | | |
| 2 | 22 | EI | Х | [00] | | 00216 | Placer Order Number | | | |
| 3 | 22 | EI | Х | [O0] | | 00217 | Filler Order Number | | | |
| 4 | 250 | CE | R | [11] | | 00238 | Universal Service Identifier | | | |
| 5 | 2 | ID | Х | [00] | | 00239 | Priority – OBR | | | |
| 6 | 26 | TS | Х | [00] | | 00240 | Requested Date/Time | | | |
| 7 | 26 | TS | Х | [00] | | 00241 | Observation Date/Time | | | |
| 8 | 26 | TS | Х | [00] | | 00242 | Observation End Date/Time | | | |
| 9 | 20 | CQ | Х | [00] | | 00243 | Collection Volume | | | |
| 10 | 250 | XCN | Х | [00] | | 00244 | Collector Identifier | | | |
| 11 | 1 | ID | R | [11] | 0065 | 00245 | Specimen Action Code | | | |
| 12 | 250 | CE | Х | [00] | | 00246 | Danger Code | | | |
| 13 | 300 | ST | Х | [00] | | 00247 | Relevant Clinical Information | | | |
| 14 | 26 | TS | Х | [00] | | 00248 | Specimen Received Date/Time | | | |
| 15 | 300 | SPS | RE | [0.1] | | 00249 | Specimen Source or Segment SPM | | | |

| SEQ | LE N | DT | Usage | Card. | TBL # | ITEM# | Element name |
|-----------------|------------------|-----|----------------|-------|----------|--------------------|---|
| 16 | 250 | XCN | RE | [01] | | 00226 | Ordering Provider |
| 17 | 250 | XTN | Х | [00] | | 00250 | Order Callback Phone Number |
| 18 | 60 | ST | Х | [00] | | 00251 | Placer Field 1 |
| 19 | 60 | ST | Х | [00] | | 00252 | Placer Field 2 |
| 20 | 60 | ST | Х | [00] | | 00253 | Filler Field 1 |
| 21 | 60 | ST | Х | [00] | | 00254 | Filler Field 2 |
| 22 | 26 | TS | Х | [00] | | 00255 | Results Rpt/Status Chng – Date/Time |
| 23 | 40 | MOC | Х | [00] | | 00256 | Charge to Practice |
| 24 | 10 | ID | Х | [00] | 0074 | 00257 | Diagnostic Serv Sect ID |
| 25 | 1 | ID | <mark>R</mark> | [11] | 0123 | 00258 | Order Result Status |
| 26 | 400 | PRL | Х | [00] | | 00259 | Parent Result |
| 27 | 200 | TQ | Х | [00] | | 00221 | Quantity/Timing |
| 28 | 250 | XCN | Х | [00] | | 00260 | Result Copies To |
| 29 | 200 | EIP | Х | [00] | | 00261 | Parent |
| 30 | 20 | ID | Х | [00] | 0124 | 00262 | Transportation Mode |
| 31 | 250 | CE | Х | [00] | | 00263 | Reason for Study |
| <mark>32</mark> | <mark>200</mark> | NDL | C | [01] | | <mark>00264</mark> | Principal Result Interpreter |
| 33 | 200 | NDL | Х | [00] | | 00265 | Assistant Result Interpreter |
| <mark>34</mark> | <mark>200</mark> | NDL | RE | [00] | | <mark>00266</mark> | Technician |
| 37 | 4 | NM | Х | [00] | | 01028 | Number of Sample Containers * |
| 38 | 250 | CE | Х | [00] | | 01029 | Transport Logistics of Collected Sample |
| 39 | 250 | CE | Х | [00] | | 01030 | Collector's Comment * |
| 40 | 250 | CE | Х | [00] | | 01031 | Transport Arrangement Responsibility |
| 41 | 30 | ID | Х | [00] | 0224 | 01032 | Transport Arranged |
| 42 | 1 | ID | Х | [00] | 0225 | 01033 | Escort Required |
| 43 | 250 | CE | Х | [00] | | 01034 | Planned Patient Transport Comment |
| 44 | 250 | CE | Х | [00] | 0088 | 00393 | Procedure Code |
| 45 | 250 | CE | Х | [00] | 0340 | 01316 | Procedure Code Modifier |
| 46 | 250 | CE | Х | [00] | 0411 | 01474 | Placer Supplemental Service Information |
| 47 | 250 | CE | Х | [00] | 0411 | 01475 | Filler Supplemental Service Information |
| 48 | 250 | CWE | Х | [00] | 0476 | 01646 | Medically Necessary Duplicate Procedure Reason. |
| 49 | 2 | IS | Х | [00] | Ν | 01647 | Result Handling |

OBR-4 Universal Service Identifier (CE): This field identifies either a battery (panel) or an individual test. The first sub-field (the code), and the third (the coding system) are required.

OBR-15 Specimen source (CM): This field is required if available within LPOCT profile, because the messages of this profile do not embed any SPM segment, given that very little

⁸¹⁰ **OBR-11 Specimen Action Code (ID):** This required field will be valued to 'O' (Specimen obtained by service other than lab).

information is needed on the specimen in point of care testing. This profile applies the POCT1-A recommendations of use for this field. The following components should be valued:

- 1st component: **Specimen Source Name or Code (CWE)**, called "Specimen Type" in POCT1-A. Codes are given by table 107 in POCT1-A.
- 4th component: **Body Site (CWE)**, called "Location" in POCT1-A. Code are given by table 108 in POCT1-A.
- 7th component: **Specimen Role (CWE)**, valued to 'P' (Patient specimen).

OBR-16 Ordering Provider (XCN): This field is required if available (RE). The POCDM shall value it with the ordering physician if it knows this information.

OBR-25 Order Result Status (ID): The set of observations is considered as reviewed (i.e., technically validated) either automatically or interactively by the POCDM application (called the Observation Reviewer in POCT1-A). Therefore the status shall be valued to "F" (Final results).

OBR-32 Principal Interpreter (NDL): The field identifies who validated (reviewed) the results, and when this technical validation was performed. It shall be valued if this review has been performed interactively by a human reviewer using the POCDM actor; in this case only the two first components are required:

• Name (CNN):

- First sub-subcomponent = ID number of the reviewer
- Second sub-component = Family name
- Third component = Given name
- Stat Date/Time (TS): Date/Time of the review.
- 835 **OBR-34 Technician (NDL)**: The field is required if available (RE). It identifies the operator who produced the set of observations on the point of care device (the actor POCRG). It also locates the point of care, room, bed, facility, and dates this production. The following components are to be valued if the information is known:
 - 6. 1st component: Name (CNN):
- 840

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- First sub-subcomponent = ID number of the reviewer
- Second sub-component = Family name
- Third component = Given name
- 2nd component: Stat Date/Time (TS): Date/Time of the testing.
- 4th component: Point Of Care (IS)
- 5th component: Room (IS)
 - 6th component: Bed (IS)
 - 7th component: Facility (HD)

3.32.6.2 Static Definition for ACK^R33: Acknowledgement Message

This message sent by the Order Filler to the POCDM is the acknowledgement message for both ORU^R30 and ORU^R31 messages.

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| Segment | Meaning | Usage | Card. | HL7 chapter | | | | | | | | |
|---------|-------------------------|-------|-------|-------------|--|--|--|--|--|--|--|--|
| MSH | Message Header | R | [11] | 2 | | | | | | | | |
| MSA | Message Acknowledgement | R | [11] | 2 | | | | | | | | |
| [{ERR}] | Error | С | [01] | 2 | | | | | | | | |

Table3.32.6.2-1: static definition for ACK^R33

MSH-9 – Message Type, shall have its three components valued "ACK^R33^ACK"

3.32.6.2.1 Usage of MSA Segment

Table 3.32.6.2.1-1: MSA - Message Acknowledgement

| SEQ | LE N | DT | Usage | Card. | TBL # | ITEM# | Element name |
|-----|---------|----|-------|-------|----------|-------|-----------------------------|
| 1 | 2 | ID | R | [11] | 0008 | 00018 | Acknowledgement code |
| 2 | 20 | ST | R | [11] | | 00010 | Message Control Id |
| 3 | 80 | ST | R | [00] | | 00020 | Text Message |
| 5 | | | Х | [00] | | 00022 | Delayed Acknowledgment Type |
| 6 | 250 | CE | Х | [00] | 0357 | 00023 | Error Condition |

855 The general specification of use of this segment by the IHE Laboratory Technical Framework is given in section 3.2 of the present volume 2.

The particularity of use in the context of the Order Filler acknowledging a POCT observation set to the POCDM is as follows:

MSA-3 – Text Message (ST), is usage R (required). This field contains the filler order number sent by the Order Filler to the POCDM.

3.32.7 Expected Actions

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When receiving an ORU^AR30, the Order Filler performs the following sequence of actions:

- 1. It generates a new order to store this set of point of care observations within.
- 2. It sends back to the POCDM the acknowledgement message ACK^R33, including the filler order number.
- 3. Using Transaction LAB-2 of LSWF profile, the Order Filler propagates this new order to the Order Placer, and requires a placer order number for it. The placer order number is sent back by the Order Placer to the Order Filler.
- 4. The Order Filler stores the placer order number within the order in its database.
- 870 When receiving an ORU^R31, the Order Filler performs the following sequence of actions:
 - 1. It tries to match an existing order in its data base, corresponding to this set of observations. The criteria used may depend upon site-defined policies. They should include the patient, the ordering provider, the facility where the point of care tests was performed, the date-time of the observations and the ordering provider.
- 875 2. If no order can be matched, the Order Filler proceeds as if it had received an ORU^R30 (see the sequence of actions above).

- 3. If an order is matched, the Order Filler stores the results in this order, and acknowledges the order to the POCDM, sending back the filler order number in the acknowledgement.
- Using Transaction LAB-1 of LSWF profile, the Order Filler notifies the arrival of the POCT results to the Order Placer.

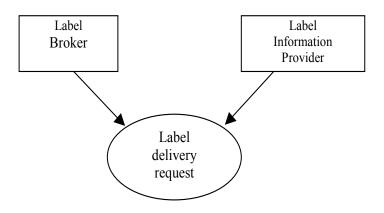
3.33 Label Delivery Request (LAB-61)

3.33.1 Scope

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This transaction is used by the Label Information Provider to send label delivery instructions to the Label Broker.

3.33.2 Use Case Roles



Actor: Label Broker

Role: The Label Broker receives labeling instructions to issue the specimen container labels andstick them on the appropriate containers.

Actor: Label Information Provider

Role: The Label Information Provider transmits the labeling instructions to the Label Broker.

3.33.3 Referenced Standard

HL7 v2.5, Chapter 4

895 3.33.4 Interaction Diagram

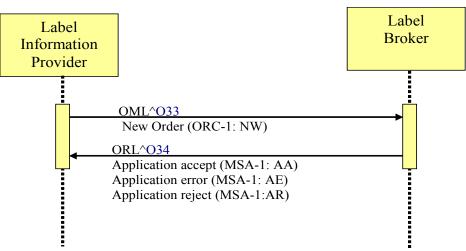


Figure 3.33.4-1: Interaction diagram for [LAB-61]

3.33.4.1 Message Static Definitions

This transaction contains the messages used to send labeling instructions from the Label 900 Information Provider to the Label Broker.

3.33.4.2 Trigger Events

OML (O33): Label information sent by the Label Information Provider.

ORL (O34): Application acknowledgement of the Label information sent by Label Broker.

3.33.4.3 Message Semantics

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age Semantics Table 3.33.4.3-1: OML^O33

| Segment | Meaning | Usage | Card. | HL7 chapter | | | | | | | |
|---------|--------------------------------|-------|-------|-------------|--|--|--|--|--|--|--|
| MSH | Message Header | R | [11] | 2 | | | | | | | |
| [| PATIENT begin | R | [11] | | | | | | | | |
| PID | Patient Identification | R | [11] | 3 | | | | | | | |
| [PV1] | Patient Visit | RE | [01] | 3 | | | | | | | |
|] | PATIENT end | | | | | | | | | | |
| { | SPECIMEN begin | R | [1*] | | | | | | | | |
| SPM | Specimen | R | [11] | 7 | | | | | | | |
| [{SAC}] | Specimen Container | 0 | [0*] | | | | | | | | |
| { | ORDER begin | R | [1*] | | | | | | | | |
| ORC | Common Order (for one battery) | R | [11] | 4 | | | | | | | |
| [{TQ1}] | Timing Quantity | RE | [01] | 4 | | | | | | | |
| [| OBSERVATION REQUEST begin | 0 | [O1] | | | | | | | | |
| OBR | Observation Request | R | [11] | 4 | | | | | | | |
| [TCD] | Test Code Details | 0 | [01] | 13 | | | | | | | |
| O}] | Observation Result | 0 | [0*] | 7 | | | | | | | |

| Segment | Meaning | Usage | Card. | HL7 chapter |
|---------|-------------------------|-------|-------|-------------|
| BX}] | | | | |
|] | OBSERVATION REQUEST end | | | |
| } | ORDER end | | | |
| } | SPECIMEN end | | | |

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

This message carries the specimen container labeling instructions in the SPECIMEN segment group: The SPM segment contains the specimen ID (SPM-2), specimen type (SPM-4), specimen source site (SPM-8), specimen collection amount (SPM-12), container type (SPM-27)... Optionally, the SAC segment may be used to deliver additional information on the physical container to be selected by the Label Broker.

| Segment | Mooning | llaaga | Card | LI 7 chapter |
|-------------|-------------------------|--------|-------|--------------|
| Segment | Meaning | Usage | Card. | HL7 chapter |
| MSH | Message header | R | [11] | 2 |
| MSA | Message Acknowledgement | R | [11] | 2 |
| [{ERR}] | Error | С | [0*] | 2 |
| [| RESPONSE begin | 0 | [01] | |
| [PID] | Patient Identification | 0 | [01] | 3 |
| { | SPECIMEN begin | 0 | [0*] | |
| SPM | Specimen | R | [11] | 7 |
| [{SAC}] | Specimen Container | 0 | [0*] | 13 |
| [{ | ORDER begin | 0 | [0*] | |
| ORC | Common Order | R | [11] | 4 |
| [{TQ1 }] | Timing/Quantity | RE | [01] | 4 |
| [OBR] | Observation Request | R | [11] | 4 |
| }] | ORDER end | | | |
| } | SPECIMEN end | | | |
|] | RESPONSE end | | | |

Table 3.33.4.3-2: ORL^O34

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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 Broker does not accept the labeling instruction (MSA-1 = AE or AR)

3.33.4.4 OBR Segment

| SEQ | LEN | DT | Usage | Card. | TBL # | ITEM# | Element name |
|-----|-----|---------|-------|-------|----------|-------|---------------------------------------|
| 1 | 4 | SI | 0 | [01] | | 00237 | Set ID – OBR |
| 2 | 22 | EI | R | [11] | | 00216 | Placer Order Number |
| 3 | 22 | EI | RE | [01] | | 00217 | Filler Order Number |
| 4 | 250 | CE | R | [11] | | 00238 | Universal Service Identifier |
| 5 | 2 | ID | Х | [00] | | 00239 | Priority – OBR |
| 6 | 26 | TS | Х | [00] | | 00240 | Requested Date/Time |
| 7 | 26 | TS | Х | [00] | | 00241 | Observation Date/Time # |
| 8 | 26 | TS | Х | [00] | | 00242 | Observation End Date/Time # |
| 9 | 20 | CQ | Х | [00] | | 00243 | Collection Volume * |
| 10 | 250 | XC N | 0 | [0*] | | 00244 | Collector Identifier * |
| 11 | 1 | ID | RE | [01] | 0065 | 00245 | Specimen Action Code * |
| 12 | 250 | CE | Х | [00] | | 00246 | Danger Code |
| 13 | 300 | ST | Х | [00] | | 00247 | Relevant Clinical Information |
| 14 | 26 | TS | Х | [00] | | 00248 | Specimen Received Date/Time * |
| 15 | 300 | SPS | Х | [00] | | 00249 | Specimen Source |
| 16 | 250 | XC N | R | [11] | | 00226 | Ordering Provider |
| 17 | 250 | XT N | RE | [02] | | 00250 | Order Callback Phone Number |
| 18 | 60 | ST | Х | [00] | | 00251 | Placer Field 1 |
| 19 | 60 | ST | Х | [00] | | 00252 | Placer Field 2 |
| 20 | 60 | ST | Х | [00] | | 00253 | Filler Field 1 + |
| 21 | 60 | ST | Х | [00] | | 00254 | Filler Field 2 + |
| 22 | 26 | TS | Х | [00] | | 00255 | Results Rpt/Status Chng - Date/Time + |
| 23 | 40 | MO C | Х | [00] | | 00256 | Charge to Practice + |
| 24 | 10 | ID | С | [01] | 0074 | 00257 | Diagnostic Serv Sect ID |
| 25 | 1 | ID | Х | [00] | 0123 | 00258 | Result Status + |
| 26 | 400 | PRL | Х | [00] | | 00259 | Parent Result + |
| 27 | 200 | TQ | Х | [00] | | 00221 | Quantity/Timing |
| 28 | 250 | XC N | 0 | [0*] | | 00260 | Result Copies To |
| 29 | 200 | EIP | Х | [00] | | 00261 | Parent |
| 30 | 20 | ID | Х | [00] | 0124 | 00262 | Transportation Mode |
| 31 | 250 | CE | 0 | [01] | | 00263 | Reason for Study |
| 32 | 200 | ND L | 0 | [01] | | 00264 | Principal Result Interpreter + |
| 33 | 200 | ND L | 0 | [01] | | 00265 | Assistant Result Interpreter + |
| 34 | 200 | ND | 0 | [01] | | 00266 | Technician + |

Table 3.33.4.4-1: OBR Segment

| SEQ | LEN | DT | Usage | Card. | TBL # | ITEM# | Element name |
|-----|-----|---------|-------|-------|----------|-------|--|
| | | L | | | | | |
| 35 | 200 | ND L | 0 | [01] | | 00267 | Transcriptionist + |
| 36 | 26 | TS | 0 | [01] | | 00268 | Scheduled Date/Time + |
| 37 | 4 | NM | 0 | [01] | | 01028 | Number of Sample Containers * |
| 38 | 250 | CE | 0 | [01] | | 01029 | Transport Logistics of Collected Sample * |
| 39 | 250 | CE | 0 | [01] | | 01030 | Collector's Comment * |
| 40 | 250 | CE | Х | [00] | | 01031 | Transport Arrangement Responsibility |
| 41 | 30 | ID | Х | [00] | 0224 | 01032 | Transport Arranged |
| 42 | 1 | ID | Х | [00] | 0225 | 01033 | Escort Required |
| 43 | 250 | CE | Х | [00] | | 01034 | Planned Patient Transport Comment |
| 44 | 250 | CE | 0 | [01] | 0088 | 00393 | Procedure Code |
| 45 | 250 | CW E | 0 | [01] | 0340 | 01316 | Procedure Code Modifier |
| 46 | 250 | CE | 0 | [01] | 0411 | 01474 | Placer Supplemental Service Information |
| 47 | 250 | CE | 0 | [01] | 0411 | 01475 | Filler Supplemental Service Information |
| 48 | 250 | CW E | Х | [00] | 0476 | 01646 | Medically Necessary Duplicate Procedure Reason. |
| 49 | 2 | IS | 0 | [01] | 0507 | 01647 | Result Handling |

3.33.5 Expected Actions

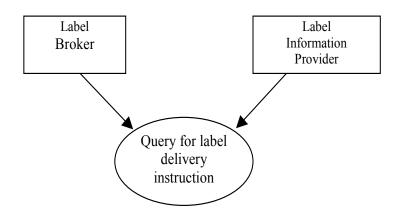
925 The OML message with Order Control Code 'NW' received from the Label Information Provider, contains the specimen container labeling instructions for the Label Broker. The Label Broker will reply with an ORL^O34 message with either "Accept" (MSA-1 = AA) or "Reject" (MSA-1 = AR) or "Error" (MSA-1 = AE).

3.34 Query for Label Delivery Instruction (LAB-62)

3.34.1 Scope

This transaction is used by the Label Broker to query the specimen container labeling instructions from the Label Information Provider.

935 **3.34.2 Use Case Roles**



Actor: Label Broker

Role: The Label Broker sends a query to the Label Information Provider in order to get the labeling instructions related to the laboratory test orders for a patient.

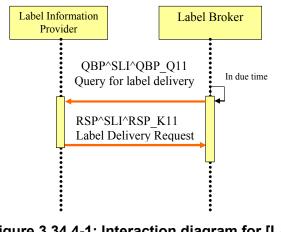
940 Actor: Label Information Provider

Role: The Label Information Provider responds to the query with the labeling instructions.

3.34.3 Referenced Standard

HL7 version 2.5:

3.34.4 Interaction Diagram



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Figure 3.34.4-1: Interaction diagram for [LAB-62]

3.34.5 Message Static Definitions

3.34.5.1 Trigger Events

QBP(Q11) : Query for specimen container labeling instructions sent by the Label Broker.
 RSP(K11) : Response including the labeling instructions sent by the Label Information Provider.

3.34.5.2 Message Semantics

| Segment | Meaning | Usage | Card. | HL7 chapter | | | | | | | |
|---------|----------------------------|-------|-------|----------------|--|--|--|--|--|--|--|
| MSH | Message header | R | [11] | 2 | | | | | | | |
| [{SFT}] | Software Segment | 0 | [0*] | 2 | | | | | | | |
| QPD | Query Parameter Definition | R | [11] | 5 | | | | | | | |
| RCP | Response Control Parameter | R | [11] | 5 | | | | | | | |
| [DSC] | Continuation Pointer | 0 | [01] | 2 | | | | | | | |

Table 3.34.5.2-1: QBP^SLI^QBP_Q11

MSH-9 - Message Type (MSG) shall be valued as: QBP^SLI^QBP_Q11

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Table 3.34.5.2-2: RSP^SLI^RSP_K11

| Segment | Meaning | Usage | Card. | HL7 chapter |
|---------|------------------------------------|-------|-------|----------------|
| MSH | Maaaaa haadaa | R | [1 1] | 2 |
| | Message header | | [11] | |
| [{SFT}] | Software Segment | 0 | [0*] | 2 |
| MSA | Message Acknowledgement | R | [11] | 2 |
| [ERR] | Error | Ο | [01] | 2 |
| QAK | Query Acknowledgement | R | [11] | 5 |
| QPD | Query Parameter Definition | R | [11] | 5 |
| [| PATIENT begin | С | [01] | |
| PID | Patient Identification | R | [11] | 3 |
| PV1 | Patient Visit | Ο | [01] | 3 |
| [{OBX}] | Observation related to the patient | 0 | [0*] | 7 |
| { | SPECIMEN begin | R | [1*] | |
| SPM | Specimen | R | [11] | 7 |
| [{OBX}] | Observation related to specimen | 0 | [0*] | 7 |
| [{SAC}] | Specimen Container | Ο | [0*] | 13 |
| { | ORDER begin | R | [1*] | |
| ORC | Common Order | R | [11] | 4 |
| [{TQ1}] | Timing/Quantity | RE | [01] | 4 |
| [| OBSERVATION REQUEST begin | 0 | [01] | |
| OBR | Observation Request | R | [11] | 4 |
| [TCD] | Test Code Details | 0 | [01] | 13 |
| [{OBX}] | Observation Result | 0 | [0*] | 7 |

| Segment | Meaning | Usage | Card. | HL7 chapter |
|---------|-------------------------|-------|-------|----------------|
|] | OBSERVATION REQUEST end | | | |
| } | ORDER end | | | |
| } | SPECIMEN end | | | |
|] | PATIENT end | | | |

MSH-9 - Message Type (MSG) shall have its two first components respectively valued to "RSP" and "K11".

Condition predicate for PATIENT segment group: This segment group is present if and only if the LIP has labeling instructions available matching the query criteria. If not the reply message shall contain only the first segments from MSH to QPD, the QAK segment indicating with QAK-2 "Query Response Status" valued "NF" (i.e., no data found, no error) that there was no available data matching the query parameters.

3.34.5.3 QPD Segment

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| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name | |
|-----|-----|----|-------|-------|------|-------|----------------------|--|
| 1 | 60 | CE | R | [11] | | 01375 | Message Query Name | |
| 2 | 32 | ST | R | [11] | | 00696 | Query Tag | |
| 3 | 80 | CK | С | [01] | | 00105 | Patient ID | |
| 4 | 250 | CX | С | [01] | | 00149 | Patient Visit Number | |
| 5 | 22 | EI | С | [01] | | 00218 | Placer Group Number | |
| 6 | 22 | EI | С | [01] | | 00216 | Placer Order Number, | |
| 7 | 22 | EI | С | [01] | | 00217 | Filler Order Number | |
| 8 | 53 | DR | С | [01] | | | Search Period | |

Table 3.34.5.3-1: QPD segment

QPD-1 Message Query Name (CE), required

Must be valued "SLI^Specimen Labeling Instructions^IHE_LABTF"

QPD-2 Query Tag (ST), required

Unique to each query message instance. This identifies the query instance. It is used to match the response with the query.

QPD-3 Patient Identifier, conditional

Contains a patient unique identifier, as defined in PID-3.

QPD-4 Patient Visit Number, conditional Contains a patient visit number, as defined in PV1-19.

975 **QPD-5 Placer Group Number,** conditional

Contains a placer group number, as defined in ORC-4.

QPD-6 Placer Order Number, conditional

Contains a placer order number, as defined in transaction LAB-1 (OBR-2).

QPD-7 Filler Order Number, conditional

980 Contains a filler order number, as defined in transaction LAB-1.(OBR-3)

Condition predicate: At least one of the fields QPD-3, QPD4, QPD-5, QPD-6, QPD-7 must be valued. In case QPD-3 or QPD-4 is used and there is more than one pending test order for the patient id or the visit number, it is the responsibility of the application implementing the Label Information Provider Actor to decide whether to pick up one or all of the pending orders. The business rules governing this decision are out of the scope of this Integration Profile.

QPD-8 Search Period (DR), conditional

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This field contains a range of date/times

| | | | | | | 5 | |
|-----|-----|----|-----|------|-----------------------|----------|---------------|
| SEQ | LEN | DT | OPT | TBL# | COMPONENT NAME | COMMENTS | SEC.REF. |
| 1 | 26 | TS | 0 | | Range Start Date/Time | | <u>2.A.77</u> |
| 2 | 26 | TS | 0 | | Range End Date/Time | | <u>2.A.77</u> |

HL7 Component Table - DR – Date/Time Range

990 Condition predicate: This criterion can be used when no order identifier is available, that is, when field QPD-5, QPD-6, QPD-7 are empty. QPD-8 is used in conjunction with QPD-3 or QPD-4.

Use case: It happens that the patient comes to the specimen collection room on another day than the scheduled one. Therefore a range of dates is a convenient criterion if the only information brought by the patient is a patient identifier or a visit identifier.

| | | | | | | - | |
|-----|-----|----|-------|-------|------|-------|--------------------------|
| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
| 1 | 1 | ID | R | [11] | 0091 | 00027 | Query Priority |
| 2 | 10 | CQ | 0 | [01] | 0126 | 00031 | Quantity Limited Request |
| | | NM | | | | | |
| | | CE | | | | | |
| 3 | 60 | CE | R | [11] | 0394 | 01440 | Response Modality |
| 7 | 256 | ID | 0 | [0*] | | 01594 | Segment group inclusion |

3.34.5.4 RCP Segment

Table 3.34.5.4-1: RCP segment

RCP-1 Query Priority(ID), required

Shall be fixed to "I" (=Immediate).

1000 RCP-2 Quantity Limited Request (CQ), optional

As for the 1st component "Quantity"(NM), Number of records that will be returned in each increment of the response. If no value is given, the entire response will be returned in a single increment.

As for the 2nd component "Units"(CE), "RD"(=Records) is always set. If no value is given, the default is RD.

RCP-3 Response Modality (CE), required

Shall be fixed to "R" (=Realtime).

RCP-7 Segment group inclusion (ID), optional

Specifies those optional segment groups which are to be included in the response. If this field is not valued, all segment groups will be included.

3.34.6 Expected Actions

The Label Information Provider parses the query parameters, and selects the appropriate pending test order(s) matching these parameters, according to its own business rules, and builds the response, which is sent back immediately to the Label Broker.

3.35 Laboratory Code Set Management (LAB-51)

3.35.1 Scope

This transaction is used by the Code Set Master actor to distribute entire code sets to Code Set Consumer actors. A code set may contain battery, test and observation codes. This transaction is initiated on a scheduled based (e.g., weekly) or whenever the organization of the laboratory changes (e.g., because of the addition/removing of an instrument, specialties).

3.35.2 Use Case Roles

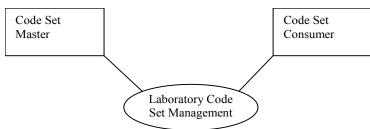


Figure 3.35.2-1: Use Case Roles for the Laboratory Code Set Management transaction

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Actor: Code Set Master

Role: Sends a full code set.

Actor: Code Set Consumer

Role: Receives a code set, and notifies the Code Set Master of its acceptance or refusal.

1030 3.35.3 Referenced Standard

HL7 2.5.1 Chapter 8 (Master Files)

HL7 2.5.1 Chapter 2 : 2.10.3 (Batch protocol), 2.15.2 (BHS segment), 2.15.3 (BTSsegment)

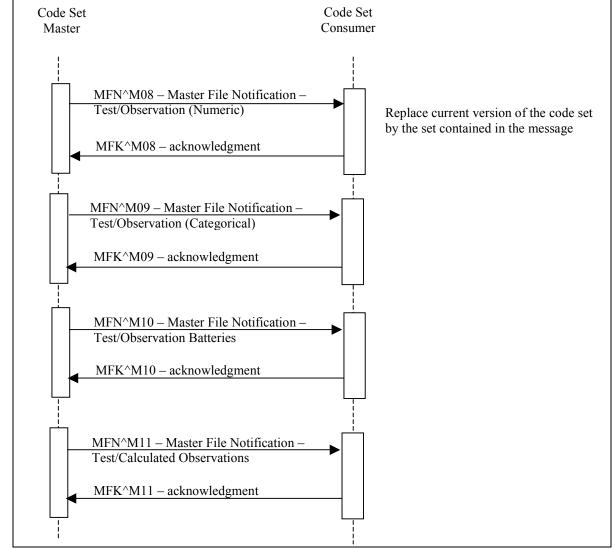
3.35.4 Interaction Diagrams

The interaction diagrams show the message flow between a Code Set Master and a Code Set 1035 Consumer. Four messages are defined for this transaction:

- MFN^M08 Master File Notification Test/Observation (Numeric). This message is used for codes related to individual tests with numeric results. This message should not be used for battery or profile definitions. If the result of the test is a formulaic expression (a calculation) of other tests, MFN^M11 should be used instead of this message.
- MFN^M09 Master File Notification Test/Observation (Categorical). This message is used for codes related to individual tests with results that are NOT numeric. This message should not be used for battery or profile definitions. If the result of the test is a formulaic expression of other tests, MFN^M11 should be used instead of this message

- MFN^M10 Master File Notification Test/Observation Batteries. This message is used for codes that identify batteries or profiles. This message should not be used to for individual tests.
 - MFN^M11 Master File Notification Test/Calculated Observations. This message is used for codes related to individual tests with calculated results. This message should not be used for battery or profile definitions.
- 1050 In order to simplify the management of observation codes (OBX-3) and battery codes (OBR-4), the MFN^M08, MFN^M09 and MFN^M11 messages will be used to distribute observation codes only (OBX-3), and MFN^M10 will be used to distribute battery codes (OBR-4).

The definitions of atomic tests (M08, M09) shall in all cases precede the definitions of batteries and calculated tests (M10, M11).

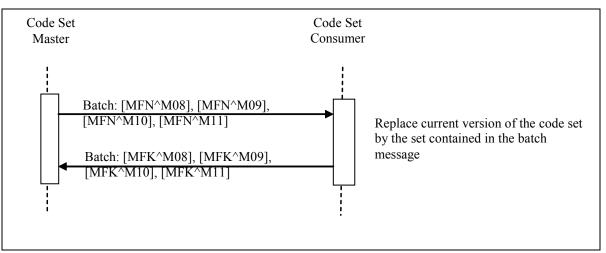


1055 **3.35.4.1 Laboratory Code Set Management**

Figure 3.35.4.1-1: Interaction diagram for [LAB-51]

In order to fully synchronize the code set between the Code Set Master and the Code Set Consumer 4 messages shall be sent.

1060 3.35.4.2 Laboratory Code Set Management with Batch Option





The Code Set Master sends a single batch containing 1 to 4 MFN messages, and the Code Set Consumer responds with a single batch acknowledgement containing the corresponding acknowledgement MFK messages.

3.35.5 Message Static Definitions

3.35.5.1 Trigger Events

MFN^{M08} – the Code Set Master sends a full set of observation codes.

1070 MFN^M09 – the Code Set Master sends a full set of non-numeric observation codes.

MFN^M10 - the Code Set Master sends a full set of battery codes.

MFN^M11 – the Code Set Master sends a full set of calculated observation codes.

3.35.5.2 Message Semantics

HL7 2.5 Chapter 8 MFN^M08 message. Refer to HL7 Standard for general message semantics.
The OM2 segment can be used to transport the Units of Measure if necessary.

| Segment | Meaning | Usage | Card. | HL7 |
|---------|----------------------------|-------|-------|-----|
| MSH | Message Header | R | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFE | Master File Entry | R | [11] | 8 |

Table 3.35.5.2-1: MFN^M08 static definition

| Segment | Meaning | Usage | Card. | HL7 |
|---------|-------------------------------------|-------|-------|-----|
| OM1 | General Segment | R | [11] | 8 |
| [OM2] | Numeric Observation Segment | 0 | [01] | 8 |
| [OM4] | Observations that Require Specimens | 0 | [01] | 8 |
| } | MASTER FILE ENTRY end | | | |

See section 3 in the present volume 2 for the description of MFI and MFE segments.

1080 **MFI-1 Master File Identifier (CE)**, shall contain the value "OMA" (Numerical Observation Master File).

HL7 2.5 Chapter 8 MFN^{M09} message. Refer to HL7 Standard for general message semantics. The construction of the message is roughly the same as MFN^{M08}. The OM3 segment can be used to transmit categorical results for a test (such a "high"/"low", or "reactive"/"unreactive"/" "transactive") or to indicate a vocabulary for the results (e.g., SNOMED).

| Segment | Meaning | Usage | Card. | HL7 |
|---------|--|-------|-------|-----|
| MSH | Message Header | R | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFE | Master File Entry | R | [11] | 8 |
| OM1 | General Segment | R | [11] | 8 |
| [| MF_TEST_CAT_DETAIL begin | 0 | [01] | 8 |
| OM3 | Categorical Service/Test/Observation Segment | R | [11] | 8 |
| [{OM4}] | Observations that Require Specimens | 0 | [0*] | 8 |
|] | MF_TEST_CAT_DETAIL end | | | |
| } | MASTER FILE ENTRY end | | | |

Table 3.35.5.2-2: MFN^M09 static definition

HL7 2.5 Chapter 8 MFN^M10 message. Refer to HL7 Standard for general message semantics.
The construction of the message is roughly the same as MFN^M08.

| Segment | Meaning | Usage | Card. | HL7 |
|---------|----------------------------|-------|-------|-----|
| MSH | Message Header | R | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFE | Master File Entry | R | [11] | 8 |
| OM1 | General Segment | R | [11] | 8 |

Table 3.35.5.2-3: MFN^M10 static definition

| Segment | Meaning | Usage | Card. | HL7 |
|---------|-------------------------------------|-------|-------|-----|
| [| MF_TEST_BATT_DETAIL begin | RE | [01] | 8 |
| OM5 | Observation Batteries | R | [11] | 8 |
| [{OM4}] | Observations that Require Specimens | 0 | [0*] | 8 |
|] | MF_TEST_BATT_DETAIL end | | | |
| } | MASTER FILE ENTRY end | | | |

See section 3 in the present volume 2 for the description of MFI and MFE segments.

1095 **MFI-1 Master File Identifier (CE),** shall contain the value "OMC" (Observation Batteries Master File).

HL7 2.5 Chapter 8 MFN^M11 message. Refer to HL7 Standard for general message semantics. The construction of the message is roughly the same as MFN^M08. The OM6 segment can be used to detail the rule or formula used to determine the value of the test. The OM2 segment can be used to specify the units of measure if the formula results in a numeric value.

| Segment | Meaning | Usage | Card. | HL7 |
|---------|--|-------|-------|-----|
| MSH | Message Header | R | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFE | Master File Entry | R | [11] | 8 |
| OM1 | General Segment | R | [11] | 8 |
| [| | | | |
| OM6 | Observation calculated from other observations | 0 | [01] | 8 |
| OM2 | Numeric Observation Segment | 0 | [01] | 8 |
|] | | | | |
| } | MASTER FILE ENTRY end | | | |

Table 3.35.5.2-4: MFN^M11 static definition

See section 3 in the present volume 2 for the description of MFI and MFE segments.

1105 **MFI-1 Master File Identifier (CE)**, required, shall contain the value OMD (Calculated Observations Master File).

3.35.5.2.1 Master File Notification – Test/Observation (Numeric)

This message is used to transmit observation codes, i.e., codes sent in the OBX-3 field (Observation Identifier). Observations must have continuous values (data of type numeric, date, or time stamp).

3.35.5.2.2 Master File Notification – Test/Observation (Categorical)

This message is used to transmit the code of observations where the value is free text and other non-numeric data types.

3.35.5.2.3 Master File Notification – Test/Observation Batteries

1115 This message is used to transmit battery codes, i.e., codes sent in the OBR-4 field (Universal Service Identifier).

3.35.5.2.4 Master File Notification – Test/Calculated Observation

This message is used to transmit the code of observations where the value is derived from one or more quantities or direct observations.

1120 3.35.5.2.5 Acknowledge Message

Applications that receive HL7 messages defined in the IHE Laboratory Technical Framework shall send acknowledgements using the HL7 original acknowledgement mode. The Master File Application Acknowledgement message is defined in HL7 2.5 Chapter 8. The structure of the acknowledgement messages is the same for all acknowledgements:

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| Segment | Meaning | Usage | Card. | HL7 |
|---------|----------------------------|-------|-------|-----|
| MSH | Message Header | R | [11] | 2 |
| MSA | Acknowledgment | R | [11] | 2 |
| [{ERR}] | Error | С | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | С | [0*] | 8 |
| MFA | Master File ACK Segment | R | [11] | 8 |
| } | MASTER FILE ENTRY end | | | |

Table 3.35.5.2.5-1: MFK^M08, MFK^M09, MFK^M10, MFK^M11 Static Definition

The construction of MSH, MSA and ERR segments is defined in section 3.1 of the IHE Laboratory Technical Framework, Volume II. The ERR segment shall be used in case of negative acknowledgement, i.e., when the receiving application sends an error on one Master File entry.

The MASTER FILE ENTRY segment group is conditional upon the presence of errors (see the description of field MFI-6). The segment group shall only be populated with MFA Segment for those master file entries that could NOT be accepted. If the entire batch can be accepted by the receiver then the acknowledgement message shall not contain any MFA segments.

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3.35.5.3 OM1 – General Segment

| 1 | 1 | 40 |
|---|---|----|
|---|---|----|

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Table 3.35.5.3-1: OM1 – General Segment

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|-----|-------|-------|-------|-------|--|
| 1 | 4 | NM | R | [11] | | 00586 | Sequence Number - Test/Observation Master File |
| 2 | 250 | CE | R | [11] | | 00587 | Producer's Service/Test/Observation ID |
| 3 | 12 | ID | 0 | [0*] | 0125 | 00588 | Permitted Data Types |
| 4 | 1 | ID | R | [11] | 0136 | 00589 | Specimen Required |
| 5 | 250 | CE | R | [11] | | 00590 | Producer ID |
| 7 | 250 | CE | 0 | [0*] | | 00592 | Other Service/Test/Observation IDs for the Observation |
| 8 | 200 | ST | R | [1*] | | 00593 | Other Names |
| 12 | 1 | ID | 0 | [01] | 0136 | 00597 | Orderability |
| 18 | 1 | IS | R | [11] | 0174 | 00603 | Nature of Service/Test/Observation |
| 19 | 250 | CE | RE | [01] | 99999 | 00604 | Report Subheader |
| 20 | 20 | ST | RE | [01] | | 00605 | Report Display order |
| 30 | 250 | CWE | 0 | [01] | 0177 | 00615 | Confidentiality Code |
| 31 | 250 | CE | 0 | [0*] | 9999 | 00616 | Observations Required to Interpret the Observation |

OM1-1 Sequence Number – Test/Observation Master File (NM), required, shall contain a sequence number from 1 to n (number of records).

OM1-2 MFN Producer's Service/Test/Observation ID (CE) is required. Only the first three sub-fields (Identifier, Text and Name of Coding System) are required. The last 3 components of the CE data type shall not be valued.

(MFN^M08 and MFN^M10 and MFN^M11 messages)

OM1-3 Permitted Data Types (ID), optional, should contain numerical, date or time stamp data types.

(MFN^M09 message)

1150 **OM1-3 Permitted Data Types (ID)**, optional, should contain data types other than numerical, date or time stamp.

OM1-4 Specimen Required (ID), required, contain the value Y if one or more specimen are required to obtain this observation, and N if a specimen is not required.

OM1-5 Producer ID (CE), required, uniquely identifies the service producing the observation. 1155 Only the first three sub-fields (Identifier, Text and Name of Coding System) are required.

OM1-7 Other Service/Test/Observation IDs for the Observation (CE) is optional and repeating. It can be used to send mapped/translated codes to the destination system. This field

can be used to convey the mapping of local codes to reference code sets such as LOINC or SNOMED CT.

1160 **OM1-8 Other Names (ST)**, required, contains aliases or synonyms for the name in the context of the Order Placer. By default, this field can contain the same value as OM1-2 (2nd sub-field).

OM1-12 Orderability (ID), optional, indicates whether or not a service/test/observation is an orderable code. For example, blood differential count is usually an orderable "test," MCV, contained within the differential count, is usually not independently orderable.

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Table 3.35.5.3-2: HL7 Table 0136 – Yes/No Indicator Values

| Value | Description |
|-------|---|
| Y | The service/test/observation is an orderable code |
| Ν | The service/test/observation is not orderable |

(MFN^M08 and MFN^M09 messages)

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value A (atomic observation).

(MFN^M10 message)

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value P (battery consisting of one or many independent atomic observations), F (functional procedure) and S (superset of batteries or procedure ordered under a single code unit).

1175 (MFN[^]M11 message)

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value C (single observation calculated via a rule or formula from other independent observations).

OM1-19 Report Subheader (CE), required if known, contains an optional string that defines the preferred header under which this observation should be listed on a standard display.

1180 **OM1-20 Report Display Order (ST),** required if known, contains an optional string that defines the absolute sort order in which this observation is presented in a standard report or display that contains the many observations.

OM1-30 Confidentiality Code (CWE), optional, contains the degree to which special confidentiality protection should be applied to the observation. For example, a tighter control may be applied to an HIV test than to a CBC. This field can especially be useful if all

observations for the OM1 record can be treated in the same manner.

Table 3.35.5.3-3: HL7 Table 0177 – Confidentiality Code (Subset)

| Value | Description |
|-------|-----------------|
| V | Very restricted |
| R | Restricted |
| U | Usual control |

OM1-31 Observations Required to Interpret the Observation (CE), optional.

1190 This field contains the list of supporting observations (e.g., patient temperature) needed by the laboratory to perform the ordered test.

Each of these supporting observations appears as a coded test that must have been sent ahead of the current test, in the same catalog, published through transaction LAB-51.

The observations specified here should be sent to the diagnostic service as OBX segments along with the order (OBR) segment in LAB-1 messages.

3.35.5.4 OM2 – Numeric Observation Segment Table 3.35.5.4-1: OM2 – Numeric Observation Segment

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|-----|-------|-------|------|-------|--|
| 2 | 250 | CE | R | [11] | | 00627 | Units of Measure |
| 3 | 10 | NM | RE | [0*] | | 00628 | Range of Decimal Precision |
| 6 | 250 | RFR | 0 | [0*] | | 00631 | Reference (Normal) Range For Ordinal And Continuous Observations |

OM2-2 Units of Measure (CE), required. Used only if the test contained in OM1 has numeric results. Contains the customary units of measure for the test.

OM2-3 Range of Decimal Precision (NM), required if known. Used only if the test contained in OM1 has numeric results. Specifies the total length in characters of the field needed to display the observation, and the number of digits displayed to the right of the decimal point. This is coded as a single number in the format <length>.<decimal-digits>. For example, a value of 6.2

1205 implies 6 characters total (including the sign and decimal point) with 2 digits after the decimal point. For integer values, the period and <decimal-digits> portion may be omitted (that is, 5.0 and 5 are equivalent). More than one such mask may be transmitted (separated by repeat delimiters) when it is necessary to define possible multiple display formats.

OM2-6 Reference (Normal) Range for Ordinal and Continuous Observations, Optional.
 This field contains the reference (normal) ranges for "numeric" observations/tests with a nature code of A or C (see OM1-18 - Nature of Service/Test/Observation). The use of this field is discouraged (but not forbidden) by IHE. This field can identify different reference (normal) ranges for different categories of patients according to age, sex, race, and other patient conditions. Reference (normal) ranges however also depend on the Analyzer being used, a factor

1215 which isn't included in this field. Without having knowledge of the Analyzer generic statements about reference ranges may be clinically misleading and dangerous.

3.35.5.5 OM4 Segment: Observations that Require Specimens

The OM4 segment is used to convey information related to the (collection of) specimen required for the test/battery. This information can be used by Order Placers (e.g., at the ward) to collect the specimen.

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| | | | | · · · · | | | | | | |
|-----|-----|----|-------|---------|------|-------|---------------------------|--|--|--|
| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name | | | |
| 3 | 60 | ΤХ | R | [11] | | 00643 | Container Description | | | |
| 4 | 20 | NM | 0 | [01] | | 00644 | Container Volume | | | |
| 6 | 250 | CE | 0 | [01] | | 00646 | Specimen | | | |
| 10 | 20 | CQ | 0 | [01] | | 00650 | Normal Collection Volume | | | |
| 11 | 20 | CQ | 0 | [01] | | 00651 | Minimal Collection Volume | | | |

Table 3.35.5.5-1: OM4 – Observations that Require Specimens

OM4-3 Container Description (TX), required. Used only if OM1-4 contains "Y"; contains a textual description of the type of container used for collection of the sample, e.g., "Red capped 1225 tube #2".

OM4-4 Container Volume (NM), optional, indicates the capacity of the container.

OM4-6 Specimen (CE), optional. See SPM-4 for additional information. The actor shall use one and the same vocabulary table for OM4-6 and SPM-4 if the Code Set Master is also an Order Filler actor.

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OM4-10 Normal Collection Volume (CQ), optional, contains the normal specimen volume required by the lab. This is the amount used by the normal methods and provides a sufficient amount to repeat the procedure at least once if needed. The default unit is milliliters (ml).

OM4-11 Minimal Collection Volume (CQ), optional, contains the volume needed by the most specimen sparing method (e.g., using micro techniques). The minimum amount allows for only 1235 one determination. The default unit is milliliters (ml).

3.35.5.6 OM5 – Observation Batteries

Table 3.35.5.6-1: OM5 – Observation Batteries

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|----|-------|-------|------|-------|---|
| 2 | 250 | CE | R | [1*] | | 00655 | Test/Observations Included within an Ordered Test Battery |

OM5-2 Test/Observations Included within an Ordered Test Battery, required, contains the codes and names of all tests/observations included within a single battery. 1240

If the OM1 segment defined serum electrolytes, this field might look like the following: 84132^{potassium}AS4~84295^{sodium}AS4~82435^{chloride}AS4~82374^{HCO3^AS4}

3.35.5.7 MFA - Master File Acknowledgement Segment

The MFA – Master File Acknowledgment segment is defined in the following table.

Table 3.35.5.7-1: MFA – Master File Acknowledgment Segment

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|----|-------|-------|------|-------|-------------------------|
| 1 | 3 | ID | R | [11] | 0180 | 00664 | Record-Level Event Code |
| 2 | 20 | ST | R | [11] | | 00665 | MFN Control ID |

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|----|-------|-------|------|-------|----------------------------------|
| 3 | 26 | TS | 0 | [01] | | 00668 | Event Completion Date/Time |
| 4 | 250 | CE | R | [11] | 0181 | 00669 | MFN Record Level Error Return |
| 5 | 250 | CE | R | [11] | | 01308 | Primary Key Value - MFA |
| 6 | 3 | ID | R | [11] | 0355 | 01320 | Primary Key Value Type - MFA |

MFA-1 Record-Level Event Code (ID), required, shall contain the value MAD (add record to master file).

1250 **MFA-2 MFN Control ID (ST)** is required and contains an identifier that uniquely identifies the change to the record.

MFA-4 MFN Record Level Error Return (CE), required, contains the status of the requested update. The actors of IHE Laboratory Technical Framework should support the following values:

1255

Table 3.35.5.7-2: MFN record-level error return

| Value | Description |
|-------|---|
| S | Successful posting of the record defined by the MFE segment |
| U | Unsuccessful posting of the record defined by the MFE segment |

MFA-5 Primary Key Value – MFA, required, uniquely identifies a record of the code set. It contains the same value as MFE-4.

MFA-6 Primary Key Value Type - MFA (ID), required, contains the value CE (coded element).

3.35.6 Expected Actions

The Code Set Consumer must replace its corresponding code set by the received code set. Codes which have been removed from the code set are not to be used by the receiving system any more from the effective date/time given in the message. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added

1265 be deleted but be flagged as disabled/invalid for backward compatibility reasons. New ad codes are usable from the effective date/time given in the message.

3.35.7 Batch Message Static Definitions

3.35.7.1 Trigger Events

BHS

1270 [MFN^M08] – the Code Set Master sends a full set of observation codes.

[MFN^M09] - the Code Set Master sends a full set of non-numeric observation codes.

[MFN^M10] – the Code Set Master sends a full set of battery codes.

[MFN^M11] – the Code Set Master sends a full set of calculated observation codes. BTS

1275 3.35.7.2 Message Semantics

The semantics combines those of the message static definitions of section 18.5.2

3.35.7.3 Batch Message

| Segment | Meaning | Usage | Card | HL7 |
|---------|---|-------|------|-----|
| BHS | Batch Header Segment | R | [11] | 2 |
| { | | | | |
| [| Start MFN^M08 message (Test/Observation Numeric) | 0 | [01] | 8 |
| MSH | Message Header | R | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFE | Master File Entry | R | [11] | 8 |
| OM1 | General Segment | R | [11] | 8 |
| [OM2] | Numeric Observation Segment | 0 | [01] | 8 |
| [OM4] | Observations that Require Specimens | 0 | [01] | 8 |
| } | MASTER FILE ENTRY end | | | |
|] | End MFN^M08 message | | | |
| | | | | |
| [| Start MFN^M09 message (Test/Observation Categorical) | 0 | [01] | 8 |
| MSH | Message Header | R | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFE | Master File Entry | R | [11] | 8 |
| OM1 | General Segment | R | [11] | 8 |
| [| MF_TEST_CAT_DETAIL begin | 0 | [01] | 8 |
| OM3 | Categorical Service/Test/Observation Segment | R | [11] | 8 |
| [{OM4] |] Observations that Require Specimens | 0 | [0*] | 8 |
|] | MF_TEST_CAT_DETAIL end | | | |
| } | MASTER FILE ENTRY end | | | |
|] | End MFN^M09 message | | | |
| | | | | |
| [| Start MFN^M10 message (Test/Observation Batteries) | 0 | [01] | 8 |
| MSH | Message Header | R | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |

Table 3.35.7.3-1: Batch Message Static Definition

| | Segm | ent | | Meaning | Usage | Card | HL7 |
|-----|---------------------------------------|-----|---------|---|-------|------|-----|
| | { | | | MASTER FILE ENTRY begin | R | [1*] | 8 |
| | | MFE | | Master File Entry | R | [11] | 8 |
| | | OM1 | | General Segment | R | [11] | 8 |
| | | [| | MF_TEST_BATT_DETAIL begin | RE | [01] | 8 |
| | | | OM5 | Observation Batteries | R | [01] | 8 |
| | | | [{OM4}] | Observations that Require Specimens | 0 | [01] | 8 |
| | |] | | MF_TEST_BATT_DETAIL end | | | |
| | } | | | MASTER FILE ENTRY end | | | |
|] | | | | End MFN^M10 message | | | |
| | | | | | | | |
| [| | | | Start MFN^M11 message (Test/Observation Numeric) | 0 | [01] | 8 |
| | MSH | | | Message Header | R | [11] | 2 |
| | MFI | | | Master File Identification | R | [11] | 8 |
| | { | | | MASTER FILE ENTRY begin | R | [1*] | 8 |
| | · · · · · · · · · · · · · · · · · · · | MFE | | Master File Entry | R | [11] | 8 |
| | | OM1 | | General Segment | R | [11] | 8 |
| | | [| | | | | |
| | | | OM6 | Observation calculated from other observations | | [01] | 8 |
| | | | OM2 | Numeric Observation Segment | | [01] | 8 |
| | |] | | | | | |
| | } | | | MASTER FILE ENTRY end | | | |
|] | | | | | | | |
| } | | | | | | | |
| BTS | | | | Batch Trailer Segment | R | [11] | 2 |

1280

3.35.7.3.1 Batch Message Acknowledgement

| Segment | Meaning | Usage | Card | HL7 |
|---------|------------------------------|-------|------|-----|
| BHS | Batch Header Segment | R | [11] | 2 |
| { | | | | |
| [| Start MFK^M08 acknowledgment | 0 | [01] | 2 |
| MSH | Message Header | R | [11] | 2 |
| MSA | Acknowledgment | R | [11] | 2 |
| [{ERR}] | Error | С | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFA | Master File ACK segment | R | [11] | 8 |

 Table 3.35.7.3.1-1:
 Batch Message Acknowledgment Static Definition

IHE Laboratory Technical Framework, Volume 2b (LAB TF-2b): Transactions Part B

| Segment | Meaning | Usage | Card | HL7 |
|---------|------------------------------|-------|------|-----|
| } | MASTER FILE ENTRY end | | | |
|] | End MFK^M08 message | | | |
| | | | | |
| [| Start MFK^M09 acknowledgment | 0 | [01] | 2 |
| MSH | Message Header | R | [11] | 2 |
| MSA | Acknowledgment | R | [11] | 2 |
| [{ERR}] | Error | С | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFA | Master File ACK segment | R | [11] | 8 |
| } | MASTER FILE ENTRY end | | | |
|] | End MFK^M09 message | | | |
| | | | | |
| ſ | Start MFK^M10 acknowledgment | 0 | [01] | 2 |
| MSH | Message Header | R | [11] | 2 |
| MSA | Acknowledgment | R | [11] | 2 |
| [{ERR}] | Error | С | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFA | Master File ACK segment | R | [11] | 8 |
| } | MASTER FILE ENTRY end | | | |
|] | End MFK^M10 message | | | |
| | | | | |
| ſ | Start MFK^M11 acknowledgment | 0 | [01] | 2 |
| MSH | Message Header | R | [11] | 2 |
| MSA | Acknowledgment | R | [11] | 2 |
| [{ERR}] | Error | С | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | R | [1*] | 8 |
| MFA | Master File ACK segment | R | [11] | 8 |
| } | MASTER FILE ENTRY end | | | |
| 1 | End MFK^M11 message | | | |
| } | | | | |
| BTS | Batch Trailer Segment | R | [11] | 2 |

3.35.7.4 BHS – Batch Header Segment

1285

Table 3.35.7.4-1: Batch Header Segment Static Definition

Card. SEQ LEN DT USAGE TBL# ITEM# Element name 1 1 STR [1..1] 00081 Batch Field Separator 2 3 ST R [1..1] 00082 Batch Encoding Characters 3 227 HD R [1..1] 00083 Batch Sending Application

| SEQ | LEN | DT | USAGE | Card. | TBL# | ITEM# | Element name |
|-----|-----|----|-------|-------|------|-------|-----------------------------|
| 4 | 227 | HD | R | [11] | | 00084 | Batch Sending Facility |
| 5 | 227 | HD | R | [11] | | 00085 | Batch Receiving Application |
| 6 | 227 | HD | R | [11] | | 00086 | Batch Receiving Facility |
| 7 | 26 | TS | R | [11] | | 00087 | Batch Creation Date/Time |
| 8 | 40 | ST | Х | [00] | | 00088 | Batch Security |
| 9 | 20 | ST | | | | 00089 | Batch Name/ID/Type |
| 10 | 80 | ST | | | | 00090 | Batch Comment |
| 11 | 20 | ST | RE | [01] | | 00091 | Batch Control ID |
| 12 | 20 | ST | RE | [01] | | 00092 | Reference Batch Control ID |

BHS-1 Batch Field Separator, required: The IHE Laboratory Technical Framework requires that applications support HL7-recommended value that is | (ASCII 124).

1290 **BHS-2 Batch Encoding Characters**, required: This field contains the four characters in the following order: the component separator, repetition separator, escape character, and subcomponent separator. The IHE Laboratory Technical Framework requires that applications support HL7-recommended values ^~\& (ASCII 94, 126, 92, and 38, respectively).

1295 BHS-4 Batch Sending Facility (HD), required:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

The IHE Laboratory Technical Framework requires that this field be populated with:

First component (required): Namespace ID. The name of the organizational entity responsible for the sending application.

1300 Second component (optional): The URI (OID) of the organizational entity responsible for the sending application.

Third component (optional): The type of identification URI provided in the second component of this field. The codification of these three components is entirely site-defined. It may be detailed in the national extensions of this framework.

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BHS-6 Batch Receiving Facility (HD), required:

Components: <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

The IHE Laboratory Technical Framework requires that this field be populated with:

First component (required): Namespace ID. The name of the organizational entity responsible for the receiving application.

Second component (optional): The URI (e.g., OID) of the organizational entity responsible for the receiving application.

Third component (optional): The type of identification URI provided in the second component of this field. The codification of these three components is entirely site-defined. It may be detailed

1315 in the national extensions of this framework.

BHS-11 Batch Control Id (ST), required in the initiating message: This field is used to uniquely identify a particular batch. It must be echoed back in BHS-12 – reference batch control ID of the responding batch of HL-7 MFK messages. The combination of this identifier and the name of the batch sending application (BHS-3) should be unique across the Healthcare enterprise.

1320 **BHS-12 Reference Batch Control (ID)**, required in the responding message: This field contains the value of the Batch Control Id (BHS-11) of the initiating batch of HL-7 MFN messages.

3.35.7.5 BTS – Batch Trailer Segment

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Table 3.35.7.5-1: Batch Trailer Segment Static Definition

| SEQ | LEN | DT | USAGE | Card. | TBL# | ITEM# | Element name |
|-----|-----|----|-------|-------|------|-------|---------------------|
| 1 | 10 | ST | 0 | [01] | | 00093 | Batch Message Count |
| 2 | 80 | ST | 0 | [01] | | 00090 | Batch Comment |
| 3 | 100 | NM | 0 | [0*] | | 00095 | Batch Totals |

3.35.7.6 MFK Segment

Applications that receive HL7 messages defined in the IHE Laboratory Technical Framework shall send acknowledgements using the HL7 original acknowledgement mode. The Master File Application Acknowledgement message is defined in HL7 2.5 Chapter 8. The structure of the acknowledgement messages is the same for all acknowledgements:

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Table 3.35.7.6-1: MFK^M08, MFK^M09, MFK^M10, MFK^M11 Static Definition

| Segment | Meaning | Usage | Card. | HL7 |
|---------|----------------------------|-------|-------|-----|
| MSH | Message Header | R | [11] | 2 |
| MSA | Acknowledgment | R | [11] | 2 |
| [{ERR}] | Error | С | [11] | 2 |
| MFI | Master File Identification | R | [11] | 8 |
| { | MASTER FILE ENTRY begin | С | [0*] | 8 |
| MFA | Master File ACK Segment | R | [11] | 8 |
| } | MASTER FILE ENTRY end | | | |

The construction of MSH, MSA and ERR segments is defined in section 3.1 of the IHE Laboratory Technical Framework, Volume II. The ERR segment shall be used in case of negative acknowledgement i.e. when the receiving application sends an error on one Master

1335 negative acknowledgement, i.e., when the receiving application sends an error on one Master File entry.

The MASTER FILE ENTRY segment group is conditional upon the presence of errors (see the description of field MFI-6). The segment group shall only be populated with MFA Segment for those master file entries that could NOT be accepted. If the entire batch can be accepted by the receiver then the acknowledgement message shall not contain any MFA segments.

3.35.8 Expected Actions

The Code Set Consumer must replace its corresponding code set by the received code set. Codes which have been removed from the code set are not to be used by the receiving system any more from the effective date/time given in the message. Codes which have been removed should not

1345 be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes are usable from the effective date/time given in the message.

4 Real World Use Cases

4.1 Guidelines

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1350 Each of the real world use cases in this section are to be considered as a template for handling a category of laboratory testing throughout all the transactions of the Laboratory Technical Framework. Only the major steps and interactions are described.

Each use case is described by a storyboard that describes the complete workflow in chronological order, completed by an interaction diagram, and illustrated by the most significant messages of this workflow.

The message descriptions are abbreviated, to focus on the main points of interest.

For brevity, only some of the application acknowledgements are shown.

The actors' names are abbreviated with their initials (OP, OF, AM, ORT). These abbreviations are also used in the MSH-3 (sending application) and MSH-5 (receiving application) fields.

1360 All use cases assume that the placer order is related to a placer group number (ORC-4).

All tests are identified in OBX segments by their LOINC code when available.

Colors point out key information in the messages.

4.2 First Example for Barcode Labeling (LBL)

4.2.1 Storyboard

- 1365 1. Dr. Yamada examines the patient (ID: 1111222) and orders liver function tests and blood count through the HIS terminal.
 - 2. The patient goes to the blood collecting room.
 - 3. The receptionist for blood collecting checks the test orders and accepts the reception through the HIS terminal.
- 1370 4. The HIS sends the label information to the barcode labeling robotic system.
 - 5. The robotic system issues the containers with barcode label.
 - 6. The blood collector takes blood of the patient.

Human actors and organizations participating to the process:

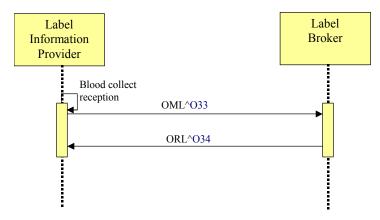
| Assigning authority: | Suzuki national hospital |
|----------------------|--|
| Placer: | Enter-gastric department |
| Label Broker: | LBL system |
| Ordering facility: | Enter-gastric department |
| Patient: | Taro Toyota, Patient hospital identifier: 1111222, Patient visit number: 3333444, class = outpatient |

Orderer: Dr. Yamada. ID number 14789

ID numbers used by the workflow: 1375

| ID number | Value | Assigned by |
|---|---------|-------------------------------|
| Patient hospital ID | 1111222 | Admission office (ADT) |
| Patient visit number | 3333444 | Admission office (ADT) |
| Observation Order Code: liver function test | 1234561 | Enter-gastric department (OP) |
| Observation Order Code: Blood count | 1234562 | Enter-gastric department (OP) |

4.2.2 Interaction Diagram



4.2.3 Messages

LAB-61(LIP \rightarrow LB): New Label Delivery Request transmitted to the LB

| 1380 | |
|------|---|
| | MSH ^~\& LIP Enter-gastric department LB LBL system |
| | 200701121348 OML^O33^OML_O33 001 P 2.5 USA EN |
| | PID 1 1111222^^^Suzuki National Hospital^PI Toyota^Taro^^^^L 19810101 M |
| | PV1 1 0 3333444 |
| 1385 | SPM 1 1234560001 001^Venous blood P 20070112 1 021^Chemistry |
| | ORC NW 1234561 200701121348 14789^Yamada^Jiro 14789^Yamada^Jiro 051^Enter- |
| | gastric department |
| | TQ1 R |
| 1200 | OBR 1234561 17432^liver function^local 6.0 14789^Yamada^Jiro |
| 1390 | SPM 1 1234560002 001^Venous blood P 20070112 1 015^hematology |
| | ORC NW 1234562 200701121348 14789^Yamada^Jiro 14789^Yamada^Jiro 051^Enter- |
| | gastric department |
| | TQ1 R |
| 1205 | OBR 1234562 18655^blood count^local 2.0 14789^Yamada^Jiro |
| 1395 | |

1395

The related acknowledgement message isn't shown.

4.3 Second Example for Barcode Labeling (LBL)

4.3.1 Storyboard

1. Dr. Yamada examines the patient (ID: 1111222) and orders liver function tests and blood count through the HIS terminal.

- 2. The patient goes to the blood collecting room.
- 3. The patient inserts his ID card to the reception machine for blood collecting.
- 4. The barcode labeling robotic system sends the query for label delivery to the HIS
- 5. The HIS sends the label information back to the barcode labeling robotic system.
- 6. The robotic system issues the containers with barcode label. 1405
 - 7. The blood collector takes blood of the patient.

Human actors and organizations participating to the process:

| Assigning authority: | Suzuki national hospital |
|----------------------|---|
| Placer: | Enter-gastric department |
| Label Broker: | LBL system |
| Ordering facility: | Enter-gastric department |
| Patient: | Taro Toyota, Patient hospital identifier: 1111222, Patient visit number: 3333444, class = outpatient |

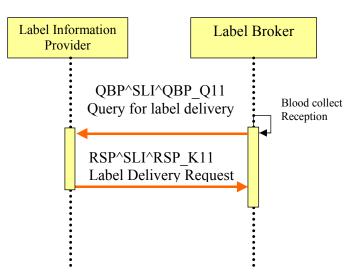
Orderer: Dr. Yamada. ID number 14789

ID numbers used by the workflow:

| ID number | Value | Assigned by |
|--|---------|-------------------------------|
| Patient hospital ID | 1111222 | Admission office (ADT) |
| Patient visit number | 3333444 | Admission office (ADT) |
| Observation Order Code (liver function test) | 1234561 | Enter-gastric department (OP) |
| Observation Order Code (Blood count) | 1234562 | Enter-gastric department (OP) |

1410

4.3.2 Interaction Diagram



4.3.3 Messages

LAB-62 (LB→LIP): Query for label delivery

1415

MSH|^~\&|LB|LBL system |LIP|Enter-gastric department |200701121348||
QBP^SLI^QBP_Q11|001|P|2.5|||||USA||EN
QPD|SLI^Specimen Labeling Instructions^IHE_LABTF|0001|1111222
RCP|I||R

1420 LAB-62 (LIP→LB): Label Delivery Request transmitted to the LB

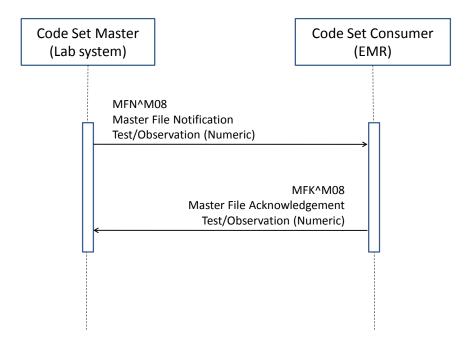
1435 OBR||1234562||18655^blood count^local||||2.0|||||14789^Yamada^Jiro

4.4 First Example Laboratory Code Set Management: Numeric Observations

4.4.1 Storyboard

This example reflects a use case in which a laboratory information system is broadcasting its catalog of tests, without the batch option. The interaction below carries the numeric tests.

4.4.2 Interaction Diagram



4.4.3 Messages

The message below is a Dutch (NLD) language example containing a master file definition for numeric tests. The master file has the version ID "1.2". The (optional) OM4 segment defines the type of container (e.g., "stolbuis rode dop4" = red capped blood tube #4) and specimen type (e.g., "BLDV^volbloed" = venous blood) which is associated with a test. This information is used by the OP in those cases where the OP is responsible for collecting the sample.

```
1450
       MSH|^~\&|OF|LabSystem|OP||20050205094510||MFN^M08^MFN M08|2106|T|2.5|||||NLD|8859/1|NL
       MFI|OMA|OF OMA NL 1.2|REP|||ER|
       MFE|MAD|1846||1846^CREABL/Creatinine^L|CE|
       OM1|1|1846^CREABL/Creatinine^L|NM|Y|K231^Klinisch Chemisch
1455
       Laboratorium^L||Creatinine||||||||A|
       OM2|1|umo1/1|6.0||
        OM4|1||stolbuis rode dop4||ml|BLDV^volbloed^HL70487|
       MFE|MAD|1848||1848^CREAUV/Creatinine^L|CE|
       OM1|2|1848^CREAUV/Creatinine^L|NM|Y|K231^Klinisch Chemisch
1460
       Laboratorium^L|||Creatinine||||||||A|
       OM2|2|mmol/1|6.0||
        OM4|2||24-uurs bokaal|||UR^urine^HL70487|
       MFE | .... (other master file entries not shown)
```

1465 Response message:

Note that those additions that are successful are not explicitly acknowledged. Each OM1 segments that is problematic to the receiver causes a MFA segment to be present in the acknowledgement message. In this example, all updates are accepted except for 1848.

1470 MSH|^~\&|OP||OF|LabSystem|20050205094520||MFK^M08^MFK_M01|234443|T|2.5|||||NLD|8859/1| NL| MSA|AA|2106| MFI|OMA|OF_OMA_NL_1.2|REP|||ER| MFA|MAD|1848||U^Duplicate ID|1848^CREAUV/Creatinine^L|CE

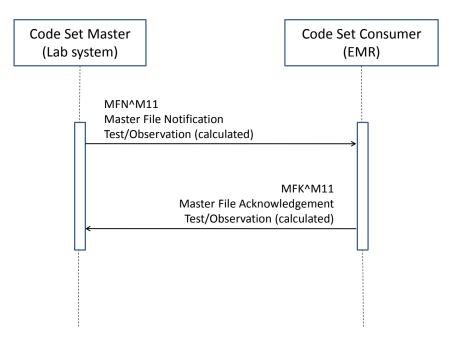
1475

4.5 Second Example of Laboratory Code Set Management: Calculated Observations

4.5.1 Storyboard

This example reflects a use case in which a laboratory information system is broadcasting its catalog of tests, without the batch option. The interaction below carries the calculated tests.

4.5.2 Interaction Diagram



4.5.3 Messages

1485 The message below is a Dutch (NLD) language example containing a master file definition for calculated numeric tests. The calculation algorithm is shown (in textual form) in the OM6 segment.

MSH|^~\&|OF|LabSystem|OP||20050205094520||MFN^M11^MFN M11|2107|T|2.5|||||NLD|8859/1|NL

1495

1490

Response message:

1500 The entire contents of the message are accepted.

```
MSH|^~\&|OP||OF|LabSystem|20050205094530||MFK^M11^MFK_M01|234450|T|2.5|||||NLD|8859/1|
NL|
MSA|AA|2107|
MFI|OMD|OF_OMD_NL_1.1|REP|||ER|
```

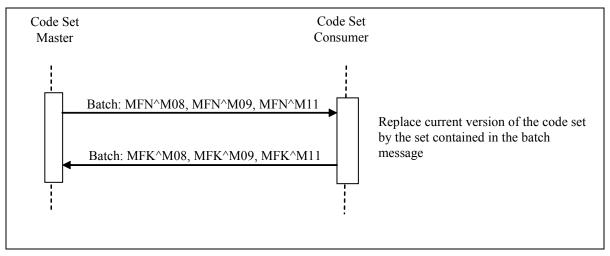
1505

4.6 Third Example of Laboratory Code Set Management: Batch Option

4.6.1 Storyboard

This example reflects a use case in which a laboratory information system is broadcasting its catalog of tests, with the batch option. A single batch carries the messages of numeric observations, categorical observations and calculated observations

4.6.2 Interaction Diagram



4.6.3 Messages

1515 The receiver shall drop all existing records and register the new code set version from the received batch.



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| | MSH ^~\& Lims Sending Facility Receiver Receiving |
|-------|--|
| | Facility 20090422165850 MFN^M09^MFN M09 M09 215 D 2.5 FR 8859/1 FRA |
| | MFI OMB Lims OMB FRA REP 20090422165850 ER |
| | MFE MAD 215 334365 334365^Freezing method^L CE |
| 1555 | OM1 1 Z00010-1^Freezing |
| 1000 | method^LOINC CE Y H^H^L HF METHODE A 0020^Other^L 00200010 |
| | OM3 1 L Various^Various freezing method^L~Ficoll freezing method^L~Light^Light |
| | freezing method^L |
| | OM4 Red-top edta tube H SG^H SG^L |
| 1560 | MATTIRed-top edta tuberth_SG h_SG L MSH ^~\& Lims Sending Facility Receiver Receiving |
| 1300 | |
| | Facility/20090422165851//MFN^M10^MFN_M10/M10_215/D/2.5////FR/8859/1/FRA |
| | MFI OMC Lims_OMC_FRA REP 20090422165851 ER |
| | MFE MAD 215_585128 585128^Electrolytes^L CE |
| 1565 | OM1 4 Z0003-1^Electrolytes^LOINC Y B^B^L Electrolytes P |
| 1565 | OM5 4 2951-2^^LOINC~12372-1^^LOINC~12466-2^^LOINC~26254-3^^LOINC |
| | OM4 purple-top glass tube P5HEPG^P5HEPG^L |
| | MFE MAD 215_585135 585135^Kidney tests^L CE |
| | OM1 5 Z0004-1^Kidney tests^LOINC Y B^B^L Kidney tests P |
| 1.570 | OM5 5 32664-7^^LOINC~14682-9^^LOINC |
| 1570 | OM4 purple-top glass tube P5HEPG^P5HEPG^L |
| | MSH ^~\& Lims Sending Facility Receiver Receiving |
| | Facility 20090422165853 MFN^M11^MFN_M11 M11_215 D 2.5 FR 8859/1 FRA |
| | MFI OMD Lims_OMD_FRA REP 20090422165853 ER |
| | MFE MAD 215_339307 339307^Calculated LDL^L CE |
| 1575 | OM1 1 22748-2^Calculated |
| | LDL^LOINC NM N B^B^L B_LDL C 0010^Chemistry^L 00100050 |
| | OM2 1 g/l^g/l^IS0 20.2 |
| | MFE MAD 215_353143 353143^Calculated Clearance^L CE |
| | OM1 2 Z010-3^Calculated Clearance^LOINC NM N B^B^L B_U_SAU C |
| 1580 | OM2 2 ml/s^ml/s^ISO 20 |
| | BTS 4 |
| | |

Response message:

The entire contents of the message are accepted.

1585 [insert response here]