

GMSIH, HL7 France H', SFIL, HL7 Germany, IHE-J, JAHIS, IHE Italy
Integrating the Healthcare Enterprise

IHE Laboratory Technical Framework
Supplement 2004-2005

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Laboratory Point Of Care Testing
(LPOCT)

Public Comment Version

June 15, 2005

Comments due July 15, 2005

20 **Foreword**

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

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

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

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

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

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

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

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

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

80 Document production

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Introduction

Laboratory Point Of Care Testing (LPOCT) is a new integration profile that will be added to Volume I of the IHE Laboratory Technical Framework. Associated with this profile come three new transactions that will be added to Volume II of the IHE Laboratory Technical Framework.

Abbreviations used in this document:

- **CLSI:** Clinical and Laboratory Standards Institute
- **DML:** Device Message Layer from standard POCT1-A

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- **LIS:** Laboratory Information System. This system usually implements the actor Order Filler in the IHE Laboratory Technical Framework.
 - **LPOCT:** Laboratory Point Of Care Testing Integration Profile
 - **Order Filler:** Actor of the IHE Laboratory Technical Framework, called the *Observation Recipient* in the POCT1-A standard.
 - **ORI:** Observation Reporting Interface between the *Observation Reviewer* and the *Observation Recipient* in the POCT1-A standard.
 - **POCDM:** Point Of Care Data Manager: actor of this LPOCT profile, named the *Observation Reviewer* in the POCT1-A standard.
 - **POCRG:** Point Of Care Result Generator: actor of this LPOCT profile, named the *Device* in the POCT1-A standard.
- 100
- **POCT:** Point Of Care Testing
 - **POCT1-A:** Point Of Care Connectivity approved standard published by CLSI
 - **QC:** Quality Control. More generally: Non-patient results.

Open Issues

This LPOCT profile of IHE Laboratory Domain, uses the standard POCT1-A from CLSI. This IHE LPOCT profile shows some usage variations with the original standard POCT1-A. These variations are highlighted in yellow in this document, and will have to be resolved during the public comment period. Comments from CLSI are particularly expected to help in this resolution.

110 Closed Issues

Minimal organizational requirements

The LPOCT profile assumes that the two actors Point Of Care Data Manager and Order Filler are provided with up-to-date patient demographics and visit data. The Order Filler achieves this goal by participating also to the Laboratory Scheduled Workflow (LSWF) described in the Laboratory Technical Framework. The POCDM may use ADT transactions of LSWF profile or transactions from other profiles such as Patient Demographics Query (PDQ) or Patient Administration Management (PAM) both described in the IT Infrastructure Technical Framework.

Results management in LPOCT process

- 120
- Given that the POCT observations are used at once by the care provider or the clinician, the profile does not handle cancellations or corrections of previous point of care observations. The second run of a specimen on a point of care device produces a new set of observations. This second run is performed because the observations produced by the first run have been rejected by

the POCDM, and therefore have not been transmitted to the Order Filler (LIS). The results uploaded to the LIS are assumed to have been technically validated (by a human or an automatic process) on the POCDM.

Minimal information to provide by the POCRG or by the POCDM

The following information SHALL be carried in the transactions, when available:

- POCRG ID
- Patient ID
- 130 - Ward staff ID
- Ordering provider ID
- Date time of specimen collection
- Reagent lot number
- Date time of observation
- Observations: Test, result (numeric, coded or textual), unit, abnormal flags, related alarms and comments

Matching a POCT set of observations with a previously existing placer order

140 When the Order Filler receives a point of care observation set from the POCDM, with the indication “match an existing order”, the Order Filler will search in its data base for an existing order for the same patient, same specimen type, same tests, ordered at the same date and approximately the same time as the observation set, and waiting for results. If it does not find any it will generate a new order.

Profile Abstract

In some situations clinical laboratory testing can be performed straightforwardly on the point of care instrument or the patient’s bedside by the ward staff, or even by the patient themselves, for instance in home care. This organization allows the ward staff to obtain immediate access to observations for some common tests, whose specimen does not need pre-analytic preparation. The results are used immediately in clinical decisions by the care givers.

150 In some areas such as North America and Europe, this point of care testing process is supervised by a clinical laboratory of the healthcare enterprise. The point of care analyzers of several wards are connected permanently or periodically to a central Point Of Care Data Manager. This central system collects point of care tests and results, related to patient specimens and QC specimens. The POCDM controls the point of care testing process and registers all the results. In addition it forwards the patient results to the LIS of the clinical laboratory supervising the point of care testing process.

Except for their quick availability and use, point of care observations are stored just like laboratory observations within the LIS.

160 LPOCT Integration Profile is designed to support this point of care testing process. This profile assumes that the LIS and the POCDM are both provided with up-to-date patient data.

Volume I – Integration Profiles

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

GLOSSARY

These definition shall be added to the Glossary chapter of volume 1:

CLSI: Clinical and Laboratory Standards Institute organization

DML: Device Message Layer defined by the standard POCT1-A

HL7: Health Level Seven consortium

LCSD: Laboratory Code Set Distribution profile

170 LDA: Laboratory Device Automation profile

LIR: Laboratory Information Reconciliation profile

LIS: Laboratory Information System

LPOCT: Laboratory Point Of Care Testing profile

LSWF: Laboratory Scheduled Work Flow profile

MLLP: HL7 Minimal Lower Layer Protocol (see IHE Laboratory Technical Framework)

ORI: Observation Reporting Interface defined by the standard POCT1-A

PAM: Patient Administration Management Integration Profile in IT Infrastructure Technical Framework

PDQ: Patient Demographics Query Integration Profile in IT Infrastructure Technical Framework

180 POCDM: Point Of Care Data Manager actor

POCRG: Point Of Care Results Generator actor

POCT: Point of care testing

QC: Quality Control

Internal Quality Control: Tests performed on an identified control specimen, with usually known target values.

External Quality Control: Tests performed on an identified control specimen whose target values are hidden, in order to control the proficiency of the organization. External QC specimens are provided by an external institution that controls and compares the results obtained by multiple healthcare enterprises. This is also called proficiency testing.

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Changes to Sections 1 – 1.X

<Include a subsection for each section/ subsection changed>

1.4 Relationship to Real-world architectures

Add the following paragraph to the end of this section

Core difference between LPOCT and LDA

When the clinical testing workflow is initiated by the analytic testing producing a set of observations, and when there is neither significant pre-analytic nor post-analytic process, then the analytic part of this workflow will be treated within the Laboratory Point Of Care Testing profile.

200 In all other cases the analytic workflow is covered by Laboratory Device Automation profile. This LDA profile supports the clinical testing workflow when it is initiated by an order, irrespective of whether this order is created at the Order Placer level or at the Order Filler level, and wherever the analyzers are located (on the point of care or in a laboratory).

Renumber section 1.6 to 1.7

Renumber section 1.7 to 1.8

Renumber section 1.8 to 1.9

1.6 History of Annual Changes

Add the following bullet to the end of the bullet list in section 1.6

- 210
- Added the Laboratory Point Of Care Testing Profile which integrates the workflow related to clinical laboratory tests performed on the point of care or on patient's bedside.

1.8 Copyright permissions

Add the following copyright statement

The Clinical and Laboratory Standards Institute (CLSI) has granted to IHE the permission to reproduce tables and figures from the POCT1-A standard. The POCT1-A tables and figures in this document are copyrighted by CLSI. All rights reserved.

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

2.1 Scope

220 ***Remove the last paragraph of this section, and add the following text at the end of it:***

~~The exchange of code sets and associated rules shared by multiple actors is beyond the scope of this integration profile. It is however assumed that the actors use common code sets when required.~~

The exchange of code sets and associated rules shared by multiple actors is within the scope of this Technical Framework, and covered by one of its profile: LCSD.

Another profile (LPOCT) of this Technical Framework covers the situation of clinical tests performed on the point of care or on patient's bedside by the ward staff or even by the patient itself (in home care settings).

2.2 Laboratory specialties

230 ***Remove the text before the table, and replace it with the following text:***

~~Not all laboratory specialties will be covered by the current framework: The 2003-2004 IHE cycle covers the workflow of disciplines that perform tests on specimens drawn from the patient, and not on the patient itself.~~

~~The table below, constructed from a subset of HL7 v2.5 Table 0074 "Diagnostic Service Section ID", points out the lab specialties addressed by the 2003—2004 cycle of IHE Laboratory Technical Framework. Other specialties may be added by future IHE cycles.~~

The Laboratory Technical Framework covers the laboratory specialties that perform tests on "in vitro" specimens taken from the patient, rather than tests performed on patients themselves.

240 The table below, constructed from a subset of HL7 v2.5 Table 0074 "Diagnostic Service Section ID", points out the laboratory specialties addressed the IHE Laboratory Technical Framework, in the role of the Order Filler. Other specialties may be added by future IHE cycles.

The excluded specialties in this table may not appear in the role of Order Filler. However some of them can still get involved in this framework in the role of Order Placer. It is the case of blood banks that order immuno-haematology tests.

2.3 Integration Profiles overview

Replace the text of this section by the following text, and add the table below:

The Laboratory Technical Framework contains the following Integration Profiles:

- Laboratory Scheduled Workflow (LSWF): covers the workflow related to tests performed by a clinical laboratory, fulfilling an order for a well-identified patient.
- Laboratory Device Automation (LDA) describes the workflow between the Automation Manager and a set of laboratory equipment involved in the testing process.
- Laboratory Point Of Care Testing (LPOCT) covers the workflow related to clinical laboratory tests performed on the point of care or on patient's bedside, by ward staff.

- Laboratory Information Reconciliation (LIR): covers the workflow related to tests performed by a clinical laboratory under exceptional situation: patient unidentified or misidentified, order not existing...
- Laboratory Code Set Distribution (LCSD) provides a way for an application owning a code set in the domain of clinical laboratory (battery, test and observation codes) to send it to other applications.

260 **Table 2.3: Integration Profiles Dependencies**

| Integration Profile | Depends on | Comment |
|---------------------------------------|---|--|
| Laboratory Scheduled Workflow | none | |
| Laboratory Information Reconciliation | Laboratory Scheduled Workflow Laboratory Device Automation | The reconciliation of observations with orders and patients requires transactions defined in both profiles LSWF and LDA |
| Laboratory Code Set Distribution | none | |
| Laboratory Device Automation | Laboratory Scheduled Workflow | |
| Laboratory Point Of Care Testing | Laboratory Scheduled Workflow | The system implementing the Order Filler actor in LPOCT shall also implement the Order Filler actor in LSWF profile. The POCDM actor shall be grouped with either the Patient Demographics Consumer actor of PDQ profile or the Patient Encounter Consumer of the PAM profile. These two profiles are defined in the IT Infrastructure Technical Framework. |

2.4 Actors in Laboratory Technical Framework

Add the following actors at the end of the list defined in section 2.4

Point Of Care Result Generator (POCRG):

This actor used in LPOCT profile is a system that produces results by automatic measure, manual entry or calculation. It identifies the results with the related patient or QC specimen ID, the operator who performs the tests, the ordering provider and the care unit. It sends this information to the POCDM. The POCRG is able to send its internal process control information to the POCDM.

270 **Point Of Care Data Manager (POCDM):**

This actor used in LPOCT profile is an application managing a set of POCRG and centralizing their results. The POCDM is ready to react to any conversation from a POCRG. The POCDM receives point of care observations from POCRG actors. It controls these observations within their context, stores them and forwards them to the Order Filler.

The POCDM is supporting the technical review (technical validation) of the results.

The application implementing a POCDM actor shall also implement the Patient Demographics Consumer actor either in PDQ profile or in PAM profile in order to have access to up-to-date patient demographics and encounter data.

280 The POCDM offers features to control the activity of its set of POCRG. It stores the quality control results of each POCRG and supervises this QC on all POCRG actors. The POCDM lets the authorized staff configure its application, and its related set of POCRGs.

| |
|--|
| <p><i>Complement the definition of the Order Filler actor with the following text:</i></p> |
|--|

290 In LPOCT profile this actor receives the point of care observation sets from the POCDM, and stores them within orders, either matched or generated for the occasion. These POCT orders are also submitted to clinical validation, and are archived for quality assurance and responsibility purposes only, since they have already been used by the medical staff in its care decisions. The clinical validation process triggers the sending of these results to the Order Result Tracker, using transaction LAB-3 of profile LSWF. POCT orders are associated to orders on the “placer side” by means of transactions LAB-1 or LAB-2 of profile LSWF.

5 Laboratory Point Of Care Testing Integration Profile

5.1 Summary of LPOCT

In some situations clinical laboratory testing can be performed straightforwardly on the point of care device or the patient's bedside by the ward staff, and even by patients themselves, in home care. These organizations enable the ward staff immediate access to common tests, whose specimen does not need any pre-analytic preparation. The results are used immediately in clinical decisions.

The point of care analyzers located in the wards send their observations to a central Point Of Care Data Manager, using a connection that can be persistent or intermittent.

300 This profile mainly addresses organizations, where point of care testing is placed under the overall supervision of a clinical laboratory of the healthcare enterprise. This supervision includes clinical validation of POCT results, internal and external Quality Control (QC) surveillance, reagent delivery, and education on good testing practices delivered to the ward staff. In these organizations (laboratory led), the laboratory clinical expert surveys the QC results on the POCDM application.

This profile can also support organizations that leave point of care testing under the responsibility of the ward medical staff using the point of care analyzers, and do not involve any laboratory in this process. These organizations will be referred as non-laboratory led organizations. (A subset of this profile will likely apply to these organizations.)

310 To fulfill the laboratory led need, the POCDM must be able to forward point of care patient results to the Order Filler application of the clinical laboratory supervising the POCT process.

The workflows covered by this LPOCT profile depend upon the kind of organization chosen, and upon the type of connection (persistent or intermittent) used by point of care devices.

LPOCT profile uses the Order Filler actor defined in LSWF profile, and introduces two new actors: Point Of Care Result Generator (POCRG), Point of Care Data Manager (POCDM).

5.2 Examples of PCRGR

- Portable analyzers enable the testing of usual parameters such as blood gas or electrolyte, from two drops of capillary blood drawn from the finger tip of a baby in a neo-natology unit.
- Analyzers installed in the surgery theatre measuring the blood gas every ten minutes during a patient operation.
- Analyzers installed at patient's bedside in intensive care unit.
- Glucose meter operated by the patient in the context of home nursing.
- A work station at which the nurse manually enters a pregnancy test, HIV stick test (non-instrumented test)...

5.3 Benefits of LPOCT

Point of care testing enables the medical staff to obtain observations quickly, thus improving efficiency. LPOCT is especially useful in emergency wards and intensive care wards.

330 The tests are performed immediately on a specimen barely collected from the patient. There is no pre-analytic operation needed (preparation of the specimen, transport, identification). In case of tests performed on a blood specimen, the required quantity of blood is usually lower than in laboratory testing. Minimizing the amount of blood taken from the patient is another advantage of LPOCT, which explains its common use within neo-natology and pediatric wards.

Point of care testing may also be worthwhile in home care: Tests performed by patients themselves, with the results sent to the central POCDM of the healthcare enterprise.

5.4 Scope of Laboratory Point Of Care Testing Integration Profile

- Point of care testing within a healthcare enterprise, or in home care under the control of a healthcare enterprise.
- All specialties of clinical laboratory that can be performed on the point of care.
- Testing on in vitro specimen, not on patients themselves.
- 340 • Tests of short time execution that do not need any significant pre-analytic process.
- Tests performed by the ward staff on the patient bedside or the point of care, or tests performed by patients themselves in home nursing. In both cases the healthcare enterprise collects and records on a central system all POCT observations.
- Observations produced by a point of care analyzer, or manually entered on a system, or calculated by a system.
- Point of care devices with persistent or intermittent link to the central point of care data manager.
- Overall supervision of the point of care testing process: This supervision may include QC surveillance, reagent management, operator certification, and centralization of results on the point of care data manager.
- 350 • This profile enables to place this supervision under the responsibility of a clinical laboratory, including uploading to the LIS all patient results.
- Currently, the remote control of the point of care testing devices by the central point of care data manager (remote commands) is left out of the scope of this profile.
- The identification process of the operators is currently not in the scope of this profile.
- The uploading of QC results from the POCDM to the LIS is currently out of scope.

- When a POCT set of observations reaches the Order Filler, these results have already been used by the care provider at the point of care, and these results are assumed to be technically validated by the POCDM. Due to these two characteristics, LPOCT profile does not handle corrections or cancellations of observations.

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5.5 Use cases

The 5 following use cases cover the various organizations and situations mentioned in the summary of this profile.

5.5.1 Observations to match with an existing order, patient identity checking

This use case involves a real-time patient identity checking. It requires a persistent link between the point of care testing device (POCRG) and the point of care data manager (POCDM).

The scenario covers the situation in which the order for point of care testing is created on the Order Placer application prior to the testing. The order number, though, is not entered on the POCRG, and is transmitted neither to the POCDM nor to the Order Filler. The Order Filler has to match an existing order in its data base.

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Note 1: The use case in which the order number would be entered on the point of care device and transmitted to the POCDM and then to the Order Filler, is considered by the IHE Laboratory Technical Framework as a normal use case of scheduled clinical laboratory testing, supported by the Integration Profiles Laboratory Scheduled Workflow and Laboratory Device Automation. The point of care device in this use case is considered as an analyzer of the clinical laboratory, even if it is remote. See Volume 1 section 1.4 “Relationship to real world architectures”.

Part 1 of the scenario

The physician orders point of care tests for a patient. This order is entered on the Order Placer application and is assigned a placer order number. As part of the LSWF profile, the Order Placer sends this new point of care order to the Order Filler, which assigns a filler order number to it, and waits for point of care observations.

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Part 2 of the scenario

To fulfill this order, the operator (physician, nurse, patient) sets a patient specimen on the point of care device implementing the POCRG actor. The operator initiates the operation, providing its own identification, a patient/visit identifier and all information relevant for testing. In addition the operator enters the indication that an order already exists for the tests to perform.

Part 3 of the scenario

The POCRG notifies this information to the POCDM (on the persistent link between the two) to check all the information provided, and to get the patient name. This patient name sent back to the point of care device is displayed so that the operator can check that he has entered the correct patient/visit identifier. If the patient is unknown to the POCDM or in other error cases, the operator will follow the enterprise policies. For instance the operator could key in the patient

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identity on the device so that this information be transmitted with the results in part 4 of the scenario.

Part 4 of the scenario

The point of care device performs the tests on the specimen, produces the results and displays them to the user.

The POCRG sends the observation set with its related data to the POCDM, including the indication “existing order to be matched”.

- 400 The POCDM checks the received observations against its own rules (result compared with normal ranges or scale limits, QC results obtained and correct ...), accepts them, stores them, and acknowledges them to the POCRG (results accepted). The POCRG displays the acknowledgment received from the POCDM. In case the POCDM detected an erroneous or suspicious result, it rejects the results, and sends back a negative acknowledgement to the POCRG.

If the results are accepted they are immediately available to inform the clinical and medical care of the patient.

Part 5 of the scenario: – order matched

Having accepted the observation set, the POCDM forwards it to the Order Filler, accompanied by the indication “existing order to be matched”.

- 410 The Order Filler searches for the existing order in its own data base, by matching a point of care testing order for the same patient, containing the same tests, and placed by the same ordering provider, at approximately the same time. It stores the received observation set into this order. If the Order Filler can't match any existing order in its data base, it generates a new order as in use case 5.5.2.

The Order Filler acknowledges the observation set to the POCDM, sending in the acknowledgment message its filler order number.

As part of the LSWF profile, the Order Filler notifies the Order Placer that the results for the POCT order have arrived (status change of the order).

Part 6 of the scenario: Clinical validation

- 420 Later on, the clinical validation of the results is performed. In the LSWF profile, this triggers the sending of these results to the Order Result Tracker, and the notification “order completed” sent to the Order Placer.

5.5.2 Unordered observations with patient identity checking

This use case involves a real-time patient identity checking. It requires a persistent link between the point of care testing device (POCRG) and the point of care data manager (POCDM). The tests are performed before the order is created. The order will be created automatically by the LIS on reception of the POCT observations.

Part 1 of the scenario

430 The operator (physician, nurse,) sets a patient specimen on the point of care device implementing a POCRG actor. The operator initiates the operation, providing its own identification, a patient identifier and all information relevant for testing.

Part 2 of the scenario

Same as Part 3 of use case 5.5.1.

Part 3 of the scenario

The point of care device performs the tests on the specimen, produces the results and displays them to the user. The POCRG sends the observation set with its related data to the POCDM.

440 The POCDM checks the received observations against its own rules (result compared with normal ranges or scale limits, QC results obtained and correct ...), accepts them, stores them, and acknowledges them to the POCRG. The POCRG displays the acknowledgment received from the POCDM. In case the POCDM detected an erroneous or suspicious result, it rejects the results, and sends back a negative acknowledgement to the POCRG.

If the results are accepted they are immediately available to inform the clinical and medical care of the patient.

Part 4 of the scenario: supervision by a clinical laboratory – order generated

Having accepted the POCT observation set, the POCDM forwards them to the Order Filler of the laboratory supervising the point of care testing process. The Order Filler stores the received results into a new filler order generated right away. The Order Filler acknowledges the observation set to the POCDM, sending in the acknowledgment message its assigned filler order number.

450 Being also involved in LSWF profile, the Order Filler obtains a placer order number from the Order Placer, using transaction LAB-2. During this transaction, the Order Placer application creates a placer order for this point of care observation set, and sends back the placer order number assigned.

In the case of an unknown patient, the reconciliation will be the task of the Order Filler application.

Part 5 of the scenario: Clinical validation

Same as Part 6 of use case 5.5.1.

5.5.3 POCRG with intermitent link – supervivion by lab – generate order

460 This variant of scenario 5.5.2, is met with POCT devices intermittently connected to the healthcare enterprise's network. In such a configuration, the tests are performed offline without real-time patient identity checking.

Part 1 of the scenario

The operator (physician, nurse,) sets a patient specimen on the point of care device implementing a POCRG actor. The operator initiates the operation, providing local identification, a patient identifier and all information relevant for testing.

Part 2 of the scenario

The POCRG performs the tests on the specimen, produces the results, qualifies them against its own rules (such as normal ranges) displays them, and stores them in its memory. The results are immediately available to inform the clinical and medical care of the patient..

470 **Part 3 of the scenario**

Later on, when a connection is established with the POCDM, the POCRG sends all the POCT observations accumulated in its memory.

The POCDM receives the observation sets, checks their information, including patient IDs, stores them, and acknowledges them to the POCRG.

The POCRG displays the acknowledgment received from the POCDM.

Part 4 and 5 of the scenario

Same as in scenario 5.5.2

5.5.4 Manual entry of point of care patient observations – generate order

480 Some point of care observations are read and entered manually (e.g. urine sticks). This scenario is met when such POCT observations are entered manually directly on the system implementing the POCDM actor. In this case the central POCT system supports – grouped with the POCDM actor – a POCRG actor dedicated to the manual entry of point of care observations.

Part 1 of the scenario

The nurse identifies herself on the POCRG (grouped with POCDM) and enters the patient ID.

The POCRG (grouped with POCDM) checks this patient ID and displays the patient full identity, and visit information, enabling the operator to verify the patient's identity.

The operator enters the observations on the POCRG. The POCDM controls the observation set against its configuration rules, rejects them or accepts them, and stores them in the latter case.

Part 2 and 3 of the scenario

490 Same as part 4 and 5 of scenarios 5.5.2 and 5.5.3

5.5.5 QC Testing on a POCRG – intermittent or persistent link with POCDM

Part 1 of the scenario

The operator initiates the operation by identifying himself (or herself) to the POCRG, entering (or scanning) the QC specimen ID.

The operator enters additional information required, such as specimen type, reagent lot number, tests to be performed.

Part 2 of the scenario

The POCRG performs the tests on the QC specimen and produces the results.

500 At once if the POCRG has a persistent connection, or when the next connection with POCDM is established, the POCRG sends the set of QC observations to the POCDM.

The POCDM receives the set of observations, verifies it against its configuration rules, stores it, and acknowledges it to the POCRG.

If the QC results fail verification the POCDM and POCRG might hide the results, just displaying “QC failed”, and block further process from this device on patient specimens. The operator performs the corrective action, and starts again the QC test.

5.6 Actors/ Transactions

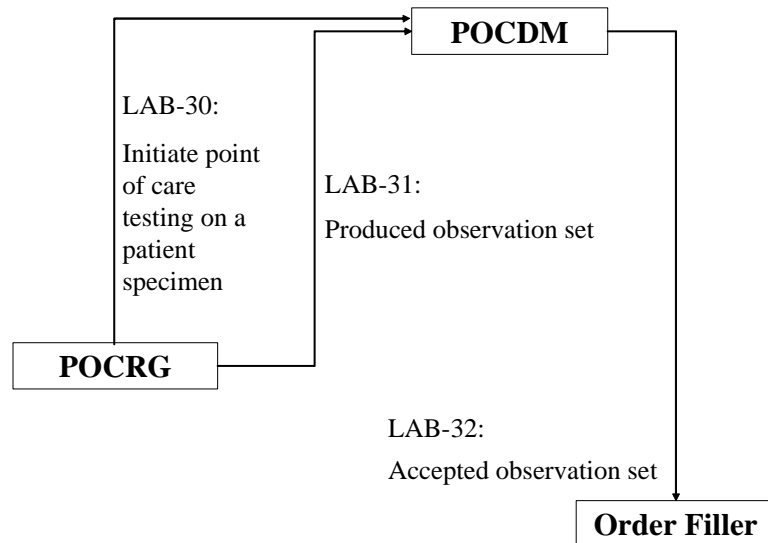


Figure 5.6-1: LPOCT Profile: Actors/Transactions Diagram

510 Figure 5.6-1 shows the actors directly involved in the Laboratory Point Of Care Testing Integration Profile and the relevant transactions between them.

Note 2: As stated in the table 2.3 “Integration Profiles dependencies”, IHE LPOCT profile assumes that the Order Filler is also involved in LSWF profile. It is also assumed that the POCDM actor is provided with up-to-date patient data, using either Patient Administration profile, or Patient Demographics Query Profile from IT Infrastructure Technical Framework.

520 Table 5.6-1 lists the transactions for each actor directly involved in the LPOCT Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume I, Section X.2.

Table 5.6-1. LPOCT Integration Profile - Actors and Transactions

| Actors | Transactions | Optionality | Section in Vol. 2 |
|--------------------------------|--------------------|----------------|-------------------|
| Order Filler | Transaction LAB-32 | R | |
| Point Of Care Data Manager | Transaction LAB-30 | O (see note 3) | |
| | Transaction LAB-31 | R | |
| | Transaction LAB-32 | R | |
| Point Of Care Result Generator | Transaction LAB-30 | O (see note 3) | |
| | Transaction LAB-31 | R | |

Note 3: Transactions LAB-30 is required for POCRG and POCDM supporting the “patient identity checking” option. See section 5.7

530 **LAB-30:** Initiates point of care testing for a patient specimen on a persistently connected POCRG: A POCRG sends to the POCDM a message containing: its own ID, the care unit ID, the ordering provider ID, the operator ID, the patient/visit ID (or QC ID) and other information related to the test to start. The POCDM identifies the operator, and checks the patient identification. It then sends the answer back to the POCRG. The answer may be positive and carry the patient’s identity, or negative and carry the reject reason.

LAB-31: POCT observations produced. The POCRG sends an observation set to the POCDM. The POCDM checks the content of this observation set, stores it and acknowledges it to the POCRG.

LAB-32: POCT observations accepted. The POCDM sends an observation set completed with the patient information, to the Order Filler. The Order Filler acknowledges it. The acknowledgement carries the filler order number attributed to this observation set.

5.7 LPOCT Integration Profile Options

540 Options that may be selected for this Integration Profile are listed in the table 5.7-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 5.7-1 Laboratory Point Of Care Testing - Actors and Options

| Actor | Options | Vol & Section |
|--------------------------------|----------------------------------|--------------------------|
| Order Filler | <i>No options defined</i> | |
| Point Of Care Data Manager | <i>Patient identity checking</i> | Vol 2, x.x.x |
| Point Of Care Result Generator | <i>Patient identity checking</i> | Vol 2, x.x.x |

Patient identity checking:

This option requires a persistent link between the point of care device implementing the POCRG actor and the central point of care data manager implementing the POCDM actor. In this situation, the POCRG and the POCDM use transaction LAB-30 to check the patient's identity, before performing the tests, ensuring that the correct patient/visit ID has been entered (or scanned) on the point of care device.

550 **5.8 LPOCT Integration Profile Process Flow**

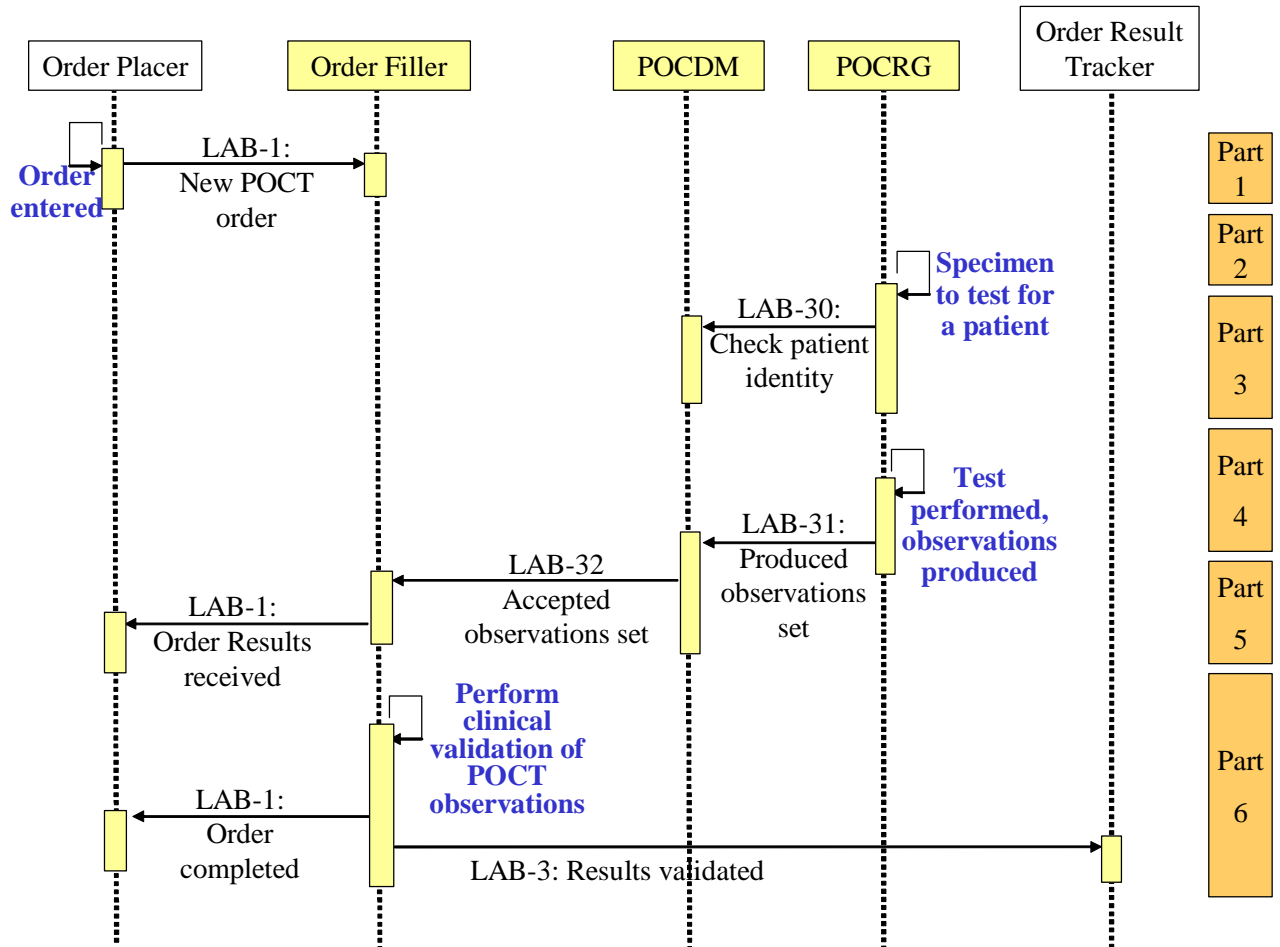
The workflow diagrams shown in this section represent each of the five use cases described in section 5.5.

Comments on the workflow diagrams of this section:

- A transaction in IHE Volume 1 is represented by a single arrow, even if it implies several messages in both directions. The arrow goes from the actor that sends the initial message to the actor that receives it. The time length of the transaction is only expressed by the height of the rectangular box centered on the actor vertical dashed line.
 - The actors involved in LPOCT profile appear in light yellow boxes. The actors involved only in LSWF profile appear in white boxes.
- 560
- The chronological parts of each scenario are represented as vertical rectangular orange boxes on the right border of the figure.
 - The actors Order Filler, POCDM, Order Placer, Order Result Tracker are supposed to be provided with up-to-date patient demographics data. The transactions delivering this patient data are not shown.

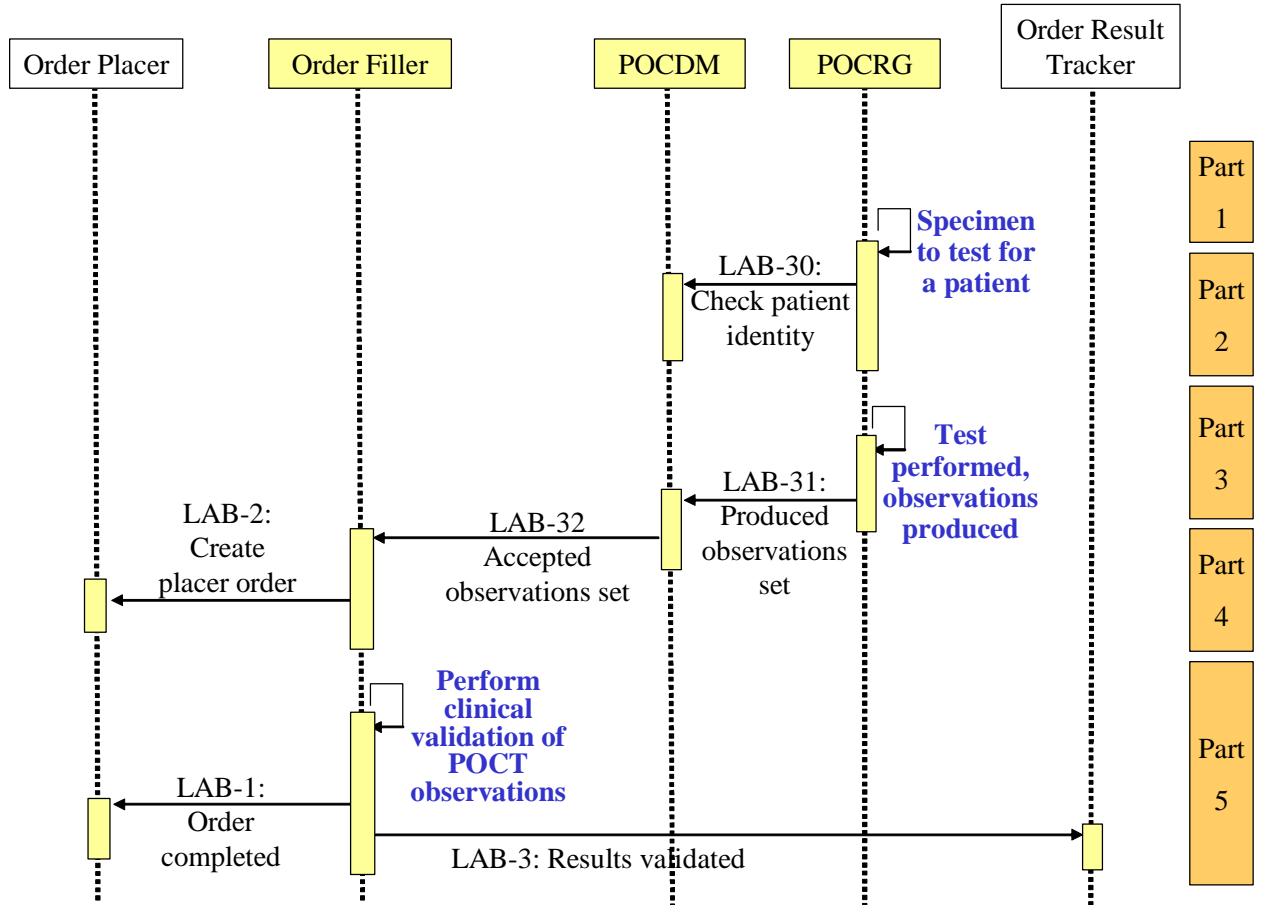
5.8.1 Real-time patient identity checking – supervision by lab – pre-existing order

This workflow diagram represents use case 5.5.1



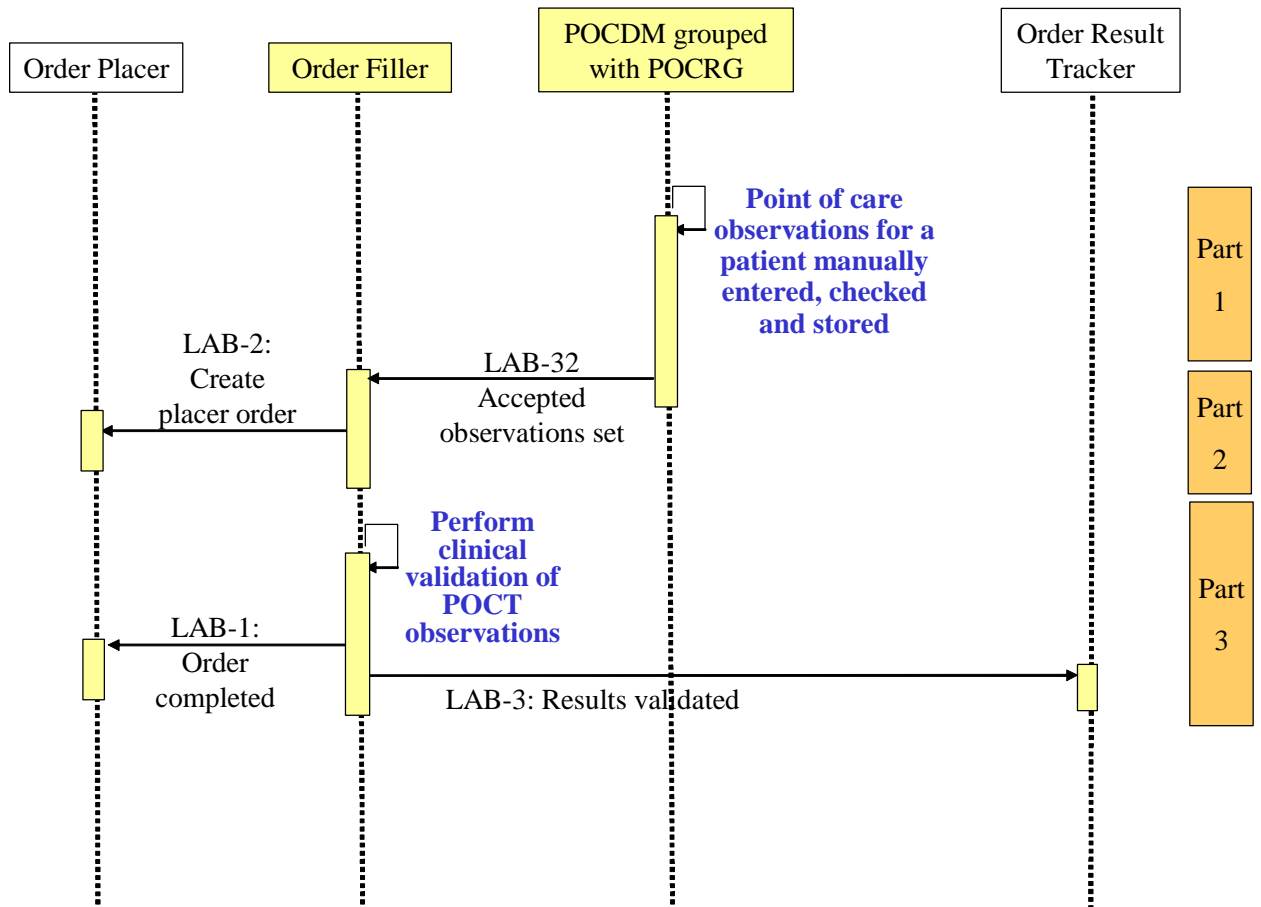
570 **5.8.2 Unordered observations with patient identity checking**

This workflow diagram represents use case 5.5.2



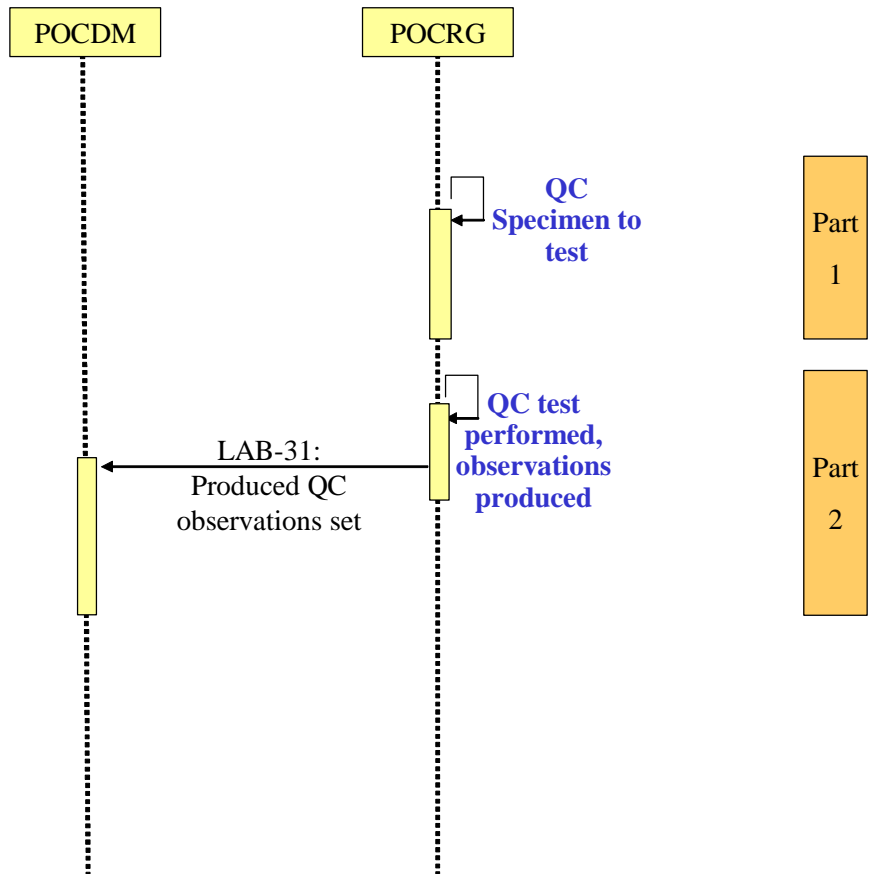
5.8.4 Manual entry of point of care patient observations – order generated

580 . This workflow diagram represents use case 5.5.4.



5.8.5 QC Testing on a POCRG – intermittent or persistent link with POCDM

This workflow diagram represents use case 5.5.5



Volume 2 - Transactions

590 IHE Transactions

1.1 Rationale for the choice of the standards to be used

Replace the entire text of this section with the following text:

For the transactions of integration profiles LSWF, LCSD, LIR, the candidate standards were: HL7 v2.3.1, v2.4, v2.5, v3.

HL7 v3 was not available in 2003 when the first profile LSWF was released. This oriented the choice towards HL7 v2.5 – the only available version of HL7 supporting both specimen and container.

600 In mid-2005, when the new profiles LCSD and LIR are released, the HL7 v3 Laboratory domain is not a balloted standard. Hence these profiles LCSD and LIR use also HL7 v2.5, which is still the most recent available version of HL7.

610 For LPOCT profile there are in 2005 two candidate standards: E1394 from ASTM and POCT1-A from CLSI. The ASTM standard is more oriented towards connections of clinical analyzers to an Automation Manager within the clinical laboratory, whilst the CLSI standard is dedicated to point of care testing, and appears more likely to be implemented in point of care analyzers and data managers by the major manufacturers in this area. Moreover, the standard POCT1-A from CLSI, uses HL7 V2.5 messages between the Point Of Care Data Manager and the Order Filler. By choosing this standard, the IHE Laboratory Committee ascertains that a large number of manufacturers will be able to implement the LPOCT profile, and offers a homogeneous solution of interoperability to laboratory information systems implementing the actor Order Filler, fully based on HL7 v2.5 messages.

For LDA profile there are in 2005 two candidate standards: E1394 from ASTM and HL7 v2.5 with its chapter 13 “Laboratory Automation” that brings some new useful segments. ASTM E1394 is limited to the connection of analyzers, whilst the LDA profile covers the connection of all robotic devices. For this reason HL7 v2.5 is the chosen standard for this profile. Another advantage of this choice is to have a homogeneous solution of interoperability for the system implementing the actor Automation Manager.

620 In 2005, the Laboratory Technical Framework still uses two transactions from the Radiology Technical Framework: "Patient Registration [RAD-1]" and "Patient Update [RAD-12]". These two transactions adopted without change, with their messages using HL7 V2.3.1, are not described in this document, and the reader is referred to the "Radiology Technical Framework Volume 2". However, the transaction "Patient Update [12]" triggers a specific action from the Order Filler that sends a specific message of transaction LAB-4 to the Automation Manager (See chapter 7 of this document). These two transactions RAD-1 and RAD-12 will be replaced in

2006 by a reference to the new IHE IT Infrastructure profile “Patient Administration Management” also based on HL7 v2.5

For backward compatibility with HIS implementing the ADT actor, and supporting only the pipe encoding mechanism, this encoding mechanism is required for the messages described in this volume. The XML encoding of these messages is optional and is usable when peer actors support it.

630

2 CONVENTIONS

Add the following section at the end of this chapter

2.4 Implementation notes for POCT1-A Device Messaging Level (DML)

The transactions LAB-30 and LAB-31 between the actors POCRG and POCDM rely on *Device Messaging Level* interface defined in Appendix B of the standard POCT1-A.. In this *DML* interface the POCRG actor is called the “*Device*” and the POCDM actor is called “*Observation Reviewer*”.

All messages of DML are encoded in XML (eXtended Markup Language). The syntax of each of these messages is defined by a DTD (Document Type Definition).

640 The *Device* communicates with the *Observation Reviewer* through an *Access Point*, which can be part of a *Device* persistently connected to the network, or be a subsystem that consolidates data from one or more *Devices* onto an established communication link with the *Observation Reviewer* (POCDM).

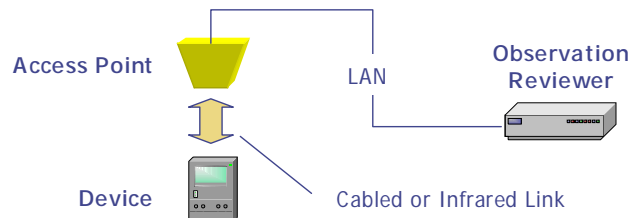


Figure excerpt from POCT1-A

This IHE LPOCT profile does not describe the protocol between the *Device* and the *Access Point*, and recommends that manufacturers refer to and adopt the standard POCT1-A specification for this layer.

650 This IHE LPOCT profile describes the use of the DML, which is the top layer of the interface between the *Device* (POCRG actor) and the *Observation Reviewer* (POCDM actor). The lower layer protocols are not described in this IHE profile. IHE recommends the use of the MLLP transport protocol between the Device Access Point and the POCDM, as this protocol is used by all profiles of IHE Laboratory Technical Framework.

2.4.1 IHE usages for DML

This IHE profile defines a usage for the objects and components of the DML interface. The conventions of this usage are the same as those defined for HL7 messages (see the IHE Technical Framework):

660

| | |
|-----|--|
| R: | Required. The sender shall populate it. |
| RE: | Required if available. The sender shall populate this component if it has relevant information for it. |
| C: | Conditional. The usage of this component depends upon a condition predicate defined in this profile. |
| O: | Optional. The usage of this component is not specified by this IHE profile. |
| X: | Not supported. This component is not supported by this IHE profile. |

2.4.2 Conversations and topics

Appendix B of POCT1-A defines two terms:

670

Conversation: A prescribed flow of messages between the Device and Observation Reviewer, having both an initialization and a termination phase. A Conversation is made up of a series of ‘Topics.’

Topic: The flow of messages to exchange a complete set of data within a Conversation (e.g., Observations, Device Events). A Topic is composed of a series of ‘Messages.’

This IHE LPOCT Profile describes only the Topic **Observations** which is used by Transactions LAB-30 and LAB-31. It is assumed that the systems implementing a POCRG actor or a POCDM actor support the other Topics listed below, according to the standard POCT1-A.

For a better understanding, an overview of the Topic **Hello** is also given in this section.

680

This IHE Profile LPOCT does not describe the lower layer protocols (transport, device access point) to be used between POCRG and POCDM actors. It assumes that the implementers follow the recommendations of the standard POCT1-A for the transport protocol.

2.4.2.1 POCT1-A “basic profile” for transaction LAB-31

To support Transaction LAB-31 of LPOCT Integration profile, a *Device* (POCRG actor) and an *Observation Reviewer* (POCDM actor) must support at least the “*Basic Profile*”, as defined in Appendix B section 4.1 of POCT1-A.. This “*Basic Profile*” specifies a minimum set of “*Topics*” that Devices and Observation Reviewers must support. These Topics are:

- Hello
- Device Status
- 690 • Observations
- Terminate

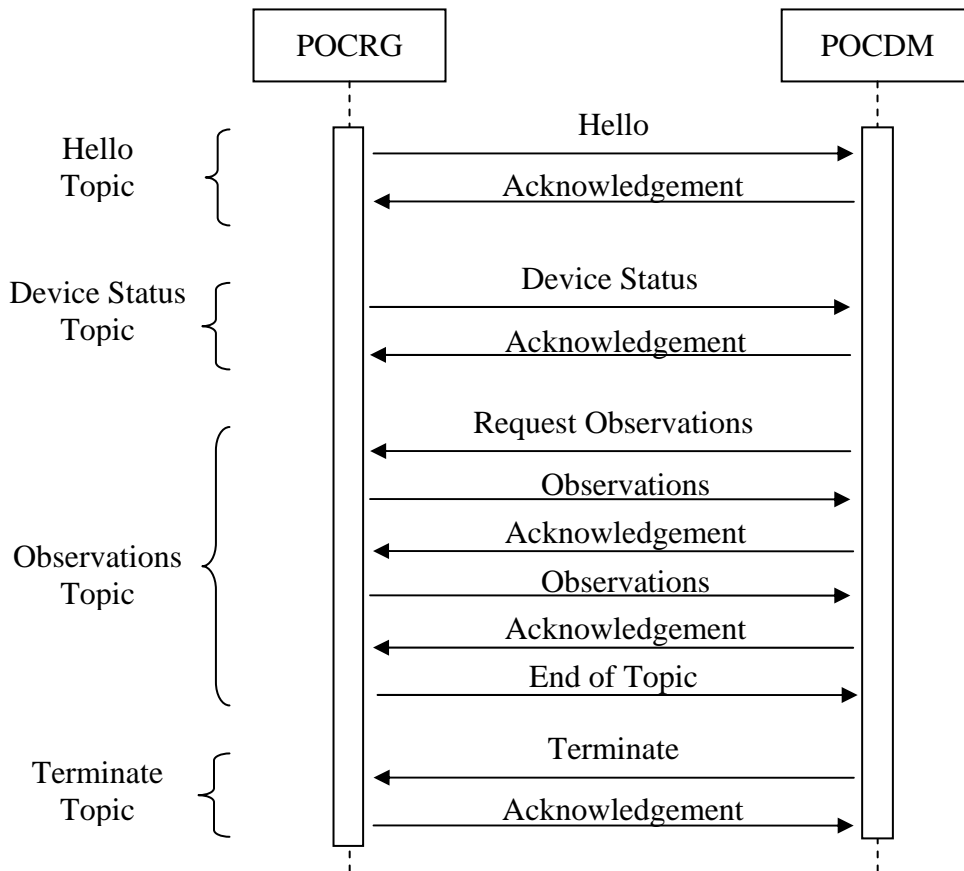


Figure 25. Error-Free Basic Profile Flow, POCT1-A – Appendix B

The “Terminate” topic can also be performed in reverse, with the POCRG sending a Terminate message and the POCDM acknowledging it. This termination can occur at any time. See section 4.1.11 of POCT1-A, Annex B.

2.4.2.2 Continuous Mode to support Transactions LAB-30 and LAB-31

700 To support the “Patient Identity Checking” option of this Profile (i.e. the transaction LAB-30 between POCRG and POCDM) the *Device* (POCRG) and the *Observation Reviewer* (POCDM) must support the “*Continuous Mode*”, as defined in Appendix B section 4.2 of POCT1-A.. This *Continuous Mode* requires that Devices and Observation Reviewers support a more complete set of *Topics*:

- Hello
- Device Status
- Directives (with at least START_CONTINUOUS Directive)
- Observations
- Keep Alive
- Termination

710

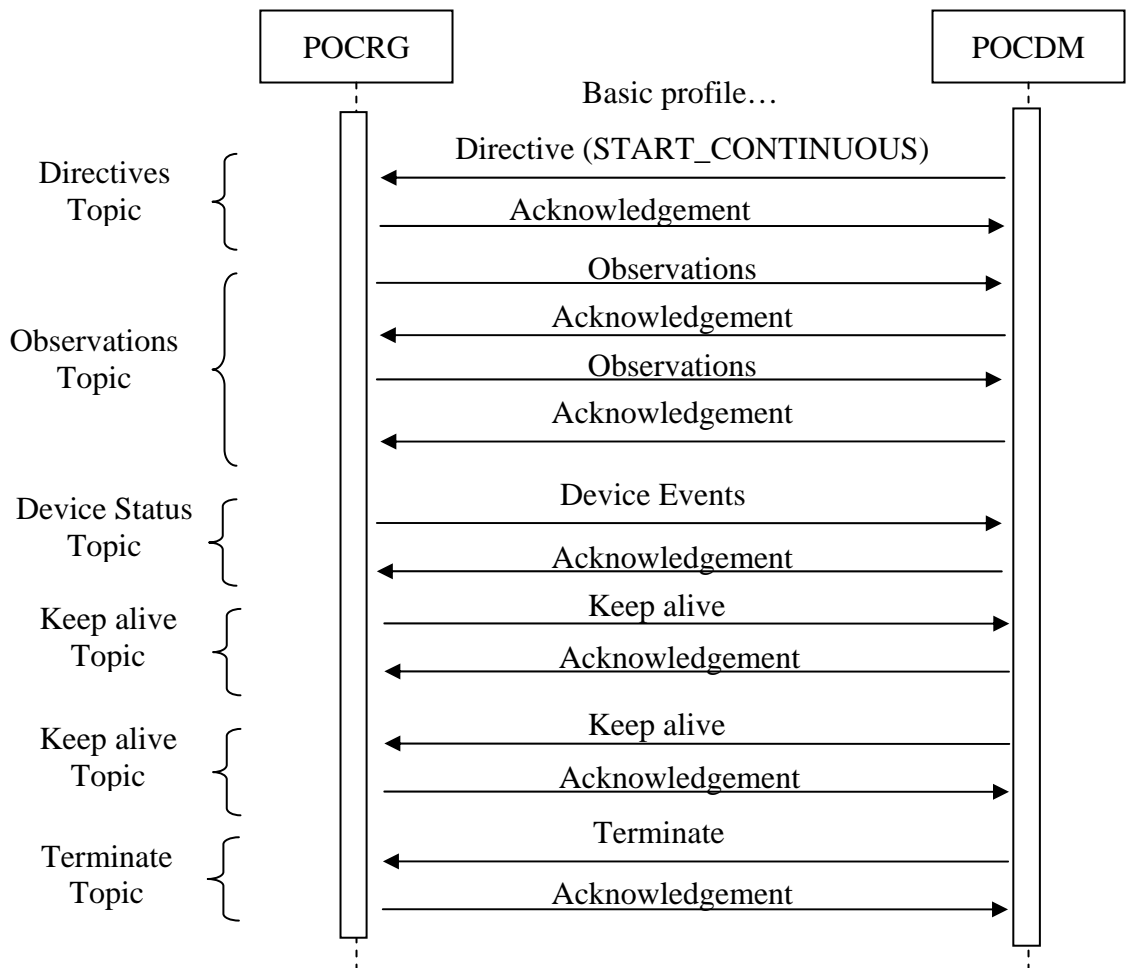


Figure 30. Ideal Continuous Mode Message Flow, POCT1-A – Appendix B

2.4.3 Characteristics of DML messages

2.4.3.1 Notation

DML messages are encoded in XML. As any XML document, a DML message is a hierarchic tree. The POCT1-A standard uses the following representation for this hierarchic structure:

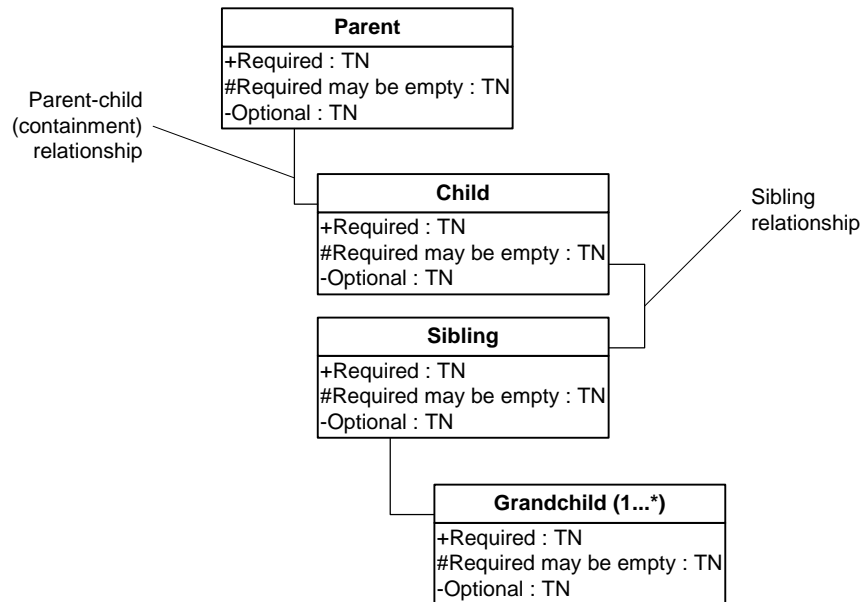


Figure 32. Message Model Example, excerpt from POCT1-A – appendix B

720

Each element is represented as an object. Object cardinality is noted as part of the object name:

- (0...1) – zero or one instance
- (0...*) – zero or more instances
- (1...*) – one or more instances
- The absence of a cardinality notation indicates one, and only one, instance.

The component of the object are sub-elements of the XML element.

- sub-elements prepended with '+' are Required
- sub-elements prepended with a '-' are Optional
- sub-elements prepended with '#' are Required if available (may be empty if there is no relevant data (which corresponds to the HL7/IHE "RE" usage code).

730

2.4.3.2 Use of the Header object in DML messages

Every message of the DML starts with a mandatory Header object encoded with the XML **<HDR>** element. This IHE profile defines the following usage for this object:

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------|-----------|-----------|-------------------|---|
| message_type | CV | X | [0..0] | A code made up of the message name and trigger value. Examples: "OBS.R01", "ACK.R01". This field is redundant with the root element of the message. It is not supported by IHE. |
| control_id | ST | R | [1..1] | A string guaranteed to uniquely identify this message instance throughout the conversation |
| version_id | ST | R | [1..1] | Set to "POCT1" for all messages that adhere to this standard |
| creation_dttm | TS | R | [1..1] | The sender's time when the message was sent. |
| encoding_chars | ST | X | [0..0] | Not used by IHE |

Example of the beginning of a message of the Hello Topic:

```
<HEL.R01>
  <HDR>
    <HDR.control_id V="10001"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2001-11-01T16:30:00-08:00"/>
  </HDR>
  ...
```

740

2.4.3.3 Hello Topic in DML

The Hello Topic contains two messages: The Hello message sent by the *Device* (POCRG) and the acknowledgement message sent by the *Observation Reviewer* (POCDM).

A Device sends the Hello message only once as the first message in a Conversation. This message identifies the *Device*, its capabilities, its status, and the *Access Point* with its unique network address and port number.

750

- The root element of this message is **<HEL.R01>**
- The header element of this message, is like in any message **<HDR>**
- The element representing the *Device* (POCRG) is **<DEV>**
- The element representing the *Device* capabilities is **<DCP>**
- The element representing the *Device* static capabilities is **<DSP>**
- The element representing the *Access Point* is **<AP>**

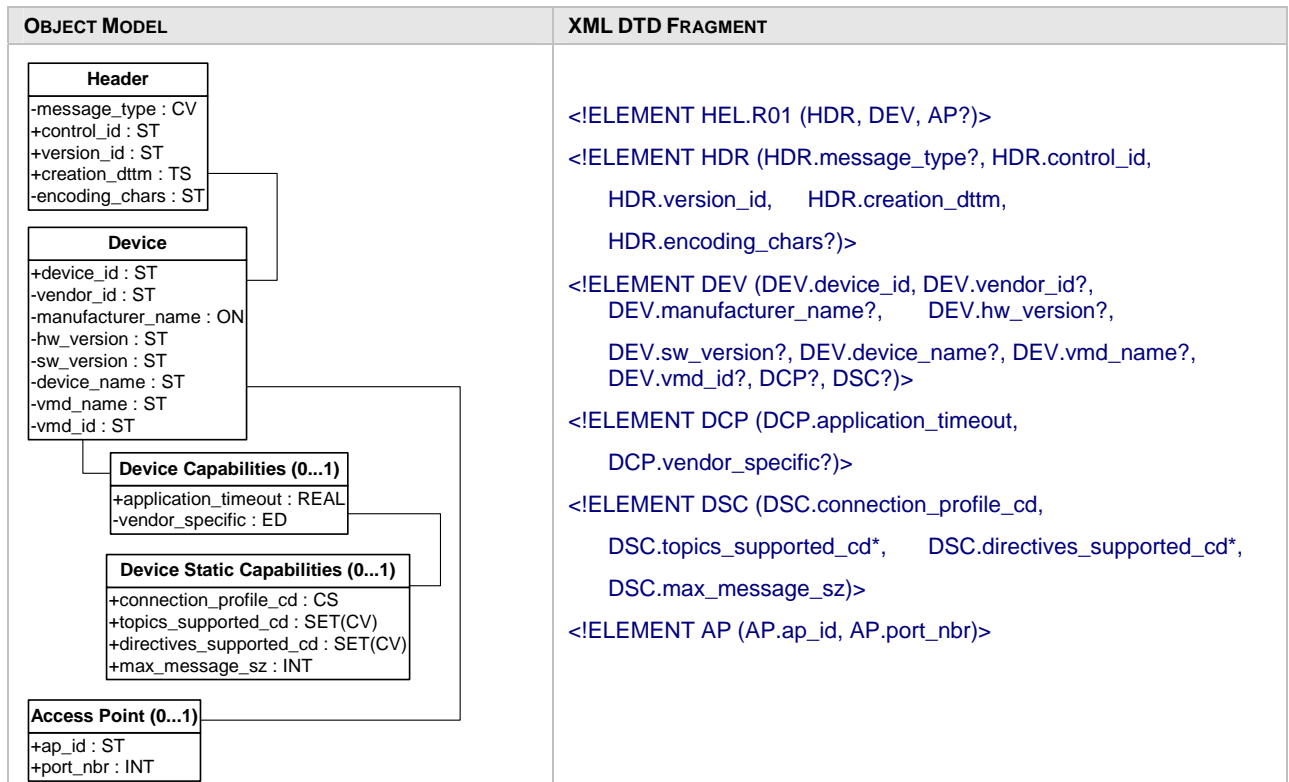


Figure 42. Hello Message Model, excerpt from POCT1-A – appendix B

Example of Hello message taken from POCT1-A – appendix B:

```

760 <HEL.R01>
      <HDR>
        <HDR.control_id V="10001"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2001-11-01T16:30:00-08:00"/>
      </HDR>
      <DEV>
        <DEV.device_id V="0A-00-19-00-00-00-23-84"/>
        <DEV.vendor_id V="BCHMX"/>
        <DEV.model_id V="8000A"/>
770 <DEV.serial_id V="42367C"/>
        <DEV.manufacturer_name V="Biochemtronix"/>
        <DEV.hw_version V="8000A-C"/>
        <DEV.sw_version V="2001-10-04"/>
        <DEV.device_name V="ICU-4 Glucose"/>
        <DCP>
          <DCP.application_timeout V="60"/>
        </DCP>
        <DSC>
780 <DSC.connection_profile_cd V="SA"/>
          <DSC.topics_supported_cd V="DTV"/>
          <DSC.topics_supported_cd V="OP_LST"/>
          <DSC.directives_supported_cd V="SET_TIME"/>
          <DSC.directives_supported_cd V="LOCK"/>
          <DSC.directives_supported_cd V="UNLOCK"/>
          <DSC.max_message_sz V="800"/>
        </DSC>
      </DEV>
    
```

790

```
<AP>
  <AP.ap_id V="00-10-9D-FF-FF-23-45-67"/>
  <AP.port_nbr V="0"/>
</AP>
</HEL.R01>
```

2.4.5 Key data types in DML for the IHE LPOCT profile

2.4.5.1 PN – Person name

The PN data type is used to communicate the elements of a person’s name. This data type may carry:

- One single attribute “V” that contains a formatted for display version of the name.
- Any of the child elements described below.

| ELEMENT | USE |
|---------|---|
| GIV | The given name component |
| MID | The middle name component |
| FAM | The family name component |
| PFX | A prefix component (e.g., “Dr.”) |
| SFX | A suffix component (e.g., “Ph.D”) |
| DEL | A delimiter character used to separate components |

800

Example: The following XML fragment illustrates how the **OPR.name** field can be used to encode the operator “Dr. John Ebert.”

```
<OPR.name V="Dr. John Ebert">
  <FAM V="Ebert"/>
  <GIV V="John"/>
  <PFX V="Dr."/>
  <SFX V="MD"/>
</OPR.name>
```

2.4.5.2 PQ – Physical Quantity

810

The PQ data type is used to communicate a measured value, with the units of measure. The attributes this data type may use are described in the following table. Either the ‘V’ and the ‘U’ attributes or the ‘NULL’ attribute must be specified.

Table 72. PQ Data Type Attributes

| FIELD | REQUIRED | USE |
|-------|----------|---|
| V | No | Contains the string representation of the value (1) |
| U | No | Indicates the units of measure for the value (2) |
| NULL | No | Indicates one of the values from Table 70 |

(1) Trailing zeros may be used in the ‘V’ attribute to indicate precision.

(2) The HL7 “ISO+” units code set, defined in a section of the HL7 v2.5 specification, comprises the default values for the PQ units attribute. This specification defines an abbreviation for a single case unit (ISO 2955-83) plus extensions, which do not collide with ISO abbreviations.

820 The following XML fragment illustrates how a device could communicate a pCO₂ value of 71.1 mmHg.

```
<OBS.value V="71.1" U="mmHg"/>
```

The following XML fragment illustrates the communication of a patient’s height value of 1.85 m

```
<PT.height V="1.85" U="m"/>
```

2.4.5.3 TS – Point in time

This data type is used to communicate a point in time. This data type may use one and only one of these two alternative attributes:

‘V’: String representation of a point in time:

830 YYYY-MM-DDTHH:MM:SS.SSxOH:OM

Where:

YYYY = four-digit year;

MM = two-digit month of the year;

DD = two-digit day of the month;

HH = 24-hour representation of the hour;

MM = minute;

SS.SS = second (optional decimal digits may follow the ‘.’ separator);

x = ‘+’ if time is GMT *plus* offset; ‘-’ if time is GMT *minus* offset;

OH = hours offset from GMT; and

840 OM = minutes offset from GMT.

‘NULL’: One of the values from Table 70:

Example: The following XML fragment illustrates how a device could communicate that an observation was made on June 1, 2005 at 5:09:10 PM, in the time zone of Tokyo that is nine hours prior to GMT:

```
<SVC.observation_dttm V="2005-06-01T17:09:10+09:00"/>
```

2.4.5.3 Table 70: Null Code Values

| VALUE | USE |
|-------|-------------------|
| NI | No Information |
| NA | Not Applicable |
| UNK | Unknown |
| NASK | Not Asked |
| ASKU | Asked But Unknown |
| NAV | Not Available |
| OTH | Other |
| PINF | Positive Infinity |
| NINF | Negative Infinity |

850 **30 Transaction LAB-30: Initiate POCT on a patient specimen**

This section describes Transaction LAB-30 of the IHE Technical Framework, used in the LPOCT profile, between the POCRG and POCDM actors.

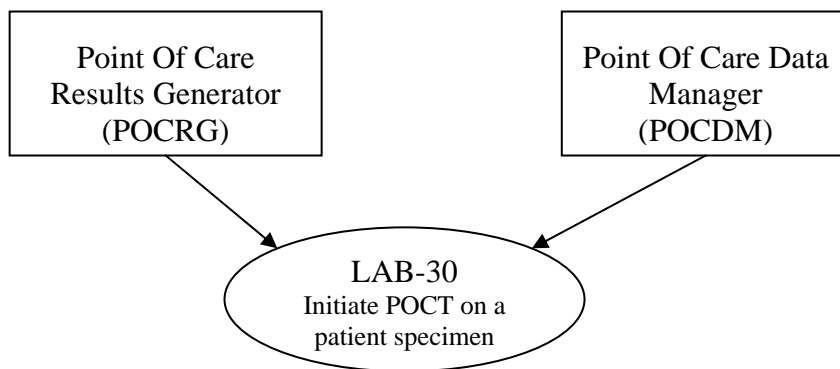
30.1 Scope

This transaction is used within LPOCT profile with the option “Patient Identity Checking”: The POCRG and POCDM actors are assumed to have a persistent link between them.

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.

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

30. 2 Use Case Roles



Actor: POCRG

870 **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 unauthorized on this device”)

30.3 Referenced Standard

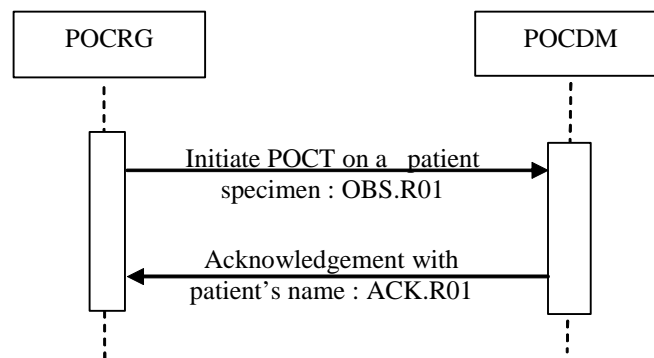
POCT1-A : Device Message Layer (DML) defined in Appendix B of POCT1-A standard.

880

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

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 PCRGM has a persistent link with the POCDM, which is the prerequisite for using transaction LAB-30.

30.4 Interaction Diagram



30.4.1 Patient identity checking

890

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 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 PCRGM, 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 a “*Observations*” *Topic* within the *Continuous Mode* of POCT1-A Device Messaging Level.

30.5 Trigger Events

900

An operator (caregiver or patient) sets a patient specimen on the point of care device (the PCRGM 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".

30.6 Message Semantics

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

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

| OBJECT MODEL | XML DTD FRAGMENT |
|---|--|
| <p>OBS.R01 Patient-related Observations</p> <p>Header</p> <ul style="list-style-type: none"> -message_type : CV +control_id : ST +version_id: ST +creation_dttm: TS -encoding_chars: ST <p>Service</p> <ul style="list-style-type: none"> +role_cd : CS +observation_dttm: TS -status_cd: CS -reason_cd: CS -sequence_nbr: INT <p>Patient</p> <ul style="list-style-type: none"> +patient_id : ST -location_dttm: ST -name: PN -birth_date: TS -gender_cd: CS -weight: PQ -height: PQ <p>Operator [0..1]</p> <ul style="list-style-type: none"> +operator_id : ST -name: PN <p>Order [0..1]</p> <ul style="list-style-type: none"> +universal_service_id : CE -ordering_provider_id: ST -order_id: CV <p>Specimen [0..1]</p> <ul style="list-style-type: none"> +specimen_dttm : TS -specimen_id: CV -source_cd: CE -type_cd: CE | <pre> <!ELEMENT OBS.R01 (HDR, SVC+)> <!ELEMENT HDR (HDR.message_type?, HDR.control_id, HDR.version_id, HDR.creation_dttm, HDR.encoding_chars?)> <!ELEMENT SVC (SVC.role_cd, SVC.observation_dttm, SVC.status_cd?, SVC.reason_cd?, SVC.sequence_nbr ?, PT, OPR?, ORD?, SPC?)> <!ELEMENT PT (PT.patient_id, PT.location?, PT.name?, PT.birth_date?, PT.gender_cd ?, PT.weight?, PT.height?)> <!ELEMENT OPR (OPR.operator_id, OPR.name?)> <!ELEMENT ORD (ORD.universal_service_id, ORD.ordering_provider_id?, ORD_order_id?)> <!ELEMENT SPC (SPC.specimen_dttm, SPC.specimen_id?, SPC.source_cd?, SPC.type_cd?)> </pre> |

30.6.1.1 Use of the Service 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 |
|------------------|-----------|-----------|-------------------|---|
| role_cd | CS | R | [1..1] | Value "OBS": Patient test observation |
| observation_dttm | TS | R | [1..1] | Starting date/time of the test |
| status_cd | ST | R | [1..1] | Value "INI": The point of care test is about to start. No observation produced yet. |
| reason_cd | ST | X | [0..0] | This code is not used in the context of LAB-30. |
| sequence_nbr | ST | X | [0..0] | This number is not used in the context of LAB-30. |

910

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.

30.6.1.2 Use of the Patient 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 |
|------------|-----------|-----------|-------------------|--|
| patient_id | ST | R | [1..1] | A unique identifier for the patient, supposed to be known from the POCDM actor |
| location | ST | RE | [0..1] | Location of the patient |
| name | PN | X | [0..0] | Patient name. Not used in the context of LAB-30. |
| birth_date | TS | X | [0..0] | Patient date of birth. Not used in the context of LAB-30. |
| gender_cd | CS | X | [0..0] | Patient gender. Not used in the context of LAB-30. |
| weight | PQ | X | [0..0] | Patient weight. Not used in the context of LAB-30. |
| height | PQ | X | [0..0] | Patient height. Not used in the context of LAB-30. |

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 | [1..1] | A unique identifier for the operator |

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------|-----------|-----------|-------------------|--|
| name | PN | RE | [0..1] | Operator's name. Required if available on the POCRG. |

30.6.1.4 Use of the Order 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 |
|----------------------|-----------|-----------|-------------------|---|
| universal_service_id | CE | R | [1..1] | 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 | [0..1] | An identifier that uniquely identifies the provider who ordered this service. |
| order_id | CV | O | [0..1] | An identifier that uniquely identifies this service instance. This field may contain an order id, accession number, or other such identifier. |

920 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 | [1..1] | Time the specimen was drawn. |
| specimen_id | CV | O | [0..1] | Code identifying the specimen |
| source_cd | CE | O | [0..1] | Location of the specimen. Coded in table 51 of POCT1-A |
| type_cd | CE | O | [0..1] | Type of the specimen. Coded in table 52 of POCT1-A |

30.6.1.6 Example message OBS.R01: Initiate POCT on a patient specimen

```
<OBS.R01>
  <HDR>
    <HDR.control_id V="12345"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2005-05-16T16:30:00+01:00"/>
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS"/>
    <SVC.observation_dttm V="2005-05-16T16:30:00+01:00"/>
    <SVC.status_cd V="INI"/>
    <PT>
      <PT.patient_id V="888888"/>
    </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>
  </SVC>
</OBS.R01>
```

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.

30.6.2 Acknowledgement with patient name – Message ACK.R01

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

| OBJECT MODEL | XML DTD FRAGMENT | | | | | | | | | | | |
|---|------------------|--------------------|------------------|------------------|---------------------|----------------------|-----------------|---------------|----------------------|----------------|-----------------------|--|
| <table border="1"> <thead> <tr> <th>Header</th> </tr> </thead> <tbody> <tr> <td>-message_type : CV</td> </tr> <tr> <td>+control_id : ST</td> </tr> <tr> <td>+version_id : ST</td> </tr> <tr> <td>+creation_dttm : TS</td> </tr> <tr> <td>-encoding_chars : ST</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Acknowledgement</th> </tr> </thead> <tbody> <tr> <td>+type_cd : CS</td> </tr> <tr> <td>+ack_control_id : ST</td> </tr> <tr> <td>-note_txt : ST</td> </tr> <tr> <td>-error_detail_cd : CV</td> </tr> </tbody> </table> | 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 | <pre><ELEMENT ACK.R01 (HDR, ACK)> <ELEMENT HDR (HDR.message_type?, HDR.control_id, HDR.version_id, HDR.creation_dttm, HDR.encoding_chars?)> <ELEMENT ACK (ACK.type_cd, ACK.ack_control_id, ACK.note_txt?, ACK.error_detail_cd?)></pre> |
| 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 | | | | | | | | | | | | |

930 **30.6.2.1 Use of the Header object**

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|---------------|-----------|-----------|-------------------|---|
| message_type | CV | X | [0..0] | Not used: Redundant with the root element of the message |
| control_id | ST | R | [1..1] | unique identifier of the instance of this acknowledgement message |
| version_id | ST | R | [1..1] | “POCT1” |
| creation_dttm | TS | C | [0..1] | date/time of creation of this acknowledgement |

30.6.2.2 Use of the Acknowledgement object

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------------|-----------|-----------|-------------------|---|
| type_cd | CS | R | [1..1] | AA: Application Accept AE: Application Error |
| ack_control_id | ST | R | [1..1] | The unique identifier of the acknowledged message |
| note_txt | ST | R | [1..1] | 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 | [1..1] | A code detailing the error. Described in Table 14 of Annex B of POCT1-A. |

Condition predicate for the field **note_txt**:

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.

Example of positive acknowledgement for patient Jeanne DUPONT:

940

```

<ACK.R01>
  <HDR>
    < HDR.control_id V="45678"/>
    < HDR.version_id V="POCT1"/>
    < HDR.creation_dttm V="2005-05-16T16:30:00"/>
  </HDR>
  <ACK>
    < ACK.type_cd V="AA"/>
    < ACK.ack_control_id V="12345"/>
    < ACK.note_txt V=" DUPONT Jeanne "/>
    < ACK.error_detail_cd V="0"/>
  </ACK>
</ACK.R01>

```

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:

```

<ACK.R01>
  <HDR>
    < HDR.control_id V="45679"/>
    < HDR.version_id V="POCT1"/>
    < HDR.creation_dttm V="2005-05-16T16:30:00"/>
  </HDR>
  <ACK>
    < ACK.type_cd V="AE"/>
    < ACK.ack_control_id V="12345"/>
    < ACK.note_txt V=" Unknown patient identifier 888888"/>
    < ACK.error_detail_cd V="202"/>
  </ACK>
</ACK.R01>

```

30.7 Expected Actions

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.

950 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.

31 Transaction LAB-31: Produced observation set

This section describes Transaction LAB-31 of the IHE Technical Framework, used in the LPOCT profile, between the POCRG and POCDM actors.

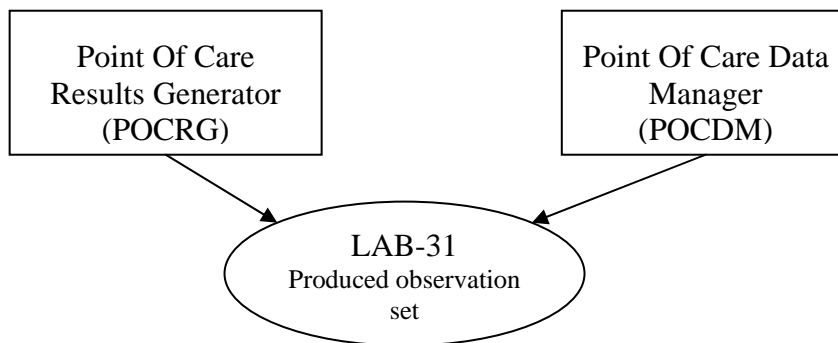
31.1 Scope

This transaction is required within LPOCT profile.

960 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.

31.2 Use Case Roles



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

970 **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.

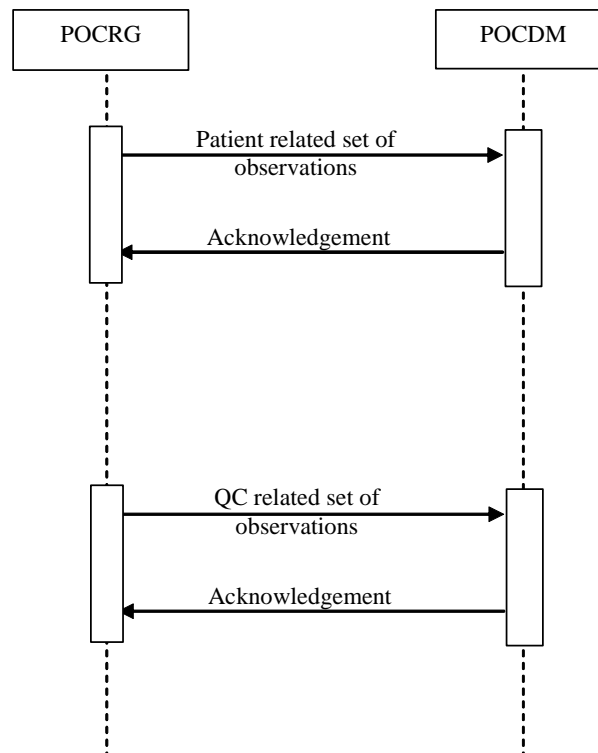
31.3 Referenced Standard

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

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.

31.4 Interaction Diagram



980

31.4.1 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.

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

31.5 Trigger Events

- The “Patient related set of observations” message is triggered by any new patient observations obtained on the POCRG actor.
- 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.

990

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:

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

1000 **31.6 Message Semantics**

<detailed description of the meaning of the transaction including any IHE specific clarifications of the message format, attributes, etc.>

31.6.1 Message OBS.R01: Patient-related set of observations

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

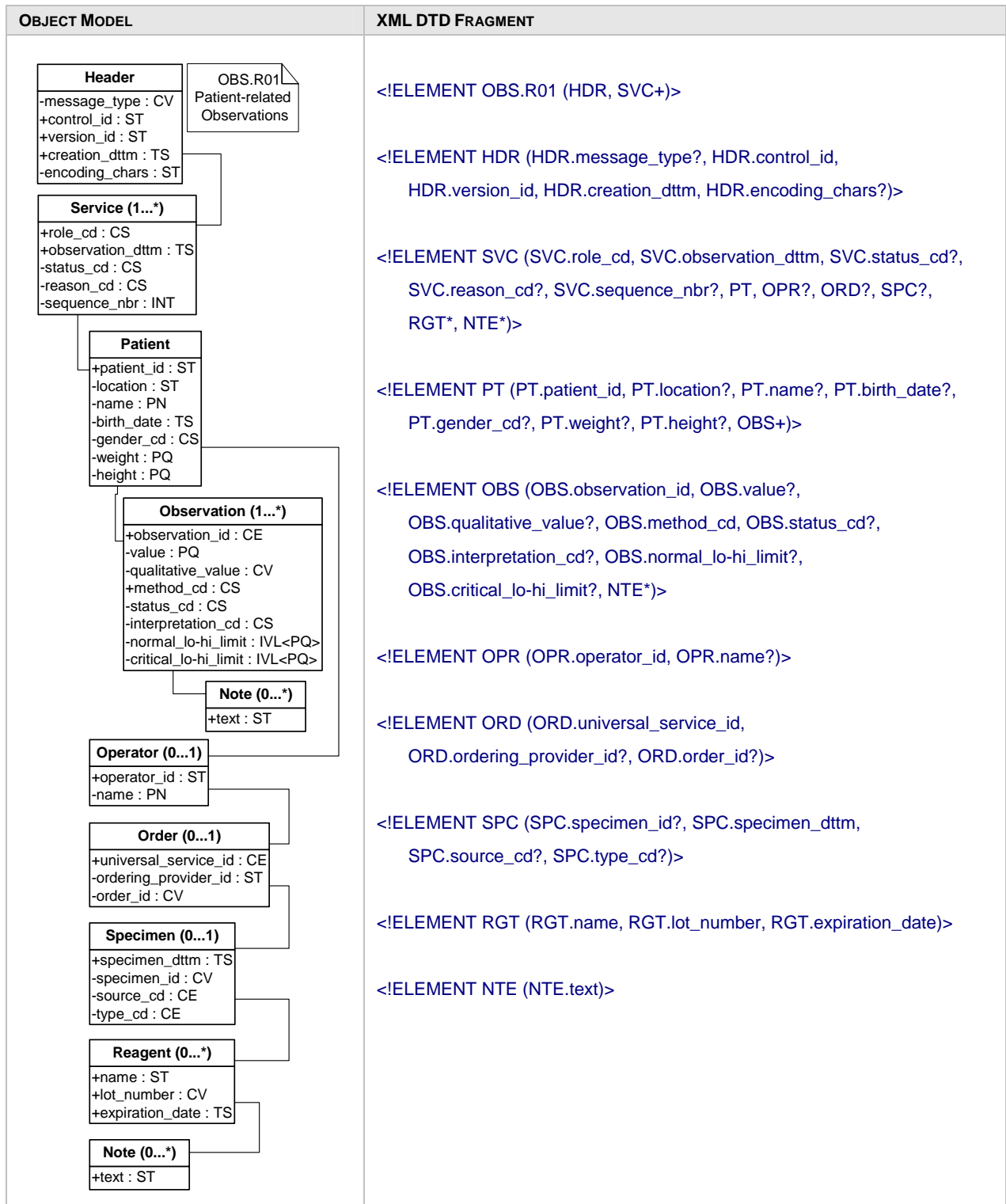


Figure 44. Patient-related Observation Message Model, POCT1-A – Appendix B

31.6.1.1 Use of the Service object

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|------------------|-----------|-----------|-------------------|---|
| role_cd | CS | R | [1..1] | Value “OBS”: Patient test observation |
| observation_dttm | TS | R | [1..1] | production date/time of this set of observations |
| status_cd | ST | R | [1..1] | One of the values listed in table 48 of POCT1-A, Annex B |
| reason_cd | ST | R | [1..1] | One of the values listed in table 49 of POCT1-A, Annex B |
| sequence_nbr | ST | O | [0..1] | 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’). |

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. |

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

| Code | Meaning | Description |
|------|---------|--|
| NEW | New | <u>Default.</u> 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 |

31.6.1.2 Use of the Patient object

1010 One and only one occurrence of Patient per Service:

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|------------|-----------|-----------|-------------------|--|
| patient_id | ST | R | [1..1] | A unique identifier for the patient, supposed to be known from the POCDM actor |
| location | ST | RE | [0..1] | Location of the patient. Required if known. |
| name | PN | RE | [0..1] | Patient name. Required if known. |
| birth_date | TS | RE | [0..1] | Patient date of birth. Required if known. |
| gender_cd | CS | RE | [0..1] | Patient gender. Required if known. |
| weight | PQ | C | [0..1] | Patient weight. Required if known and relevant for the test. |
| height | PQ | C | [0..1] | Patient height. Required if known and relevant for the test. |

31.6.1.3 Use of the Observation object

One or more occurrences of Observation per Patient:

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------------|-----------|-----------|-------------------|--|
| observation_id | CE | R | [1..1] | The test identifier, preferably coded with LOINC |
| value | PQ | C | [0..1] | The observation result, if expressed quantitatively (i.e. a numerical value with units). |
| qualitative_value | CV | C | [0..1] | 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 | [1..1] | 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 | [1..1] | Status of the result. Coded in table 37 of POCT1-A, Annex B. This IHE LPOCT profile authorizes only this value for patient-related results: A = Accepted |
| interpretation_cd | CS | C | [0..1] | Interpretation of the result (abnormal flags). Coded in table 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> | R | [1..1] | The low and high limit range for a normal result |
| critical_lo-hi_limit | IVL<PQ> | R | [1..1] | The low and high limit range outside which clinical review is required |

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.

31.6.1.4 Use of the Note object related to the Observation object

1020

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 | [1..1] | Comment of the observation |

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 | [1..1] | A unique identifier for the operator |
| name | PN | RE | [0..1] | Operator's name. Required if available on the POCRG. |

31.6.1.6 Use of the Order object

One and only one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------------|-----------|-----------|-------------------|---|
| universal_service_id | CE | R | [1..1] | 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 | [0..1] | An identifier that uniquely identifies the provider who ordered this service. |
| order_id | CV | O | [0..1] | An identifier that uniquely identifies this service instance. This field may contain an order id, accession number, or other such identifier. |

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 | [1..1] | Time the specimen was drawn. |
| specimen_id | CV | O | [0..1] | Code identifying the specimen |
| source_cd | CE | O | [0..1] | Location of the specimen. Coded in table 51 of POCT1-A, Annex B |
| type_cd | CE | R | [1..1] | Type of the specimen. Coded in table 52 of POCT1-A, Annex B |

31.6.1.8 Use of the Reagent object

Zero or one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------------|-----------|-----------|-------------------|--|
| name | ST | RE | [0..1] | The manufacturer's name for the reagent |
| lot_number | CV | R | [1..1] | The lot number of reagent used |
| expiration_date | TS | RE | [0..1] | The date past which the reagent should not be used |

31.6.1.9 Use of the Note object

1030

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 | [1..1] | Comment of the observation |

31.6.1.10 Example message of patient observations

```
<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"/>
  <PT>
    <PT.patient_id V="888888"/>
    <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>
<!-- See the end of the message on next page -->
```

```

<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>

```

31.6.2 Message OBS.R02: QC related set of observations

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

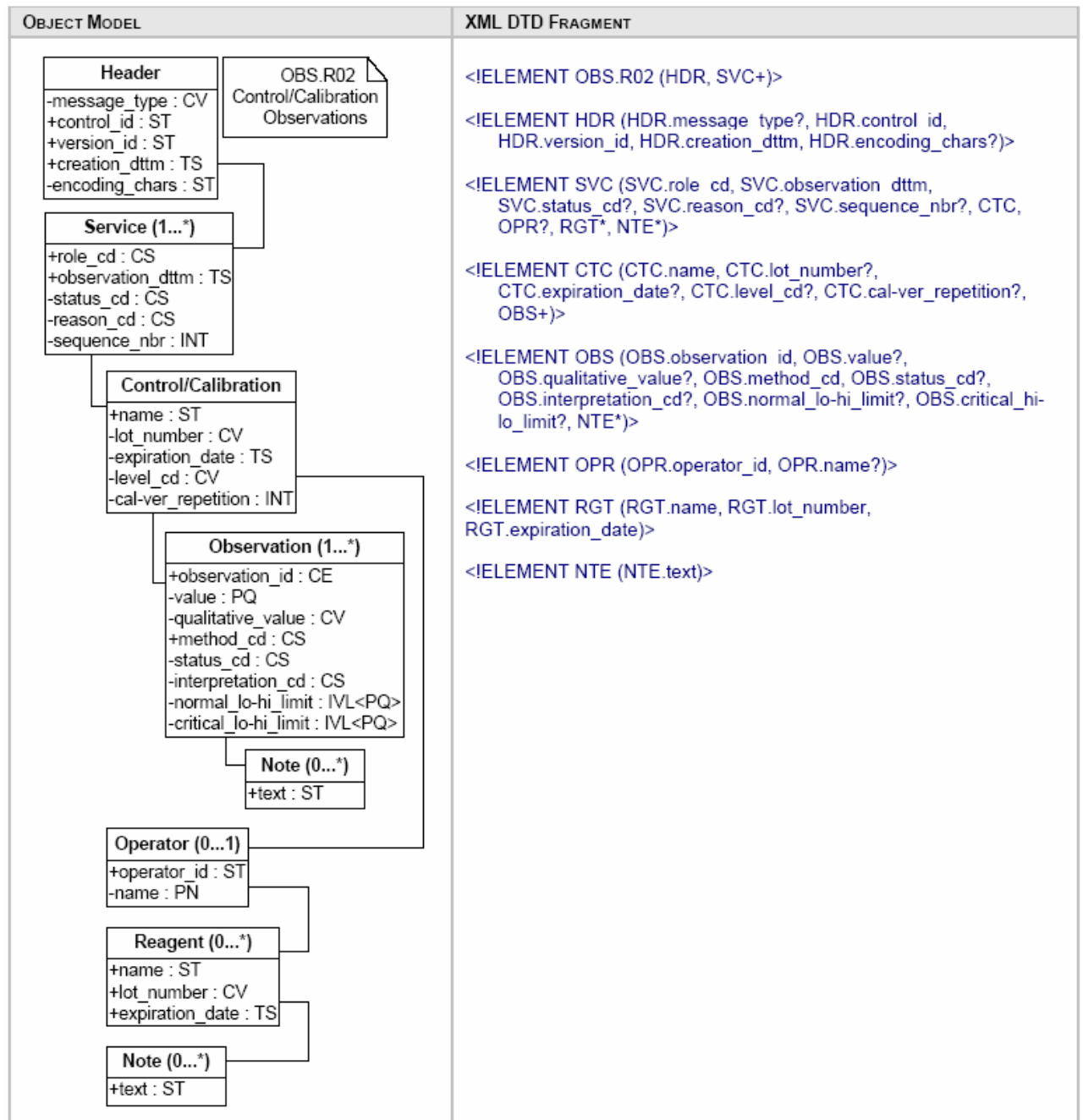


Figure 45. Nonpatient-related Observation Message Model

1040 **31.6.2.1 Use of the Service object**

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|------------------|-----------|-----------|-------------------|---|
| role_cd | CS | R | [1..1] | 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 PRF = Proficiency test |
| observation_dttm | TS | R | [1..1] | production date/time of this set of observations |
| status_cd | ST | R | [1..1] | 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 | [1..1] | 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 | O | [0..1] | 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'). |

31.6.2.2 Use of the Control/Calibration object

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

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|--------------------|-----------|-----------|-------------------|--|
| name | ST | RE | [0..1] | The manufacturer's name for the QC/Calibration material |
| lot_number | CV | R | [1..1] | The vendor-specific lot number of the QC/Calibration material |
| expiration_date | TS | RE | [0..1] | The date past which the reagent should not be used |
| level_cd | CV | C | [0..1] | The level for the QC test or for the calibration verification test. Not applicable to proficiency tests nor to calibration tests. |
| cal-ver_repetition | INT | C | [0..1] | 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. |

31.6.2.3 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 | [1..1] | The test identifier, preferably coded with LOINC |
| value | PQ | C | [0..1] | The observation result, if expressed quantitatively (i.e. a numerical value with units). |
| qualitative_value | CV | C | [0..1] | The observation result, if expressed qualitatively. |

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|----------------------|-----------|-----------|-------------------|---|
| method_cd | CS | R | [1..1] | 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 | [1..1] | 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 | C | [0..1] | 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> | RE | [0..1] | The low and high limit range for a normal result |
| critical_lo-hi_limit | IVL<PQ> | RE | [0..1] | The low and high limit range outside which clinical review is required |

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

31.6.2.4 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.

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| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------|-----------|-----------|-------------------|----------------------------|
| text | ST | R | [1..1] | Comment of the observation |

31.6.2.5 Use of the Operator object

One and only one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-------------|-----------|-----------|-------------------|--|
| operator_id | ST | R | [1..1] | A unique identifier for the operator |
| name | PN | RE | [0..1] | Operator's name. Required if available on the POCRG. |

31.6.2.6 Use of the Reagent object

Zero or one occurrence.

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------|-----------|-----------|-------------------|---|
| name | ST | RE | [0..1] | The manufacturer's name for the reagent |

| Attribute | Data Type | IHE Usage | IHE Cardinalities | Description |
|-----------------|-----------|-----------|-------------------|--|
| lot_number | CV | R | [1..1] | The lot number of reagent used |
| expiration_date | TS | RE | [0..1] | The date past which the reagent should not be used |

31.6.2.7 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 | [1..1] | Comment of the observation |

31.7 Expected Actions

1060 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.

1070 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.

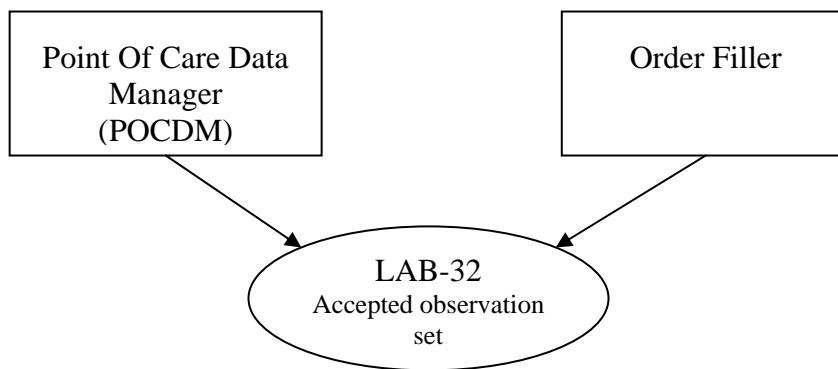
32 Transaction LAB-32: Accepted Observation Set

This section describes Transaction LAB-32 of the IHE Technical Framework, used in the LPOCT profile, between the POCDM actor and the Order Filler actor.

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.

32.2 Use Case Roles



Actor: POCDM

1080 **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.

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.

32.3 Referenced Standard

1090 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.

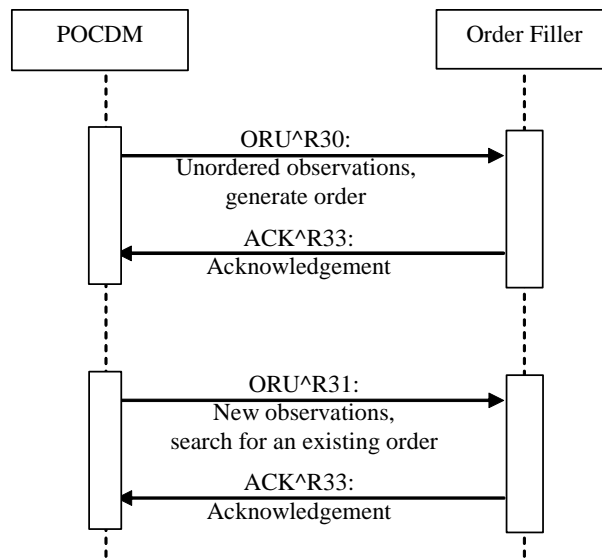
HL7 v2.5: The ORI of POCT1-A relies on HL7 v2.5 messages structures ORU defined in chapter 7 of the HL7 standard.

All implementation rules and notes specified in the Volume 2 of 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 provides the common description of segments MSH, MSA, NTE, ERR, PID, ORC, that are also applicable to this transaction LAB-32.

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32.4 Interaction Diagram



32.4.1 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.
- 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.

1110

The acknowledgement to both message structures is ACK^R33. 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 2, section 5.5.2, Note 1, this event corresponds to the normal scheduled workflow and is supported by the two IHE profiles LSWF and LDA.

32.5 Trigger Events

1120 The POCDM integrates a set of point of care observations for a patient, received from a POICRG 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.

32.6 Message Semantics

32.6.1 Common static definition for ORU^R30 and ORU^R31

Table 32.6.1-1 : static definition for ORU^R30 and ORU^R31

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

32.6.1.1 Usage of MSH segment

1130 The MSH segment has a common definition for all HL7 messages of IHE Laboratory Technical Framework. This common definition is presented in section 3.1 of L-TF Volume 2. Below are some additional recommendations for the usage of this segment within the context of this LPOCT profile.

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_R31 for the point of care observations to match with a possibly existing order

1140 Fields **MSH-15** and **MSH-16** are not used by any IHE profile of the Laboratory Technical Framework: This framework uses only the HL7 original acknowledgement mode (see section 2.3.3 of Volume 2). The acknowledgement sent back by the receiver is always an applicative acknowledgement (see section 2.3.5 of Volume 2 for IHE Laboratory Technical Framework acknowledgement policies). The Order Filler will then behave as if it had received MSH-15 valued “NE” and MSH-16 valued “AL”

32.6.1.2 Usage of PID segment

The PID segment has a common definition for all HL7 messages of IHE Laboratory Technical Framework, in section 3.1 of Volume 2. Below are some additional recommendations for the usage of this segment within the context of this LPOCT profile.

PID-3 – Patient Identifier List, is required (R) and must contain a patient unique ID shared within the healthcare enterprise.

PID-5 – Patient Name, is required if available (usage RE) and shall contain the patient identity.

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PID-7 – Date/Time of Birth, is required if available (RE) and will be valued if the POCDM knows the patient’s date of birth.

PID-8 – Administrative Sex, is required if available (RE) and will be populated with the appropriate value taken from HL7 user-defined Table 0001:

| Value | Description |
|-------|----------------|
| F | Female |
| M | Male |
| O | Other |
| U | Unknown |
| A | Ambiguous |
| N | Not applicable |

PID-18 – Patient Account Number, is required if available (RE) and will be valued if the relevant account number is known to the POCDM actor.

32.6.1.3 Usage of ORC segment

The common definition of segment ORC in Volume 3 – 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:

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Table Z.6.1.3-1 : ORC Segment

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|-----|-------|--------|------|-------|--------------------------|
| 1 | 2 | ID | R | [1..1] | 0119 | 00215 | Order Control |
| 2 | 22 | EI | X | [0..0] | | 00216 | Placer Order Number |
| 3 | 22 | EI | C | [0..0] | | 00217 | Filler Order Number |
| 4 | 22 | EI | X | [0..0] | | 00218 | Placer Group Number |
| 5 | 2 | ID | X | [0..0] | 0038 | 00219 | Order Status |
| 7 | 200 | TQ | X | [0..0] | | 00221 | Quantity/Timing |
| 8 | 200 | EIP | X | [0..0] | | 00222 | Parent |
| 9 | 26 | TS | X | [0..0] | | 00223 | Date/Time of Transaction |
| 10 | 250 | XCN | X | [0..0] | | 00224 | Entered By |
| 11 | 250 | XCN | X | [0..0] | | 00225 | Verified By |
| 17 | 250 | CE | X | [0..0] | | 00231 | Entering Organization |

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|-----|-------|--------|------|-------|---|
| 20 | 250 | CE | X | [0..0] | 0339 | 01310 | Advanced Beneficiary Notice Code |
| 21 | 250 | XON | RE | [0..1] | | 01311 | Ordering Facility Name |
| 25 | 250 | CWE | X | [0..0] | | 01473 | Order Status Modifier |
| 26 | 60 | CWE | X | [0..0] | 0552 | 01641 | Advanced Beneficiary Notice Override Reason |
| 27 | 26 | TS | X | [0..0] | | 01642 | Filler's Expected Availability Date/Time |

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 POC DM 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 format or content of this field’s value. For example, some POC DM 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).

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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.

Example: Urology^^^^^FI^^^UR01

32.6.1.4 Usage of OBR segment

Table Z.6.1.4-2 : OBR Segment

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

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|-----|-------|--------|------|-------|---|
| 12 | 250 | CE | X | [0..0] | | 00246 | Danger Code |
| 13 | 300 | ST | X | [0..0] | | 00247 | Relevant Clinical Information |
| 14 | 26 | TS | X | [0..0] | | 00248 | Specimen Received Date/Time |
| 15 | 300 | SPS | RE | [0..1] | | 00249 | Specimen Source or Segment SPM |
| 16 | 250 | XCN | RE | [0..1] | | 00226 | Ordering Provider |
| 17 | 250 | XTN | X | [0..0] | | 00250 | Order Callback Phone Number |
| 18 | 60 | ST | X | [0..0] | | 00251 | Placer Field 1 |
| 19 | 60 | ST | X | [0..0] | | 00252 | Placer Field 2 |
| 20 | 60 | ST | X | [0..0] | | 00253 | Filler Field 1 |
| 21 | 60 | ST | X | [0..0] | | 00254 | Filler Field 2 |
| 22 | 26 | TS | X | [0..0] | | 00255 | Results Rpt/Status Chng – Date/Time |
| 23 | 40 | MOC | X | [0..0] | | 00256 | Charge to Practice |
| 24 | 10 | ID | X | [0..0] | 0074 | 00257 | Diagnostic Serv Sect ID |
| 25 | 1 | ID | R | [1..1] | 0123 | 00258 | Order Result Status |
| 26 | 400 | PRL | X | [0..0] | | 00259 | Parent Result |
| 27 | 200 | TQ | X | [0..0] | | 00221 | Quantity/Timing |
| 28 | 250 | XCN | X | [0..0] | | 00260 | Result Copies To |
| 29 | 200 | EIP | X | [0..0] | | 00261 | Parent |
| 30 | 20 | ID | X | [0..0] | 0124 | 00262 | Transportation Mode |
| 31 | 250 | CE | X | [0..0] | | 00263 | Reason for Study |
| 32 | 200 | NDL | C | [0..1] | | 00264 | Principal Result Interpreter |
| 33 | 200 | NDL | X | [0..0] | | 00265 | Assistant Result Interpreter |
| 34 | 200 | NDL | RE | [0..0] | | 00266 | Technician |
| 37 | 4 | NM | X | [0..0] | | 01028 | Number of Sample Containers * |
| 38 | 250 | CE | X | [0..0] | | 01029 | Transport Logistics of Collected Sample |
| 39 | 250 | CE | X | [0..0] | | 01030 | Collector's Comment * |
| 40 | 250 | CE | X | [0..0] | | 01031 | Transport Arrangement Responsibility |
| 41 | 30 | ID | X | [0..0] | 0224 | 01032 | Transport Arranged |
| 42 | 1 | ID | X | [0..0] | 0225 | 01033 | Escort Required |
| 43 | 250 | CE | X | [0..0] | | 01034 | Planned Patient Transport Comment |
| 44 | 250 | CE | X | [0..0] | 0088 | 00393 | Procedure Code |
| 45 | 250 | CE | X | [0..0] | 0340 | 01316 | Procedure Code Modifier |
| 46 | 250 | CE | X | [0..0] | 0411 | 01474 | Placer Supplemental Service Information |
| 47 | 250 | CE | X | [0..0] | 0411 | 01475 | Filler Supplemental Service Information |
| 48 | 250 | CWE | X | [0..0] | 0476 | 01646 | Medically Necessary Duplicate Procedure Reason. |
| 49 | 2 | IS | X | [0..0] | N | 01647 | Result Handling |

1180 **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-11 Specimen Action Code (ID): This required field will be valued to ‘O’ (Specimen obtained by service other than lab).

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 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.

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:

- 1st component: Name (CNN):
 - 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)

32.6.1.5 Usage of OBX segment

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Table Z.6.1.5-3 : OBX Segment

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-------|--------|-------|--------|------|-------|-----------------------------------|
| 1 | 4 | SI | R | [1..1] | | 00569 | Set ID – OBX |
| 2 | 2 | ID | R | [0..1] | 0125 | 00570 | Value Type |
| 3 | 250 | CE | R | [1..1] | | 00571 | Observation Identifier |
| 4 | 20 | ST | X | [0..1] | | 00572 | Observation Sub-ID |
| 5 | 99999 | Varies | R | [0..1] | | 00573 | Observation Value |
| 6 | 250 | CE | C | [0..1] | | 00574 | Units |
| 7 | 60 | ST | RE | [0..1] | | 00575 | References Range |
| 8 | 5 | IS | RE | [0..1] | 0078 | 00576 | Abnormal Flags |
| 9 | 5 | NM | X | [0..0] | | 00577 | Probability |
| 10 | 2 | ID | X | [0..0] | 0080 | 00578 | Nature of Abnormal Test |
| 11 | 1 | ID | R | [1..1] | 0085 | 00579 | Observation Result Status |
| 12 | 26 | TS | X | [0..0] | | 00580 | Effective Date of Reference Range |
| 13 | 20 | ST | X | [0..1] | | 00581 | User Defined Access Checks |
| 14 | 26 | TS | R | [0..1] | | 00582 | Date/Time of the Observation |
| 15 | 250 | CE | X | [0..1] | | 00583 | Producer's ID |
| 16 | 250 | XCN | X | [0..1] | | 00584 | Responsible Observer |
| 17 | 250 | CE | RE | [0..1] | | 00936 | Observation Method |
| 18 | 22 | EI | RE | [0..0] | | 01479 | Equipment Instance Identifier |
| 19 | 26 | TS | RE | [0..0] | | 01480 | Date/Time of the Analysis |

OBX-1 Set ID - OBX (SI), required. This field contains the sequence number of the OBX, below the OBR.

OBX-2 Value Type (ID), required.

The Value Type field should be filled according to HL7 Version 2.5 standard (table 0125). For example, if the result is ">300" the Value Type "SN" (Structured Numeric) SHALL be used instead of the "ST" (String) value type that was used in previous versions of HL7. A simple numeric observation shall be typed "NM". See the details and the examples in the HL7 V2.5 (7.4.2). For an observation that consists of a time measurement (e.g. bleeding time) the TM Value Type is preferred to NM but this is not made mandatory.

1230

OBX-3 Observation Identifier (CE), required

The usage of LOINC(r) test codes for the identification of tests is recommended by IHE. Details of this free vocabulary can be found at <http://www.loinc.org>.

The first and third sub-fields “Identifier”, and “Name of Coding System” are required in all transactions. The value of the “Name of Coding System” in the case of LOINC is “LN”.

OBX-4 Observation Sub-ID (ST). This field is not used in transaction LAB-32.

OBX-5 Observation Value (varies), required.

OBX-6 Units (CE), conditional.

This field is required if the Value Type field (OBX-2) is valued either with "NM", or "SN". If valued, this field should identify SI or SI-derived units only.

1240 **OBX-7 References Range (ST)**, required if available.

This field should be valued as described in HL7 V2.5 for all observations for which it is relevant. The References range that figures in this field is supposed to be related to age and sex of the patient or to other parameters such as number of weeks of pregnancy when applicable, which makes the OBX-10 field (nature of abnormal test) unnecessary.

The format of the reference ranges is as follows:

for numeric values in the format:

a) lower limit-upper limit (when both lower and upper limits are defined, e.g., for potassium 3.5 - 4.5)

b) > lower limit (if no upper limit, e.g., >10)

1250 c) < upper limit (if no lower limit, e.g., <15)

alphabetical values: the normal value may be reported in this location

Examples of reference ranges:

- |3.5-4.5|
- |>50|
- |<0.001|
- |Non Reactive|

OBX-8 Abnormal Flags (IS), required if available.

1260 This field is required when applicable. This field is not repeatable in the IHE Laboratory Technical Framework. Among the possible values listed for this field in HL7 table 0078, the actor POCDM should support the following subset:

Table Z.6.1.5-4 : HL7 table 0078

| Value | Description | Comment |
|-------|------------------|---------|
| L | Below low normal | |

| Value | Description | Comment |
|-------|---|---------|
| H | Above high normal | |
| LL | Below lower panic limits | |
| HH | Above upper panic limits | |
| N | Normal (applies to non-numeric results) | |
| A | Abnormal (applies to non-numeric results) | |
| AA | Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units) | |
| Null | No range defined, or normal ranges don't apply | |

OBX-11 Observation Result Status (ID), required.

This field should be filled according to HL7 Table 0085 described in Chapter 7 of HL7. Given that the POCMD sends reviewed observations, the status shall be valued "F".

OBX-14 Date/Time of the Observation (TS), required if available.

This field should be valued when the OBX-5 field (Value field) is also valued. The observation date-time is the physiologically relevant date-time or the closest approximation to that date-time. In the case of tests performed on specimens, the relevant date-time is the specimen's collection date-time.

1270 **OBX-15 Producer's ID (CE)**, is not used in transaction LAB-32. The information is given within field OBR-34 "Technician".

OBX-16 Responsible Observer (XCN), is not used in transaction LAB-32. The information (common to all the observations of this set) is carried within field OBR-34 "Technician".

OBX-17 Observation Method (CE), conditional.

Condition predicate: This field is required when the value of the result may be dependant of the Observation Method and the Observation Identifier does not permit to identify the Method. With some Observation Identifiers such as LOINC(r) Codes, the identifier also identifies the Method, in which case this field does not need to be valued.

1280 **OBX-18 Equipment Instance Identifier (EI)**, required if available for transaction LAB-32: Every point of care device (POCRG actor) should be identified by a universally unique identifier in the format specified by IEEE for the EUI-64 identifier. If this EUI-64 identifier is available, it should be recorded in the 'universal ID' component of this field. If it is not available, the manufacturer's Device identifier (e.g., serial number) should be recorded in 'universal ID' component, with the Device or manufacturer name in 'universal ID type' component.

OBX-19 Date/Time of the Analysis (TS), is not used in transaction LAB-32. The information (common to all the observations of this set) is given within field OBR-34 "Technician".

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.

1290

Table 32.6.1-1 : static definition for ACK^R33

| Segment | Meaning | Usage | Card. | HL7 chapter |
|-----------|-------------------------|-------|--------|-------------|
| MSH | Message Header | R | [1..1] | 2 |
| MSA | Message Acknowledgement | R | [1..1] | 2 |
| [{ERR}] | Error | C | [0..1] | 2 |

32.6.2.1 Usage of MSH segment

The MSH segment has a common definition for all HL7 messages of IHE Laboratory Technical Framework. This common definition is presented in section 3.1 of L-TF Volume 2. Below are additional recommendations for the usage of this segment within this acknowledgement:

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

MSH-15 – Accept Acknowledgement Type, and **MSH-16 – Application Acknowledgement Type** are not used, and would be valued “NE” (Never) if they were used: This ACK message itself, does not wait for any acknowledgement.

32.6.2.2 Usage of MSA segment

1300

Table 0-5: MSA - Message Acknowledgement

| SEQ | LEN | DT | Usage | Card. | TBL# | ITEM# | Element name |
|-----|-----|----|-------|--------|------|-------|-----------------------------|
| 1 | 2 | ID | R | [1..1] | 0008 | 00018 | Acknowledgement code |
| 2 | 20 | ST | R | [1..1] | | 00010 | Message Control Id |
| 3 | 80 | ST | R | [0..0] | | 00020 | Text Message |
| 5 | | | X | [0..0] | | 00022 | Delayed Acknowledgment Type |
| 6 | 250 | CE | X | [0..0] | 0357 | 00023 | Error Condition |

The general specification of use of this segment by the IHE Laboratory Technical Framework is given in section 3.2 of Volume 2 of this framework. As a reminder, given that the original mode acknowledgement is in use throughout all IHE domains, field **MSA-1 – Acknowledgement code (ID)**, required, is used as follows:

Table 0-6: HL7 table 0008 - Acknowledgement code

| Value | Description | Comment |
|-------|--------------------------------------|--|
| AA | Original mode: Application Accept | Message accepted and integrated by the receiving application |
| AE | Original mode: Application Error | Message contains errors. It SHALL not be sent again without prior correction of these errors. |
| AR | Original mode: Application Reject | Message rejected by the receiving application. If the rejection is not related to an invalid value in the MSH segment, the sender may try again later. |

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.

1310 **32.6.2.3 Usage of ERR segment**

The usage of this segment is fully described in section 3.3 of Volume 2 of the Laboratory Technical Framework. The segment is only used in case of error.

32.7 Expected Actions

When receiving an ORU^R30, 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.
- 1320 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.

When receiving an ORU^R32, 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.
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).
- 1330 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.
4. Using Transaction LAB-1 of LSWF profile, the Order Filler notifies the arrival of the POCT results to the Order Placer.