Integrating the Healthcare Enterprise

IHE Pathology and Laboratory Medicine Technical Framework Supplement

Specimen Event Tracking (SET)

Revision 1.1 – Trial Implementation

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

Foreword

This is a supplement to the IHE PaLM Technical Framework 10.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published for trial implementation on November 23, 2021 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Pathology and Laboratory Medicine Technical Framework. Comments are invited and may be submitted at http://ihe.net/PaLM_Public_Comments.

This supplement describes changes to the existing technical framework documents.

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

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at IHE.

Information about the IHE Pathology and Laboratory Medicine domain can be found at IHE Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at Profiles and IHE Process.

The current version of the IHE Pathology and Laboratory Medicine Technical Framework can be found at PaLM Technical Framework.

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Introduction to this Supplement

Biologic specimens play a central role in diagnostic activities, as they represent one of the core elements for all use cases and processes. For this reason, it is very important to guarantee a full control of all specimens created and processed, to prevent the occurrence of critical or error situations. This can be reached by enabling specimen tracking, adding the capability to reconstruct the history of the specimens themselves: when, where and by whom they have been collected, sent to laboratory for testing, rejected due to some errors, stored at the end of their lifecycle, or collected and stored to be part of a biobank.

The new Specimen Event Tracking (SET) Profile, introduced in this supplement, has the aim to provide guidelines and use cases to enable specimen tracking inside the PaLM domain, identifying all the specimen-centric operations which are of interest to be tracked. A set of reference events and several use cases are provided for this profile.

It is important to notice that the SET Profile refers to the concept of "specimen" and "laboratory" in a generic way: a specimen is every kind of sample (blood, urine, tissue, etc.) usually taken from a patient. A laboratory is a location where the specimen is analyzed, independently from its specialty (microbiology, hematology, pathology, biochemistry, molecular biology).

Open Issues and Questions

- **SET-10** Appendix A – Set Profile custom EVN-4 values Table: to be reviewed.
- **SET-11** Create and review a PRT-4 user defined values extended table for SET. At the moment we have added values for sending and receiving roles (FE and TE). Shall we need to define others?
- **SET-12** Usage of the PRT segment in all the various trigger events/message types. Can we find a way to equalize as much as possible the usage of participation segments in all messages? Current usages are the following:
  - PRT-2 -> Should be mandatory, from an HL7 point of view
  - S38 (Specimen collected) PRT-5 (person)
  - S39 (Specimen containers produced) PRT-5 (If Human), PRT-10 (If machine), at least one of the 2 mandatory
  - S40 (Specimen collection failed) PRT-5 (person)
  - S^41 (Specimen departed) PRT-5 (person) or PRT-8 (organization) or PRT-10 (device) + PRT-4 (Role)-> FE/TE (sending or receiving) . At least the receiving must be valued
  - S^42 (Specimen arrived) PRT-5 (person) or PRT-8 (organization) or PRT-10 (device) + PRT-4 (Role)-> FE TE (sending or receiving) . Ad least the sending must be valued
  - S^43 (Specimen accepted) PRT-7 (organization unit type)
  - S^44 (Specimen rejected) PRT-7 (organization unit type)

- S^46 (Specimen Archived) PRT-9 (Participant Location)
- S^47 (Specimen Retrieved) PRT-9 (Participant Location)
- S^48 (Specimen Disposed of) PRT-9 (Participant Location)
- S^49 (Specimen Procedure step -> Derived) PRT-5 (If Human), PRT-10 (If machine), at least one of the 2 mandatory
- S^50 (Specimen Procedure step -> no Derived) PRT-5 (If Human), PRT-10 (If machine), at least one of the 2 mandatory
- S^51 (Specimen Procedure step -> Derived) PRT-5 (If Human), PRT-10 (If machine), at least one of the 2 mandatory

Closed Issues

- List of events for the profile
- Use Cases definition
- All use cases have been reviewed from a generic point of view (no derivation and groupings with other PaLM profiles' use cases/actors)
- Added Biobanks and Pathology use cases
- New Use Case 3 Specimen tracking within the Laboratory text: This new text addresses the combination of the previous use cases 3 and 5, and the related description of the new generic use case.
- **SET-1** Complete new messages review (Volume 2 of the profile, HL7 CR document). Solution: messages review completed, together with the HL7 OO group.
- **SET-2** Examples of tracking for the other profiles' use cases (specialization of the proposed generic use cases). Solution: section added
- **SET-3** Detailed Event Metadata Matrix - Attributes definition for the Specimen Identifier Changed Event: As decided during March call, the two events of de-and re-identification has been merged into one mode generic event. Do we need additional (specific, not common) attributes for this new event? Solution: no additional attributes needed.
- **SET-4** Detailed Event Metadata Matrix – Involved diagnosis Attribute: After the discussion with the HL7 Group this attribute seemed a candidate to be dropped as it has not been considered during the new HL7 messages implementation.
  - RM comments that: often in HL7 orders you do get DG1 segment (at least in the US it is required for billing – also the OBR has OBR-31 (Reason for Study), which could be used to share diagnosis information.
  - AS replies that: The problem is that the message structure created for this event does not include the OBR segment. We will decide if to change the structure or – in order not to change the approved CR too much – to drop the attributes, or also to add DG1.

- FM replies that: this is a volume 1 discussion. Not a volume 2 discussion. So, back to use case, the question is: Does the Specimen Event Tracker need to track the diagnosis associated with a specimen event? It seems that use case #4 (biobanks) would need the diagnosis. Don't you think?
- In the Use Case 4 (Biobank) introduction, for the sentence "*Several research studies for diseases like cancer, for example, identify a group of volunteers that consent to participate in the research program and to allow collection of one or more samples for the biobank storage.*" FM comments: "Here it is clearly stated that the biobank needs the diagnosis"

Solution: the attribute has been dropped.

- **SET-5** Add Section X.6 for Cross Profile Considerations, as, according to FM comment, "This section could add concrete value to show the use of SET in combination with a couple of other profiles such as LTW, LBL, ILW". Solution: section added.
- **SET-7** Table 3.Y.5.2.2.2-1 Specimen Collection Succeeded event metadata to SET^S39^SET_S38 message segments/fields mapping – Attribute Form
  - This attribute lack of precision (FM).
  - A better terminology is necessary also in Vol.1, AS proposes Proposed "Material state and nature", according to the description of "FormCode" attribute in the DAM model. Il it is OK, we can resolve the comment by replacing it in all parts of the document.
  - RM: I think we can drop this one – not sure it is really needed. If that means we have to update the DAM, we can
  - Not an information structured in usual applications, it's an attribute for a DAM perspective, probably it's not required

Solution: Form attribute dropped.

- **SET-8** Table 3.Y.5.13.2.1-1 SET_S49 message structure – OBR Observation Request (Specimen Processing):
  - Riki comment on CR--How would we track what kind of processing actually happened – in Digital Pathology we have been talking about repeating the SPM segment for each derived specimen – that's when you have to send the order – here we are just tracking each step, but should we include all the children from aliquoting steps maybe?
  - The overall S50 message needs further review, especially for both SGH and SGT segments usage. Do we need additional iterations with the HL7 OO group?

Solution: The message structures have been reviewed and finalized, together with the OO group, and it is OK for derived specimen support.

- **SET-9** Tables 3.Y.5.13.2.2-1 and 3.Y.5.14.2.2-1: Specimen Procedure Step Succeeded (with derived specimens), Specimen archived event metadata to SET^S49^SET_S49 message and SPM^S50^SPM_S49 segments/fields mapping – Specimen Child Role:
  - WGMJan2019 comment: How to handle derived specimens? (i.e., urine sediment for some urinalysis results, isolate for cultures). There's the specimen type aspect and may also be container aspects/subcontainers/subcultures...
  - Extract the problem from the document and submit to Raj and Jim to see their opinion. Main problems: derivation and re-identification in biobank use case

Solution: The use case proposed by Raj has been taken as a reference for SET derivation tracking messages example. The S50 trigger event seem to support the use case in a proper way (see examples).

IHE Technical Frameworks General Introduction

The IHE Technical Framework General Introduction is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

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IHE technical documents refer to, and make use of, a number of standards developed and published by several standards development organizations. Please refer to the IHE Technical Frameworks General Introduction, Chapter 9 - Copyright Licenses for copyright license information for frequently referenced base standards. Information pertaining to the use of IHE International copyrighted materials is also available there.

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IHE Technical Frameworks General Introduction Appendices

The IHE Technical Framework General Introduction Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

*Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices to the IHE Technical Frameworks General Introduction located here.*

*Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:*

New (or modified) Actor Name	Definition
Specimen Event Informer	Captures events happening on specimens and notifies these events and related data to the Specimen Event Tracker (SET).
Specimen Event Tracker	Tracks specimen events received from the Specimen Event Informer (SEI) and records/processes these events and their related data.

Appendix B – Transactions

*Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
Track Specimen Information [LAB-40]	This transaction conveys specimen events and related data from a Specimen Event Informer (SEI) to a Specimen Event Tracker (SET). Each specimen event reports a specific macro-activity that occurred to the specimen during its lifecycle.

Appendix D – Glossary

360 *Add the following **new or modified** glossary terms to the IHE Technical Frameworks General Introduction Appendix D:*

New (or modified) Glossary Term	Definition
No new terms	

Volume 1 – Profiles

Domain-specific additions

NA

Add new Section #X

X SET (Specimen Event Tracking) Profile

The Specimen Event Tracking (SET) Profile covers use cases and transactions related to the tracking of biological specimens in vitro collected for the purpose of diagnostic testing, during their entire lifecycle, from creation to storage inside a laboratory specimen archive or a biobank for future usage, and to final disposal.

Specimen workflows can involve a ward and a laboratory in the same hospital, different laboratory facilities inside the same institution, or across different institutions. In the latter case, specimens need to be transferred by a courier service from the sending institution to the receiving institution. Another important use case to be tracked is the specimen creation for the specific purpose of becoming part of a biobank for a research institution or program.

The SET Profile tracks macro activities related to specimens, such as collecting, shipping, receiving, accepting. Micro operations part of a macro activity (e.g., decapping a tube) are out of scope of the profile.

X.1 SET Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at https://profiles.ihe.net/GeneralIntro/index.html.

Figure X.1-1 shows the actors directly involved in the SET Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping (if any), are shown in conjoined boxes.

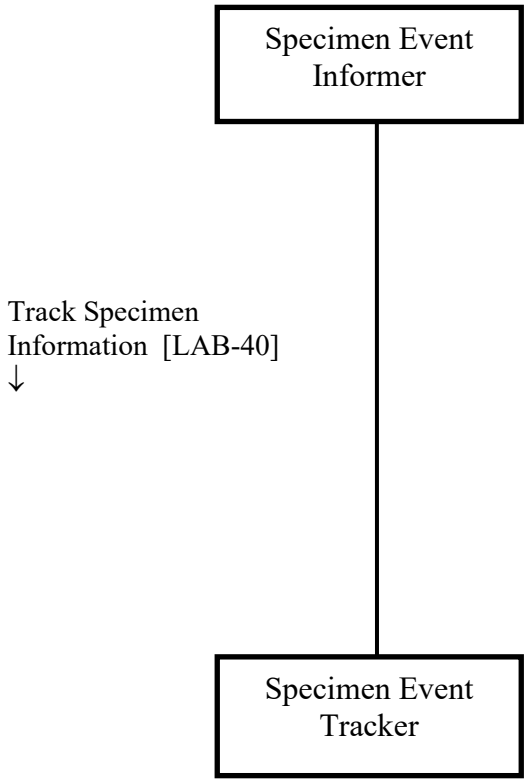


Figure X.1-1: SET Actor Diagram

395 Table X.1-1 lists the transactions for each actor directly involved in the SET Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table X.1-1: SET Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Specimen Event Informer	Track Specimen Information [LAB-40]	Initiator	R	PaLM TF-2: 3.Y
Specimen Event Tracker	Track Specimen Information [LAB-40]	Responder	R	PaLM TF-2: 3.Y

400 ### X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirement on profile's actors.

No additional requirements needed.

X.1.1.1 Specimen Event Informer (SEI)

The Specimen Event Informer (SEI) notifies specimen events and the related data to the Specimen Event Tracker (SET). For each traceable event occurring to a specimen, this actor triggers one message on [LAB-40] transaction carrying tracked information describing the specific event. Examples of traceable events on specimens include “Specimen collected in ward”, “Specimen sent to Laboratory”, “Specimen archived”.

X.1.1.2 Specimen Event Tracker (SET)

The Specimen Event Tracker (SET) tracks specimen events. It receives messages from the Specimen Event Informer (SEI) on transaction [LAB-40] and records/processes their content. The SET Profile does not specify what kind of processing of specimen event information needs to be achieved by the SET Actor. The way SET treats tracking information depends on its own usage and scope: in some cases, tracked events could simply be stored and viewed in a database, while in some other cases they could be forwarded to a specific traceability system to be further analyzed.

X.2 SET Actor Options

NA

X.3 SET Required Actor Groupings

NA

X.4 SET Overview

The aim of the SET Profile is the tracking of events reflecting macro activities performed on specimens during their life cycle. Such macro activities include specimen collection, transport, check-in, storage usage inside a biobank and final disposal.

X.4.1 Concepts

This profile addresses the tracking of specimen events. Every [LAB-40] transaction message conveys an event belonging to one of the event categories listed in the following section. Each category of events refers to a specific performed macro activity (e.g., “Specimen Collection Succeeded”, “Specimen Departed”).

X.4.1.1 SET Profile Event List

The table below lists the categories of events tracked by the SET Profile.

Table X.4.1.1-1: SET Profile Events List

Event	Description
Containers Prepared for Specimen Collection	The containers for specimen collection have been prepared (they have been selected, labeled and delivered to the specimen collector).
Specimen Collection Succeeded	The specimen has been collected by an operator (phlebotomist, physician, nurse, etc.) in a ward or in a sample collection room. Specimen collection action includes specimen identification.
Specimen Collection Failed	The specimen collection has failed. A reason for specimen collection failure SHALL be specified.
Specimen Departed	The specimen has been sent from a location to another one, which can be in the same institution, or in a remote one.
Specimen Arrived	The specimen has successfully arrived at the intended location, from an external location.
Specimen Accepted	The received specimen has been accepted after successful quality checks by the receiving institution.
Specimen Rejected	The specimen has been rejected after check-in, as it does not have the minimum quality requirements to be processed ahead. This event SHALL carry the reject reason.
Specimen Identifier Changed	A new identifier has been assigned to the specimen by a facility, institution or biobank. The new identifier assignment is a consequence of a re-identification or a de-identification procedure on the specimen. Keeping the link between the old and the new identifiers is out of scope for the SET Profile.
Specimen Archived	The specimen has been archived in a storage system or in a biobank.
Specimen Retrieved from archive	The specimen has been retrieved from a storage system or biobank, for further usage.
Specimen Procedure Step successfully produced a derived specimen	The specimen has been derived from a previous one. This event is triggered for example when a block is derived from a tissue specimen, or a slide is derived from a block. The event is also useful for biobanks, where a parent specimen is processed to create a child specimen for further testing.
Specimen Procedure Step Succeeded (with no derived specimen)	A procedure step has been successfully performed by a device on the specimen.
Specimen Procedure Step Failed	A procedure step by a device on the specimen has failed. This event SHALL carry the failure reason.
Specimen Disposed of	The specimen has been disposed of. This ends its life cycle.

X.4.1.2 Events Metadata

This section details the metadata required for each of the events listed above. All these events shall have a common set of metadata (e.g., event identifier, specimen identifier, event timestamp), complemented by a set of metadata specific of each event.

All metadata composing an event will be considered as the skeleton semantic structure for event messaging, detailed in Volume 2.

Table X.4.1.2-1: Common set of metadata for all events

Event	Description
Event Type	Type of the Event (“Event” column of Table X.4.1.1-1)
Event Registered Timestamp	Timestamp of event registration (i.e., when the event is sent from SEI to SET)
Effective time of the event	Timestamp of occurrence of the tracked event
Event Participant	Operator/Machine/device responsible for the event
Event ID	Unique identifier of the event
Event Reason	Reason for the Event
Specimen ID	Unique Identifier of the Specimen the event is related to
Specimen Container ID	Unique Identifier of the Specimen Container the event is related to
Specimen Type	Type of the tracked specimen (e.g., blood, urine)
Sending Organization	Identifier of the organization sending the event tracking message
Sending Facility	Identifier of the facility sending the event tracking message
Receiving Organization	Identifier of the organization receiving the event tracking message
Receiving Facility	Identifier of the facility receiving the event tracking message

445 **Note**: Almost all the fields listed above SHALL be populated. Concerning the Specimen Container ID attribute, this one could be optional, for example, when the tracking involves a specimen carried in only one container. Anyway, as detailed in the table below, additional tracking information about the container is strongly recommended to be provided, when available.

450 **Table X.4.1.2-2: Detailed event metadata matrix**

Event	Metadata Attribute	Data type	Description	Card.	Usage	DAM Mapping
Containers Prepared For Specimen Collection	Placer Order Number	String	The identifier assigned by the Order Placer to the test order that needs this specimen to be performed	0…*	Recommended	-
	Placer Group Number	String	The identifier assigned by the Order Placer to the laboratory requisition (group or orders), which needs this specimen to be performed	0…*	Recommended	-
	Filler Order Number	String	Identifier assigned by the Order Filler to the test order that needs this specimen to be performed	0…*	Recommended	-
	Test	String	Test performed	0…*	Recommended	-
	Producer	String /ID	Entity responsible for the delivery of labeled specimen containers	1…1	Required	Performer.identifier,
	Producer Type	String	Type of producer (Human, Robotic System)	1…1	Required	Performer.typeCode

Event	Metadata Attribute	Data type	Description	Card.	Usage	DAM Mapping
	Container Name	String	Name of the container model	0…1	Recommended	SpecimenContainer.name
	Container Material	String/Code	Material of the specimen container	0…1	Optional	SpecimenContainer.containerMaterialCode
	Container Capacity	Number/Code	Capacity of the specimen Container	0…1	Optional	SpecimenContainer.Parameters.capacity
	Container Additive	String/Code	Additive of the specimen Container	0…1	Optional	SpecimenContainer.additive
	Number of Specimen Containers	Number	Overall number of containers where the specimen has been collected	0…1	Recommended	-
	Container Height	Number	Height of the specimen container	0…1	Optional	SpecimenContainerParameters.height
Specimen Collection Succeeded	Placer Order Number	String	The identifier assigned by the Order Placer to the test order that needs this specimen to be performed	0…*	Recommended	
	Placer Group Number	String	The identifier assigned by the Order Placer to the laboratory requisition (group or orders), which needs this specimen to be performed	0…*	Recommended	
	Filler Order Number	String	Identifier assigned by the Order Filler to the test order that needs this specimen to be performed	0…*	Recommended	-
	Test	String	Test performed	0…*	Recommended	-
	Collector	String /ID	Person responsible of Specimen Collection	1…1	Required	Performer.identifier
	Description	String	Additional information on the specimen	0…1	Optional	Specimen.description
	Procedure	String	Activity performed for collection (e.g., venipuncture, biopsy)	0…1	Optional	SpecimenCollectionProcedure.ProcedureCode
	Coll. Date Range	Date/Time Range	Time range of collection duration	0…1	Conditional	SpecimenCollectionProcedure.actualCollectionDateRange
	Container Name	String	Name of the container model	0…1	Recommended	SpecimenContainer.name
	Container Material	String/ Code	Material of the specimen container (e.g., glass, Plexiglas)	0…1	Optional	SpecimenContainer.containerMaterialCode

Event	Metadata Attribute	Data type	Description	Card.	Usage	DAM Mapping
	Container Capacity	Number/ Code	Capacity of the specimen container	0…1	Optional	SpecimenContainer.Parameters.capacity
	Container Additive	String/ Code	Additive of the specimen container (e.g., EDTA)	0…1	Optional	SpecimenContainer.additive
	Number of Specimen Containers	Number	Overall number of containers where the specimen has been collected	0…1	Recommended	-
	Container Height	Number	Height of the specimen container	0…1	Optional	SpecimenContainerParameters.height
	Expiration Time	Date/Time	Expiration date of the specimen	1…1	Required	Specimen.expirationTime
Specimen Collection Failed	Placer Order Number	String	The identifier assigned by the Order Placer to the test order that needs this specimen to be performed	1…*	Required	-
	Placer Group Number	String	The identifier assigned by the Order Placer to the laboratory requisition (group or orders), which needs this specimen to be performed	1…*	Required	-
	Filler Order Number	String	Identifier assigned by the Order Filler to the test order that needs this specimen to be performed	1…*	Required	-
	Test	String	Test performed	1…*	Required	-
	Collector	String /ID	Person responsible of specimen collection	1…1	Required	Performer. identifier
	Missed Reason	String	Reason for failure of specimen collection	1…1	Required	SpecimenCollectionProcedure.missedReason
Specimen Departed	From Entity/Origin/ From Location	String/ID	Location from where the specimen has been transferred	1…1	Required	SpecimenMoveActivity.FromEntity
Specimen Arrived	To Entity/Destination/To Location	String/ID	Location where the specimen arrived	1…1	Required	SpecimenMoveActivity.toEntity
Specimen Accepted	Accept Entity	String/ID	Location where the specimen has been accepted	1…1	Required	SpecimenMoveActivity.toEntity
Specimen Rejected	Reject Entity	String/ID	Location where the specimen has been rejected	1…1	Required	SpecimenMoveActivity.toEntity

Event	Metadata Attribute	Data type	Description	Card.	Usage	DAM Mapping
	Reject Reason	String	Reason why the specimen has been rejected	1…1	Required	SpecimenMoveActivity.varianceReasonCode
Specimen Identifier Changed	Identifier Changing Entity	String/ID	Location where the change of specimen identifier occurs.	1…1	Required	SpecimenMoveActivity.toEntity
Specimen Archived	Expiration Time	Date/Time	Date after the specimen is no longer viable	1…1	Required	Specimen.expirationTime
	Original Quantity	Number	Initial volume (i.e., container capacity) of the specimen	1…1	Required	Specimen.originalSpecimenMeasurement
	Current Quantity	Number	Current volume of the specimen	1…1	Required	Specimen.currentSpecimenMeasurement
	Current Status	String	Status of the specimen at the time of archiving	1…1	Required	SpecimenCollectionProcedure.statusCode
	Archiving Location	String	Location/code where the specimen is archived	1…1	Required	
Specimen Retrieved From Archive	Expiration Time	Timestamp	Date after the specimen is no longer viable	1…1	Required	Specimen.expirationTime
	Original Quantity	Number	Initial volume (i.e., container capacity) of the specimen	1…1	Required	Specimen.originalSpecimenMeasurement
	Current Quantity	Number	Current volume of the specimen	1…1	Required	Specimen.currentSpecimenMeasurement
	Retriever Name	String	Name of the person responsible for retrieve	1…1	Required	-
	Retriever Identifier	String/ID	Identifier of the person responsible for retrieve	1…1	Required	-
	Retriever Location	String	Location where the retrieve has been performed	1…1	Required	-
Specimen Procedure Step successfully produced a derived specimen	Parent Identifier	String/ID	Parent ID of the specimen from where the specimen has been derived	1…1	Required	Specimen.specimenIdentifier
	Procedure Name	String	Description of the procedure step completed	1…1	Required	SpecimenProcessingActivity.processingProcedure
	Processing Additive	String	Substance required and added to the specimen for processing	0…1	Optional	SpecimenProcessingActivity.processingAdditive
	Temperature	Number	Temperature at which the processing occurred	0…1	Optional	SpecimenProcessingActivity.Temperature

Event	Metadata Attribute	Data type	Description	Card.	Usage	DAM Mapping
	Current Quantity	Number	Volume of the derived specimen	0…1	Optional	Specimen.currentSpecimenMeasurement
	Original Quantity	Number		0…1	Optional	Specimen.originalSpecimenMeasurement
	Specimen Child Role	String	Role of the derived specimen (e.g., aliquot, block for tissue)	0…1	Optional	Specimen.childRole
	Procedure Step Entity	String	Entity responsible for the execution of the procedure step	1…1	Required	-
Specimen Procedure Step Succeeded (with no derived specimen)	Procedure Name	String	Description of the procedure step completed	1…1	Required	SpecimenProcessingActivity.processingProcedure
	Processing Additive	String	Substance required and added to the specimen for processing	0…1	Optional	SpecimenProcessingActivity.processingAdditive
	Temperature	Number	Temperature at which the processing occurred	0…1	Optional	SpecimenProcessingActivity.Temperature
	Procedure Step Entity	String	Entity responsible for the execution of the procedure step	1…1	Required	-
Specimen Procedure Step Failed	Procedure Name	String	Description of the procedure step completed	1…1	Required	SpecimenProcessingActivity.processingProcedure
	Processing Additive	String	Substance required and added to the specimen for processing	0…1	Optional	SpecimenProcessingActivity.processingAdditive
	Temperature	Number	Temperature at which the processing occurred	0…1	Optional	SpecimenProcessingActivity.Temperature
	Unsuccessful Procedure Reason	String	Reason why the procedure was unsuccessful	1…1	Required	-
	Procedure Step Entity	String	Entity responsible for the execution of the procedure step	1…1	Required	-
	Disposure Location	String	Disposure location of the specimen	1…1	Required	-

X.4.2 Use Cases

The use cases for the SET Profile, described in detail in the following sections, are:

1. Tracking the delivery of labeled containers and the collection of specimens into these containers. This use case tracks the events of delivery of labeled containers (performed by an operator and/or a robotic system) and of specimen collection using these labeled containers. These events may occur at various specimen collection sites (e.g., ward, laboratory phlebotomy room, surgery room). This is the starting point of the specimen event tracking chain. All other use cases imply that this first one was completed at some location.
2. Tracking inter and intra organization specimen transfer. This use case tracks events related to the transfer of specimens from a location to another. The two locations may belong to the same institution in case of intra-organization transfer (for example, a collecting point in a ward sending the specimen to the laboratory), or to different institutions, no matter how distant they are from each other (for example organization A is subcontracting a test to organization B, and ships the specimen needed for this test). This use case covers all events related to the specimen departure, arrival and acceptance by the receiving location.
3. Specimen tracking within the Laboratory. This use case addresses both movements and operations that occur to the specimen inside a Laboratory. These operations could be related, for example, to IVD testing or to Pathology testing. Related workflows for this use case may include the taking in care of the specimen by a device/working station, one or more procedure steps performed on the specimen and so on. The execution of a procedure step may include a derivation operation on the specimen or not: for example, a procedure step performed on an aliquoting device imply the derivation of the specimen itself, while a procedure step performed on a centrifugation device does not.
4. Tracking specimen transfer and later usage to/by a biobank: This use case tracks events related to the transfer of a specimen to a biobank and its later retrieval and usage from this biobank. In many cases, the specimen collector is aware that the final destination of the specimen will be a biobank.

X.4.2.1 Use Case #1: Container Delivery and Specimen Collection Tracking

This use case is focused on the collection of the specimen in a location (ward, laboratory collecting room, surgery room) using containers previously delivered and labeled.

X.4.2.1.1 Container Delivery and Specimen Collection Tracking Use Case Description

The scenario starts with the labeled containers delivery; this action may be performed by a robotic system and/or manually by an operator (identified by the generic actor Specimen Container Producer). Then, the person responsible for collecting specimens (identified with the generic actor Specimen Collector) performs the specimen collection using these containers.

In some cases, the two actions of container delivery and specimen collection may be concurrent or at least recorded as a single combined event. In these cases, the data related to these two

actions will be conveyed by the single event "Specimen Collection Succeeded" in a single message on transaction [LAB-40].

In other cases, the two actions are executed at distinct points in time and recorded as such. The first action is then tracked by the event "Specimen Containers Prepared", and the second action is tracked by the event "Specimen Collection Succeeded". Each event triggers its own message on transaction [LAB-40].

If the specimen collection was unsuccessful for any reason, the use case ends with a "Specimen Collection Failed" event, instead of "Specimen Collection Succeeded".

X.4.2.1.2 Container Delivery and Specimen Collection Tracking Process Flow

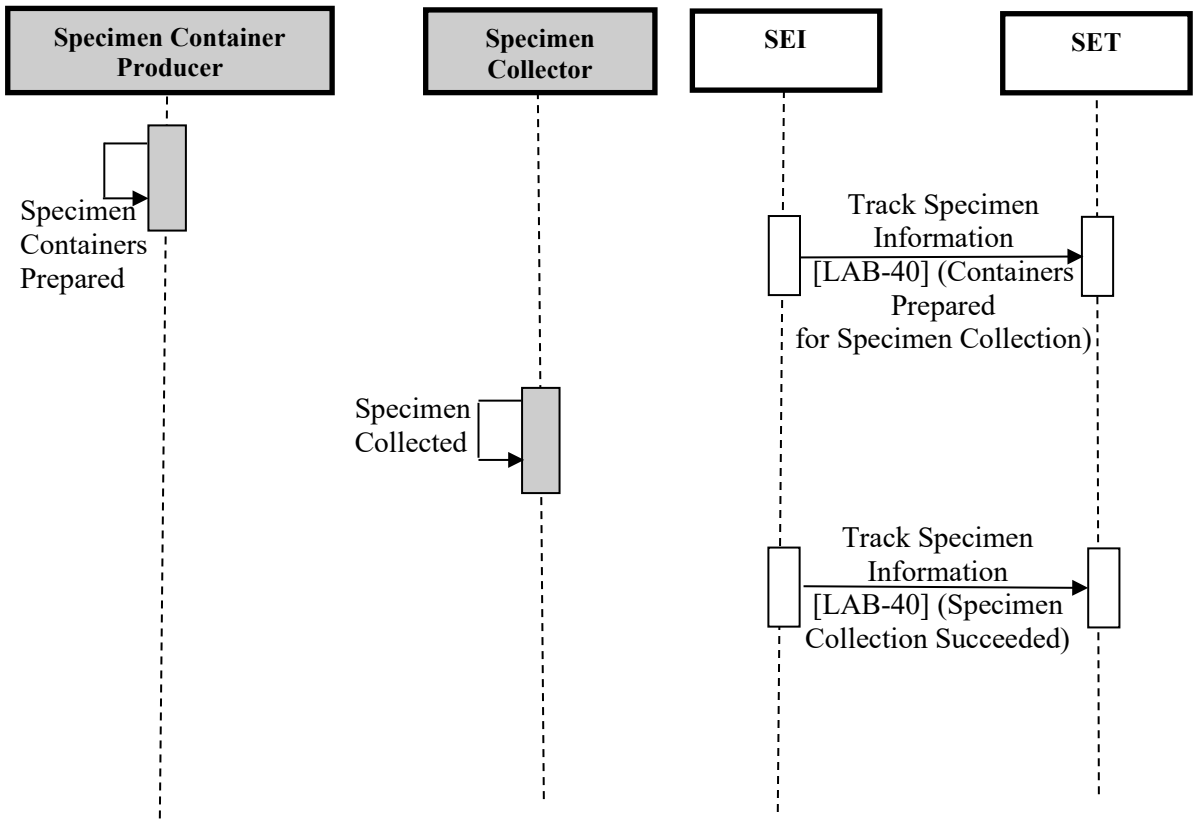


Figure X.4.2.1.2-1: Container Delivering and Specimen Collection Tracking Basic Process Flow in SET Profile

X.4.2.2 Use case #2: Specimen Inter and Intra organization transfer

This use case involves the transfer of specimens from a location to another. The two locations may belong to the same institution (intra-organization transfer) or to different institutions (inter-organization transfer) which can be close or distant from one another.

An example of inter-organization transfer is given by the shipment of a specimen to a subcontractor laboratory, for some specific test. An example of intra-organization transfer is the delivery of a specimen from the hospital ward that collected it to the in-house laboratory.

X.4.2.2.1 Specimen Inter and Intra organization transfer Use Case Description

The basic scenario starts with the shipment of specimens at the sending location. Then, the intended recipient location receives them, accepts them, and processes them for testing.

It may happen that some specimen containers need to be labeled on arrival (as they travelled without any conventional label), or need to be re-identified (and thus re-labeled).

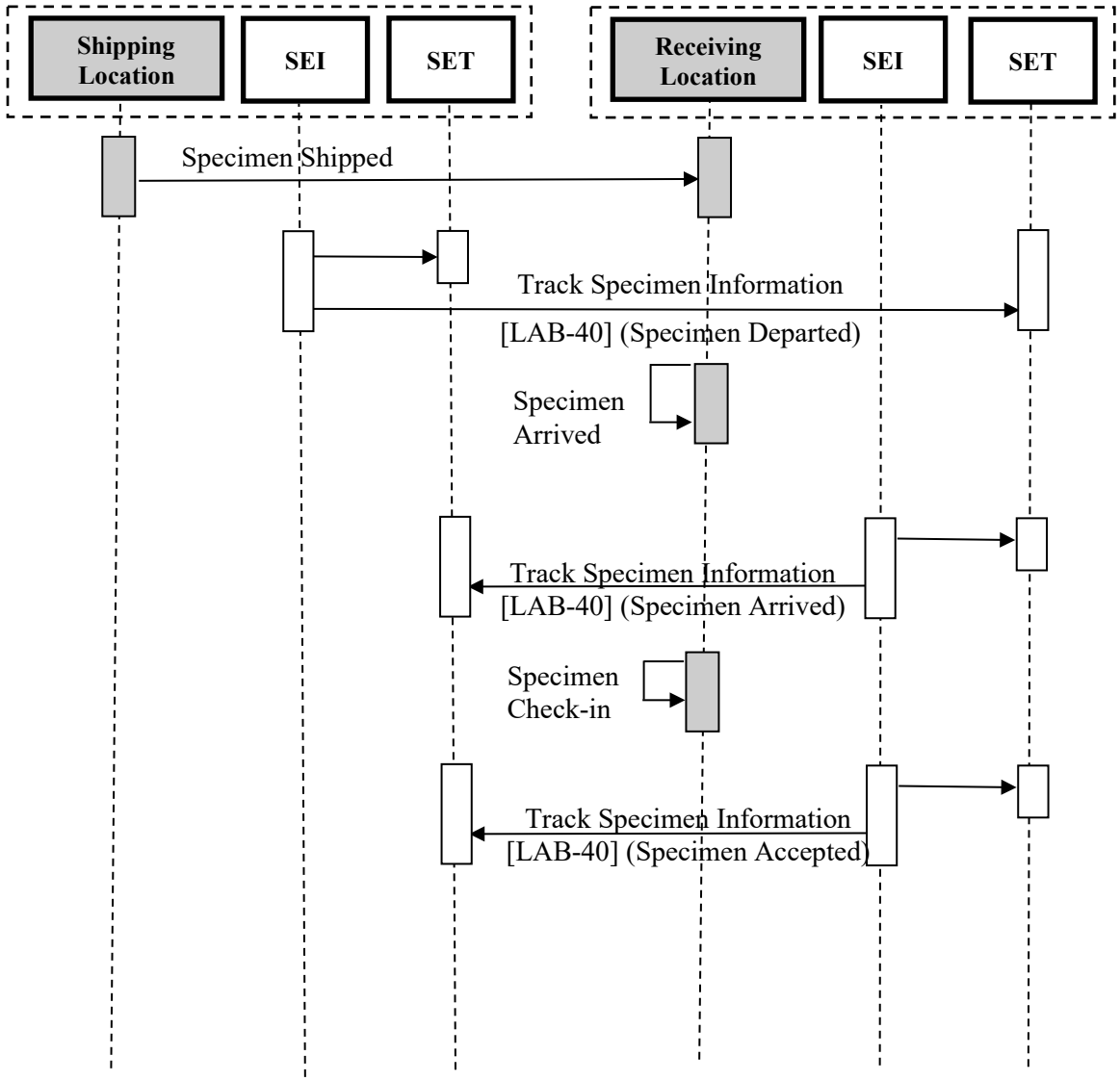
It may also happen that one or more specimens are refused by the receiving location (due to insufficient sample quantity, inappropriate or broken container, etc.).

For these reasons, this use case is sub-divided into three different process flows:

1. Specimen transferred, no re-identification by receiver
2. Specimen transferred and re-identified by receiver
3. Specimen rejected by receiver

The following sections analyze each sub-use case, showing the related sequence diagram. As the sending and receiving locations could belong to different organizations, the diagrams suppose that each organization has its own SEI and SET actors. This is only one of the possible architectures, as the same diagrams may be depicted with a unique instance for SEI and SET, as it would be common to happen in case of intra-organization transfer. The diagrams show each single event being sent to both SET actors. There might be variations to that: some of the events might interest only one of the two organizations (for example, a re-identification event might interest only the receiver's local SET). Each diagram below only refers to an example of possible architecture.

X.4.2.2.1.1 Specimen transferred, no re-identification by receiver process flow



535 **Figure X.4.2.2.1.1-1: Specimen transferred, no re-identification by receiver Basic Process Flow in SET Profile**

X.4.2.2.1.2 Specimen transferred and re-identified by receiver process flow

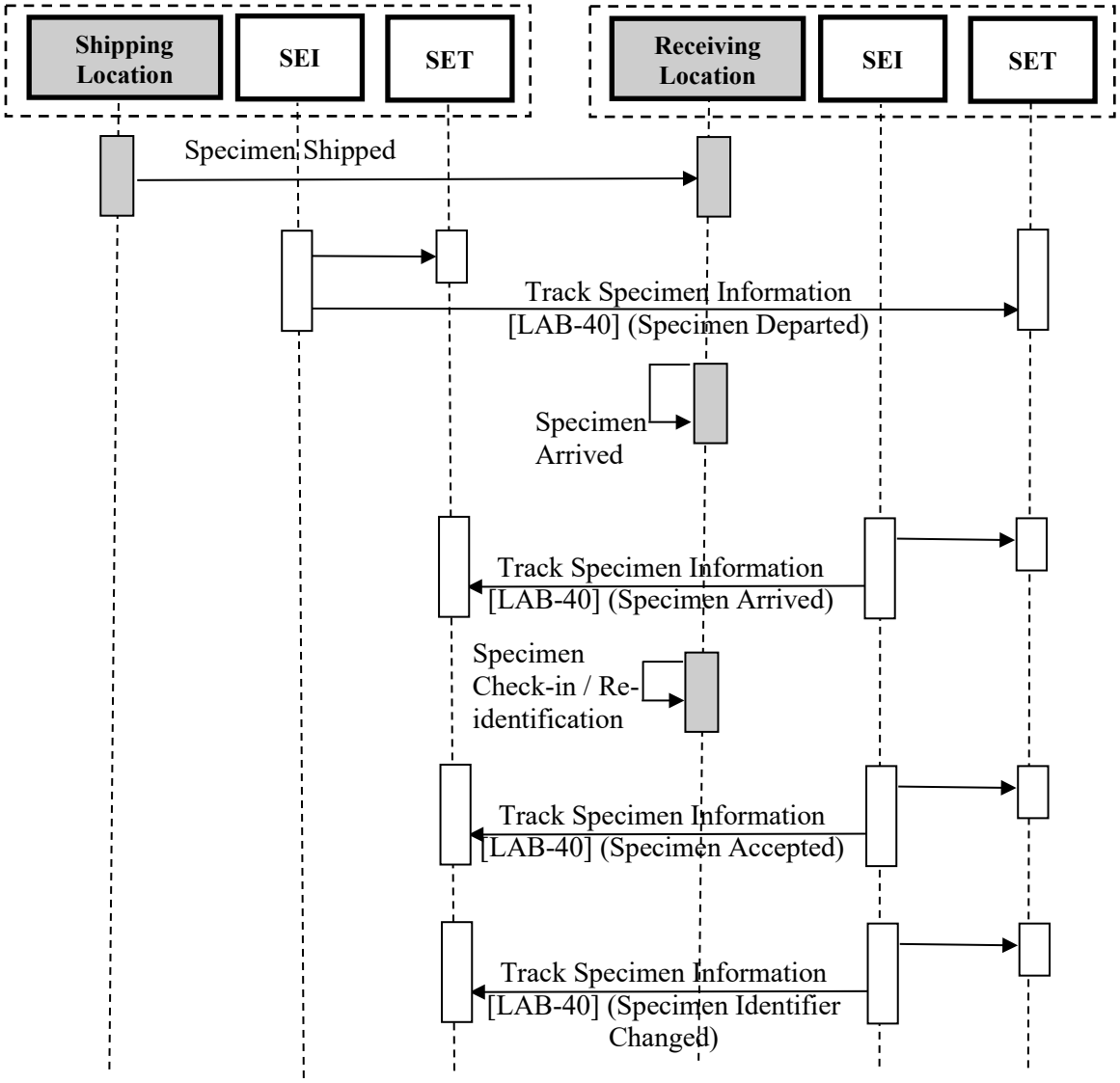


Figure X.4.2.2.1.2-1: Specimen transferred and re-identified by receiver Basic Process Flow in SET Profile

X.4.2.2.1.3 Specimen Rejected by Receiver Process Flow

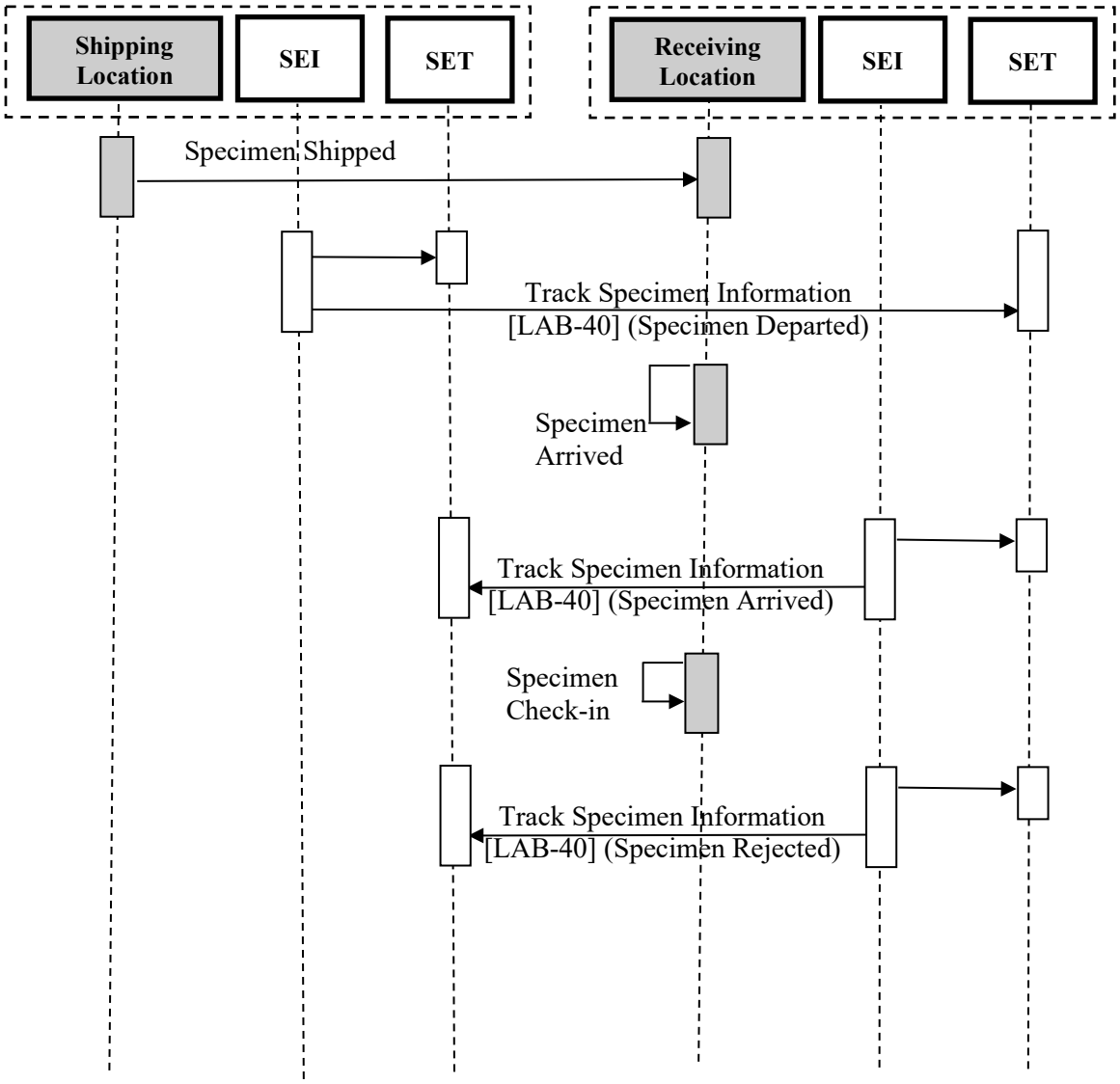


Figure X.4.2.2.1.3-1: Specimen rejected by receiver Basic Process Flow in SET Profile

X.4.2.3 Use case #3: Specimen tracking within the Laboratory

545 This use case tracks all the events on the specimen during the overall testing process involving the specimen inside a laboratory. The tracked testing process can be a complete examination procedure or a part of it. The term “laboratory” is intended a generic testing location which can be, for example, both a clinical laboratory and an anatomical pathology facility.

X.4.2.3.1 Specimen tracking within the Laboratory description

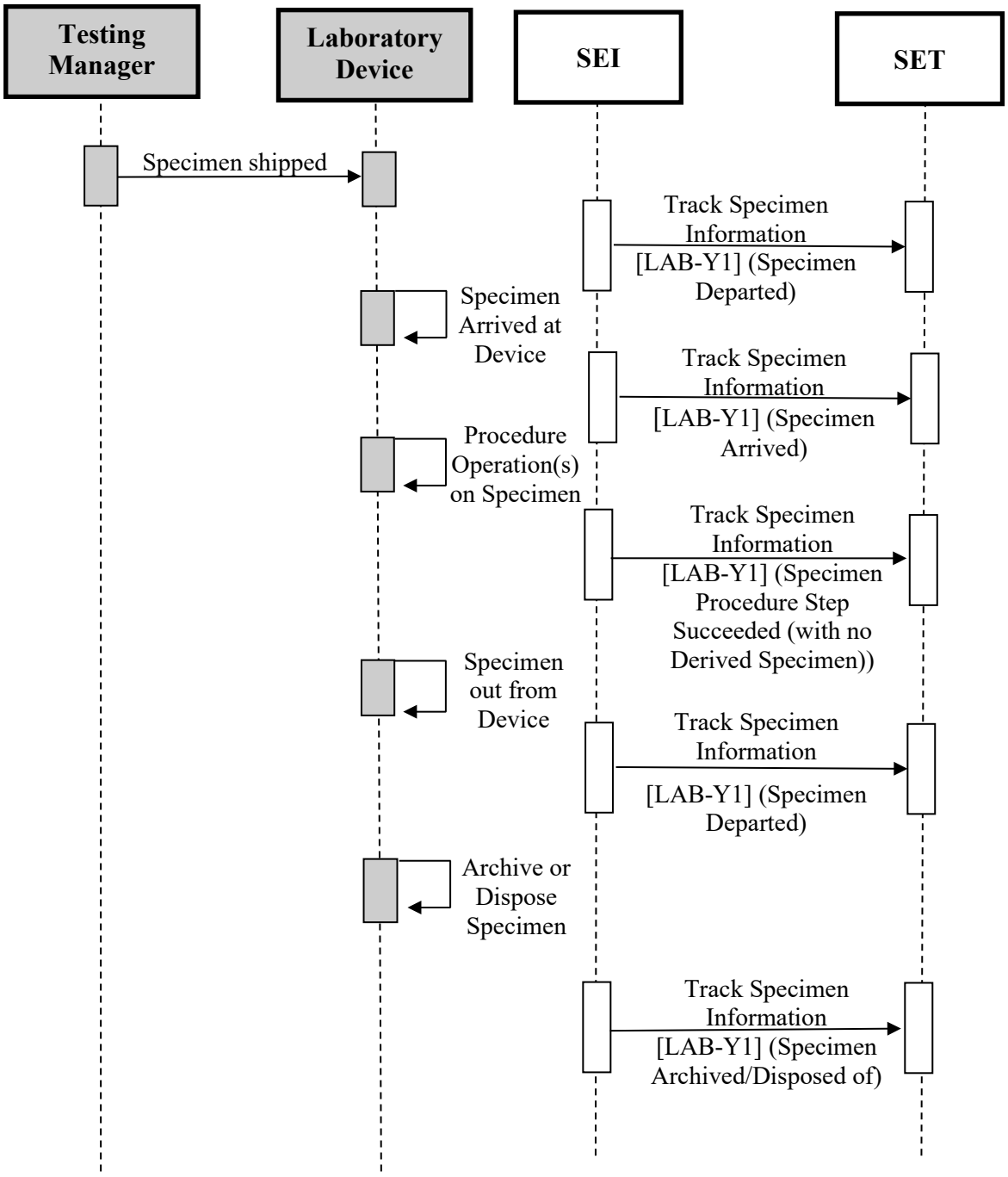
The process itself can be more or less automatized, if the location is provided with an automatized system, complete or partial, or not. Only the main events are in scope of this profile; in case of automation presence, the tracking of the specimen inside the automation itself is covered by other profiles (for example, in the context of Laboratory IVD testing, it is covered by Laboratory Testing Handoff). The processes addressed by this use case may include a derivation of the specimen, or not: this result is tracked by SET Profile defining two specific events, described later in details.

The overall tracking for this use case focusses on these events:

1. The testing manager (a person or a machine) sends the specimen for testing;
2. The specimen arrives at a Laboratory Device: this role may be played by a machine (e.g., Centrifugation) or by a working station handled by an operator (e.g., Specimen grossing station);
3. One or more procedure step is executed, according to the specific testing workflow. If this step generates a derived specimen, a specific SET event is used to track this situation (see sequence diagrams in Figure X.4.2.3.2-1 and Figure X.4.2.3.3-1);
4. The specimen - or each of the resulting derived specimen - is archived or disposed of at the end of the chain of the procedure steps.

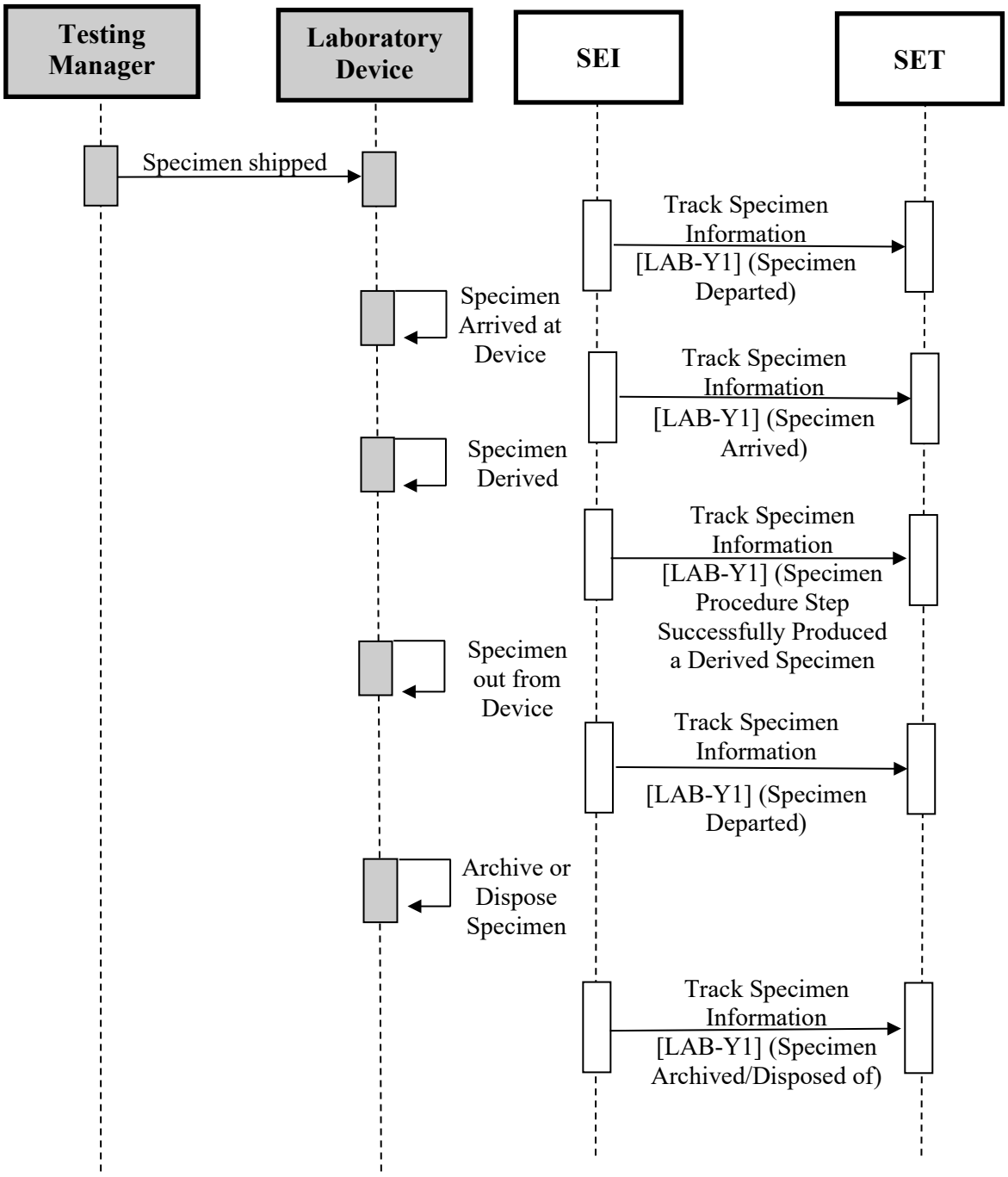
Notice that the steps 2) and/or 3) may be repeated n times, according to the number of the required procedure steps. For example, in IVD testing we may have Centrifugation, Aliquoting, Testing on 3 different analyzers, and so on; in the context of Anatomic Pathology we may have Grossing, Staining, and so on.

X.4.2.3.2 Specimen tracking within the Laboratory with no derived specimens Process Flow



575 **Figure X.4.2.3.2-1: Specimen tracking within the Laboratory with no derived Specimens Basic Process Flow in SET Profile**

X.4.2.3.3 Specimen tracking within the Laboratory with derived specimens Process Flow



580

Figure X.4.2.3.3-1: Specimen tracking within the Laboratory with derived Specimens Basic Process Flow in SET Profile

X.4.2.4 Use case #4: Biobank Specimen Tracking

This use case addresses the tracking of specimens in relation to the movement from/to a biobank.

X.4.2.4.1 Biobank Specimen Tracking description

Biobank workflows and processes vary depending on the research the specific biobank is focused on. Usually biobanks are managed by some reference laboratories, which are hosting them and, in most cases, belong to university research departments.

Several research studies for diseases like cancer, for example, identify a group of volunteers that consent to participate in the research program and to allow collection of one or more samples for the biobank storage. All specimens are shipped to the central laboratory, where technicians process them. At the arrival, the specimen is accepted, identified and archived inside the biobank. When the specimen is required for analysis (selected on query parameters such as class of patients, class of disease, etc.), it is retrieved from the biobank and a new specimen is derived from the original one in order to perform the required tests. This derived specimen is associated to a different container, and then accepted, identified and archived inside the biobank. The original specimen is also archived back inside the biobank, updating some important information as, for example the sample quantity remaining. The SET Profile identifies three use cases involving biobanks:

1. Specimen collected in a laboratory and shipped to biobank;
2. Specimen retrieved from biobank for immediate testing;
3. Specimen retrieved from biobank for testing preparation.

There are two main information flows related to the Use Cases above: the first flow is related to sample physical transport, while the second is related to any additional information provided for that sample (clinical_ID, pathology, additional information about the individual and so on). This Use Case is focused only on specimen physical tracking.

X.4.2.4.2 Specimen Shipped to Biobank

The use case starts with one of the federated biobank laboratories that collects a specimen for research purposes from a consenting patient. The specimen is collected at one of the federated biobank laboratories, and then shipped to the biobank site, where it is re-identified, according to the biobank information system, and archived for future usage. There are two main cases:

1. The biobank is not allowed to know clinical_ID and clinical data;
2. The biobank is allowed to know clinical_ID and clinical data.

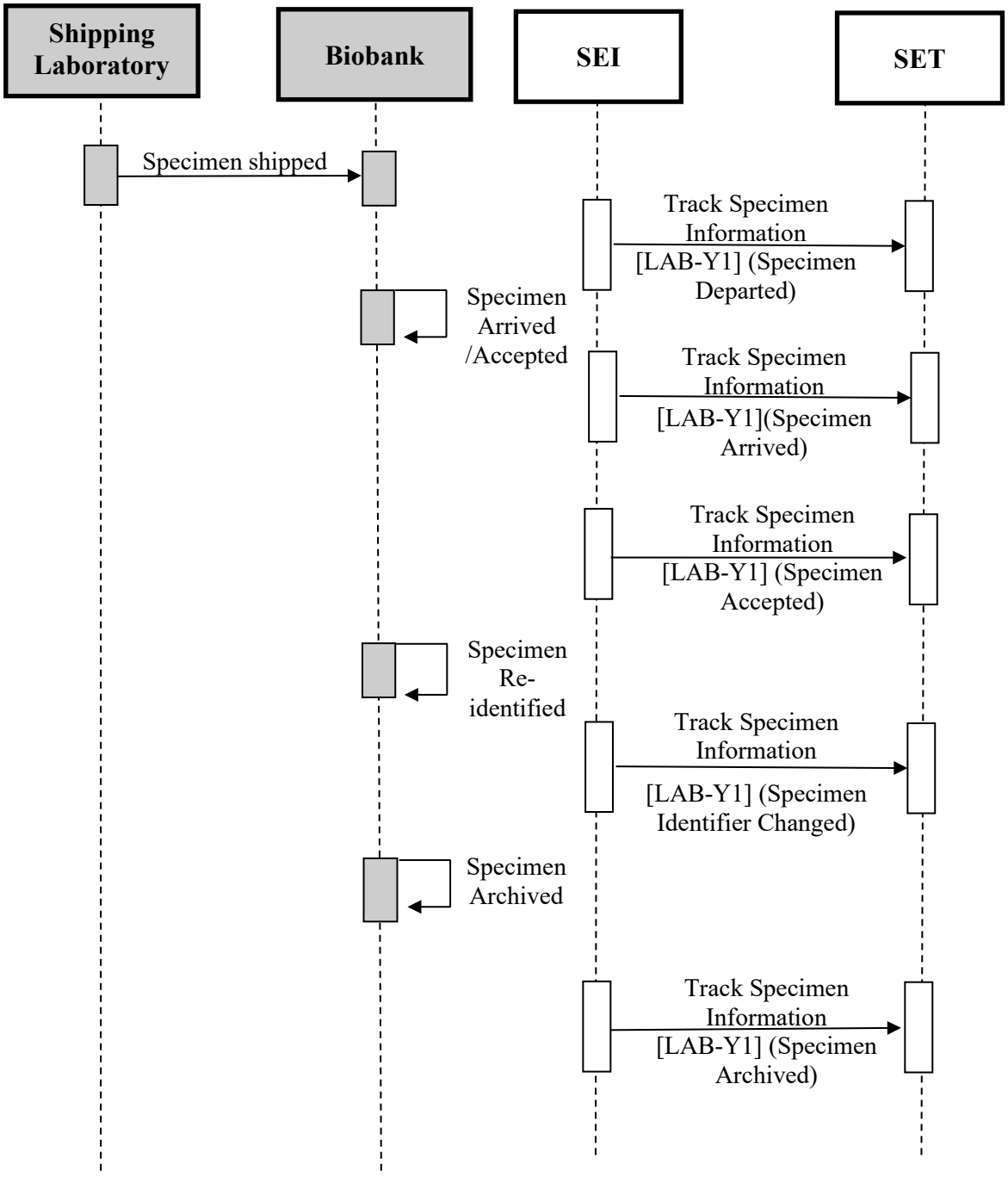
In the first case, sample de-identification occurs before the sample is shipped from the laboratory to the biobank and only the laboratory will keep track of the link between clinical_ID and biobank_ID. When the sample is requested for a trial, the biobank will never be able to provide the clinical information as it hasn't it since the sample arrival in the biobank.

In the second case, when the sample is re-identified in the biobank information system, which creates the biobank_ID and assigns it to the sample, both clinical_ID and clinical information are stored in the biobank information system, as metadata associated to the sample. When the sample is requested for a trial, the biobank will provide also the clinical information only if the study protocol allows the use of this kind of information. If the study protocol doesn't allow the use of the clinical information associated to the sample, the biobank information system will have to de-identify the sample, protecting all confidential clinical information.

The use case assumes that the specimen is always re-identified in the biobank information system, even if it already has knowledge of the ID previously assigned by the collecting laboratory. Anyway, the link between the laboratory assigned ID and the new biobank ID of the specimen is always maintained: in the first case, only by the clinical laboratory, in the second case both by the laboratory and the biobank. From the point of view of the events to track, in both cases we can identify these five below:

1. The specimen is collected at the federated laboratory research site;
2. The specimen is shipped to the biobank site;
3. The specimen arrives at the biobank site;
4. The specimen is accepted and re-identified at the biobank site: the re-identification is tracked by a generic “Specimen Identifier Changed” message. Only the changed identifier is tracked by the SET Profile. Keeping the link between previous and changed identifier is out of scope for SET;
5. The specimen is archived for further use.

X.4.2.4.2.1 Specimen Shipped to Biobank Process Flow



640

Figure X.4.2.4.2.1-1: Specimen shipped to Biobank Basic Process Flow in SET Profile

X.4.2.4.3 Specimen retrieved from Biobank for immediate testing

In this scenario, a query is executed to retrieve one or more specimens from a biobank for immediate testing. Specimens have previously been stored in the biobank with an assigned biobank_ID.

If the biobank is not allowed to maintain clinical_ID and clinical data, this information cannot be provided at specimen retrieval.

If the biobank is allowed to maintain clinical_ID and clinical data, a set of information regarding patient identifier, name, surname, date of birth, specimen type, related patient disease is also known by the biobank, and can be provided to the requester only if the study protocol allows the use of this kind of information. If the study protocol doesn't allow the use of the clinical information associated to the sample, the biobank information system will have to de-identify the sample, protecting all confidential clinical information.

Each of the retrieved specimens is always derived in order to obtain a new specimen that will be used to perform all the required tests: the derivation operation implies the labeling, and consequently the identification, of the derived specimens. The new specimen is immediately identified and accepted in the biobank information system before tests execution. It is very important that the original specimens are archived back to the biobank as soon as possible, updating some important information as the sample remaining quantity. In this use case the derived specimens will be immediately used for testing. After the testing, the specimen can be archived back in the biobank or marked as exhaust if all the sample quantity has been used for testing or if testing itself makes the derived specimen not usable anymore.

From the point of view of the SET Profile, this use case will track these specimen states:

1. The specimen is retrieved from the biobank;
2. The specimen for testing is derived from the retrieved specimen. If the study protocol doesn’t allow the use of the clinical information associated with the retrieved specimen, the derived specimens are de-identified. The de-identification is tracked by a generic “Specimen Identifier Changed” message. Only the changed identifier is tracked by the SET Profile. Keeping the link between previous and changed identifier is out of scope for SET;
3. The derived specimen is accepted;
4. The retrieved specimen is archived again in the biobank. It is very important to update the specimen status: after derivation the specimen can be usable, exhaust, not valid;
5. Tests are performed on the derived specimen.

X.4.2.4.3.1 Specimen retrieved from Biobank for immediate testing Process Flow

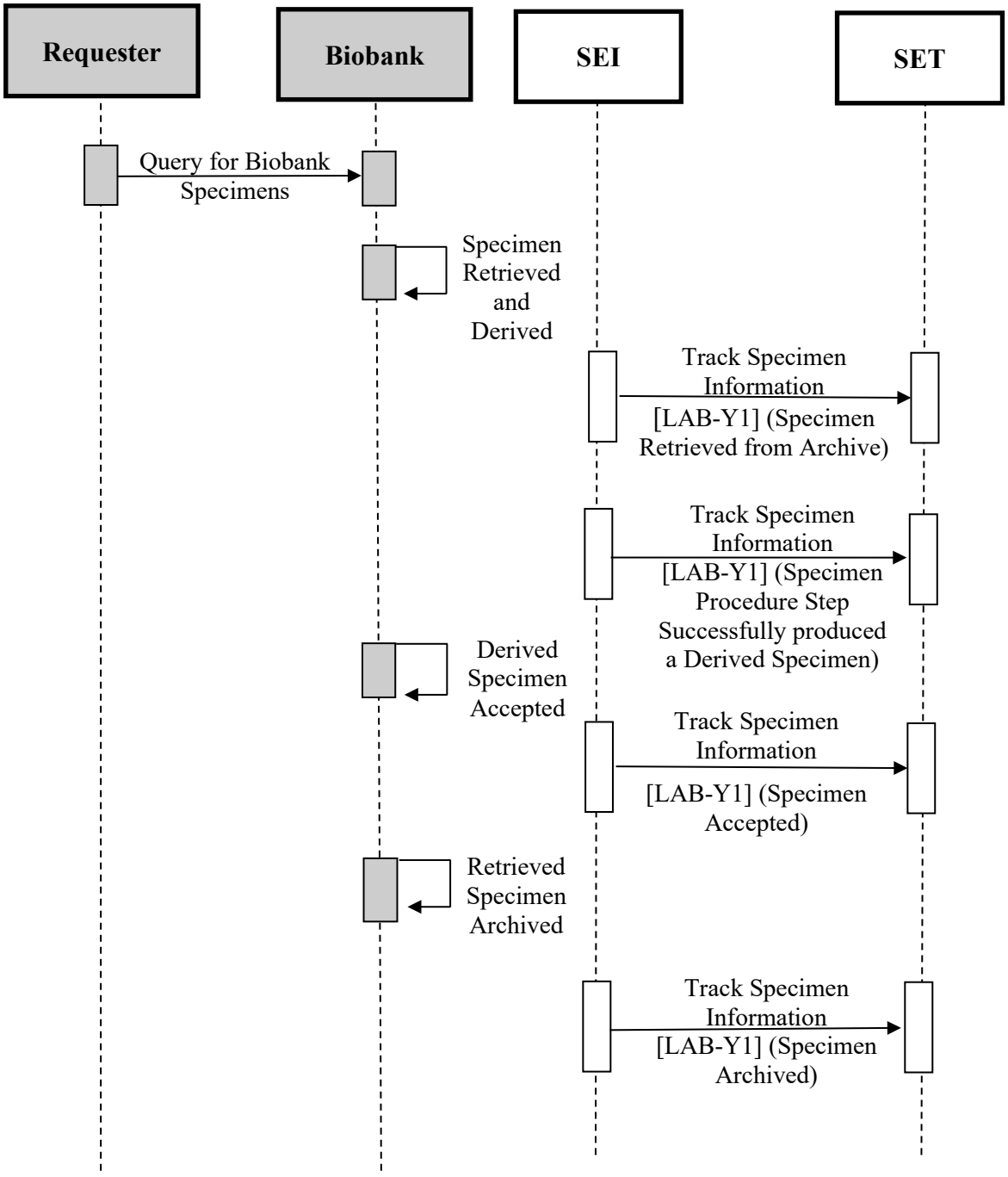
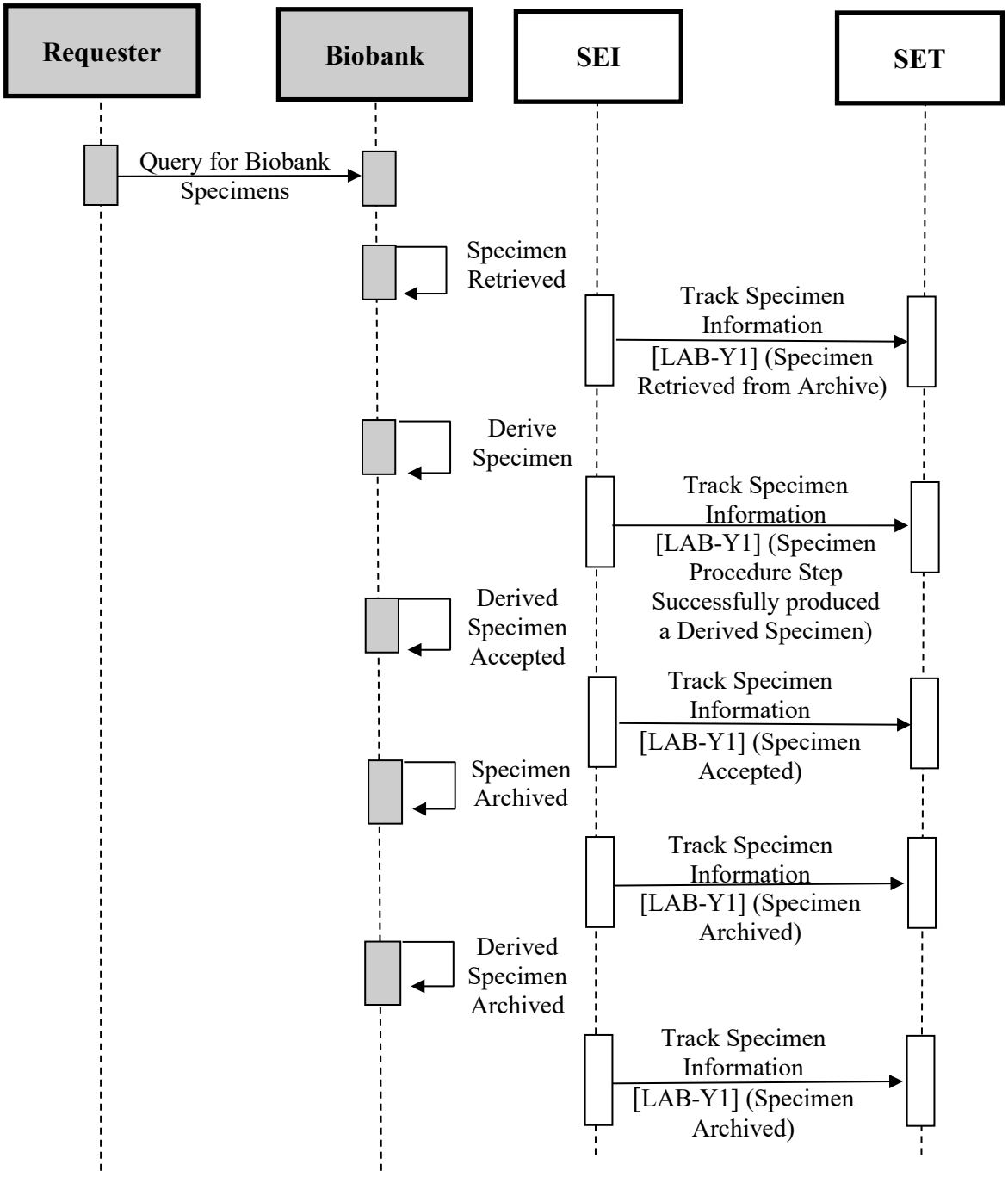


Figure X.4.2.4.3.1-1: Specimen retrieved from Biobank for immediate testing Basic Process Flow in SET Profile

X.4.2.4.4 Specimen retrieved from Biobank for testing preparation

This use case is similar to the previous one, but the derived specimen is not immediately sent for testing, but it is archived in the biobank for further use. For example, such a situation can occur when from a blood sample, retrieved from a biobank, a series of derived DNA extraction specimens are archived to be ready for further testing. As for the previous use case, if the study protocol doesn't allow the use of the clinical information associated with the retrieved specimen, the derived specimens are de-identified.

X.4.2.4.4.1 Specimen retrieved from Biobank for testing preparation Process Flow



690

Figure X.4.2.4.4.1-1: Specimen retrieved from Biobank for testing preparation Basic Process Flow in SET Profile

X.4.3 Examples of Use Cases Specialization

This section reports some specialized sequence diagrams, showing how SET Profile acts in the context of other profiles' use cases.

The following subsections show these three examples of specialization:

1. In the context of LBL Profile (LAB-62): tracking of specimen containers production and specimen collection;
2. In the context of ILW Profile: tracking of specimen movement and acceptance from requester facility to subcontractor facility;
3. In the context of LDA: tracking of specimen movement and pre-processing between Automation Manager and Laboratory Device.

X.4.3.1 Use Case Specialization #1: Specimen containers production and collection tracking, in the context of LBL Profile

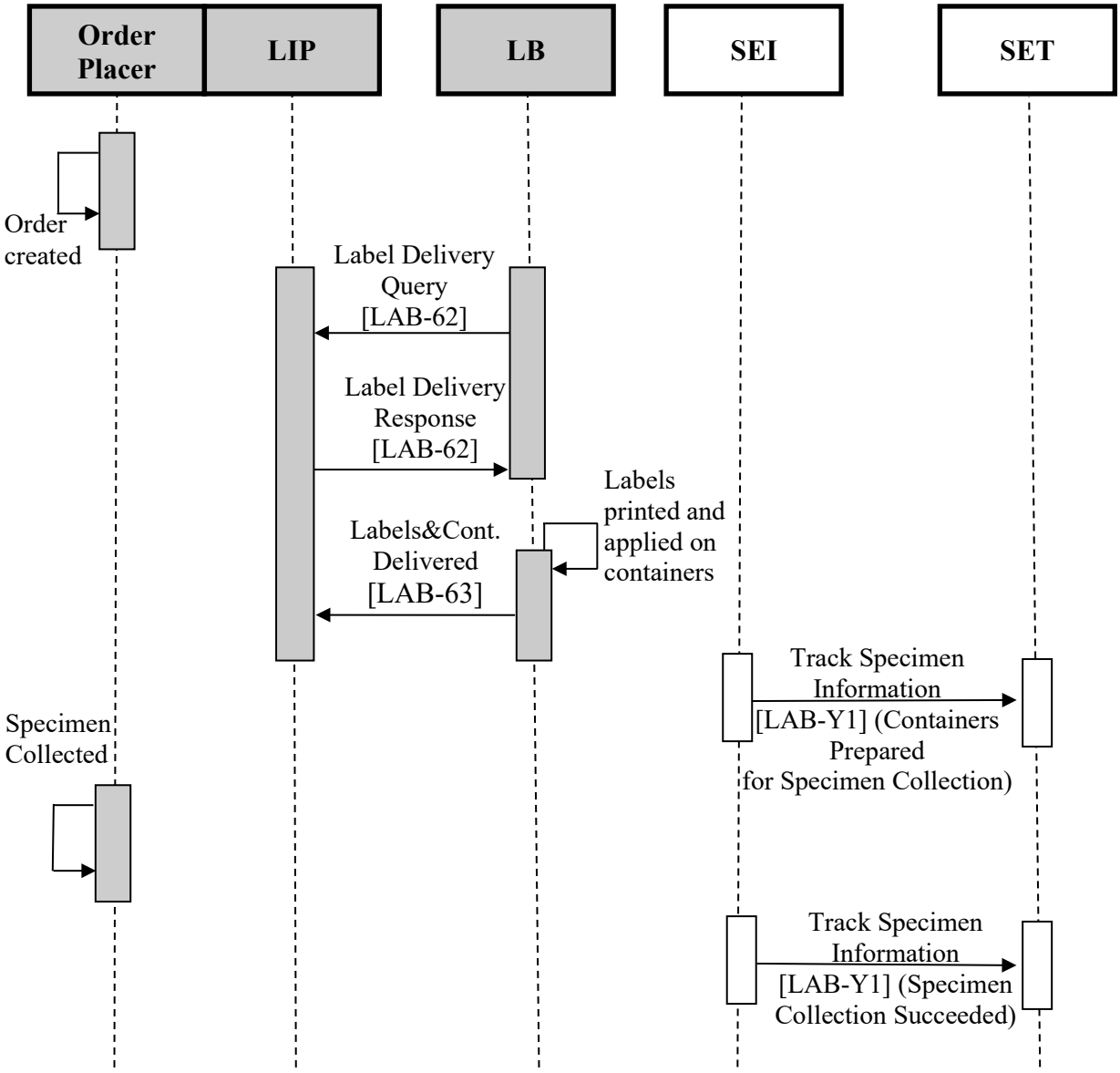
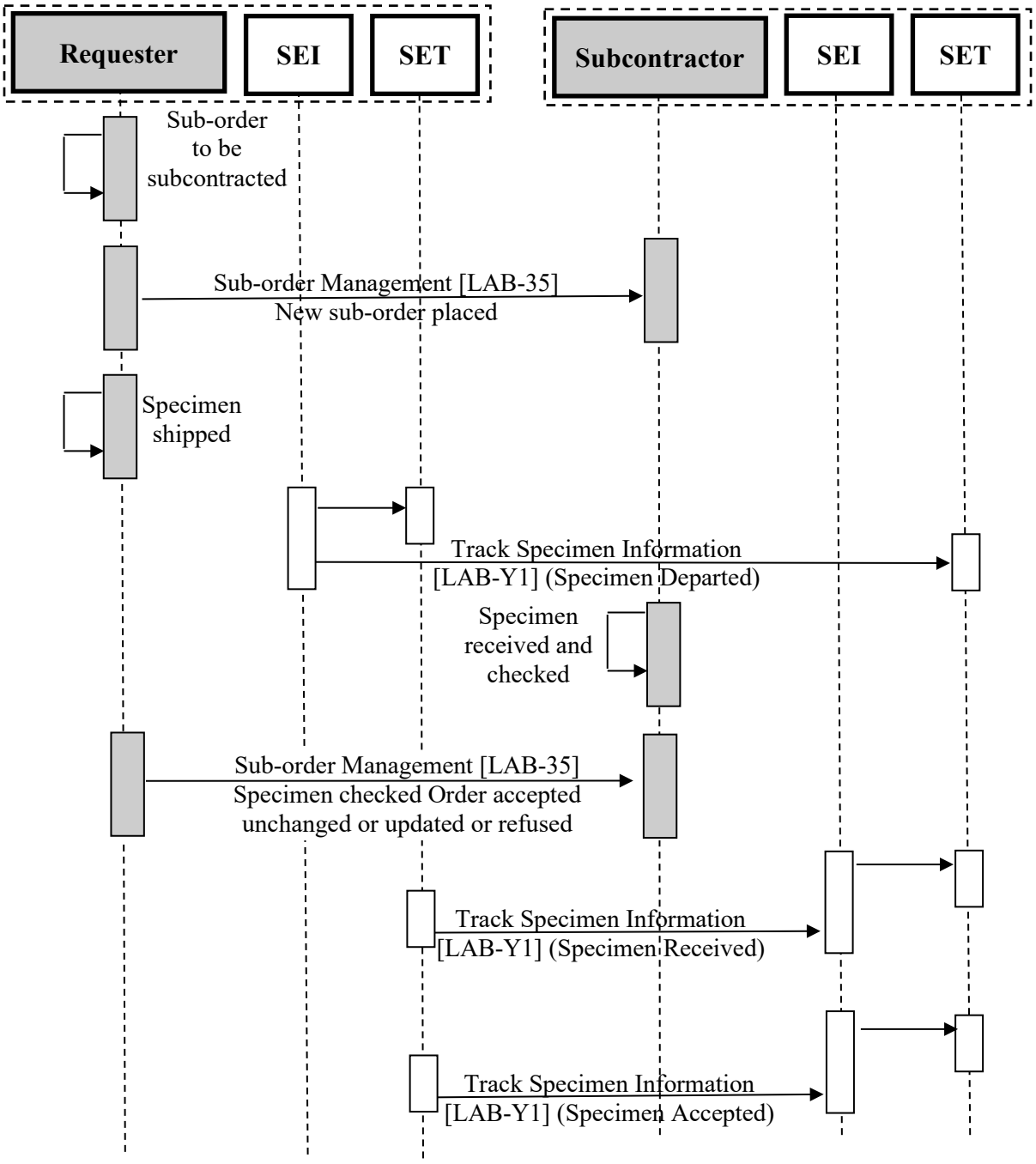


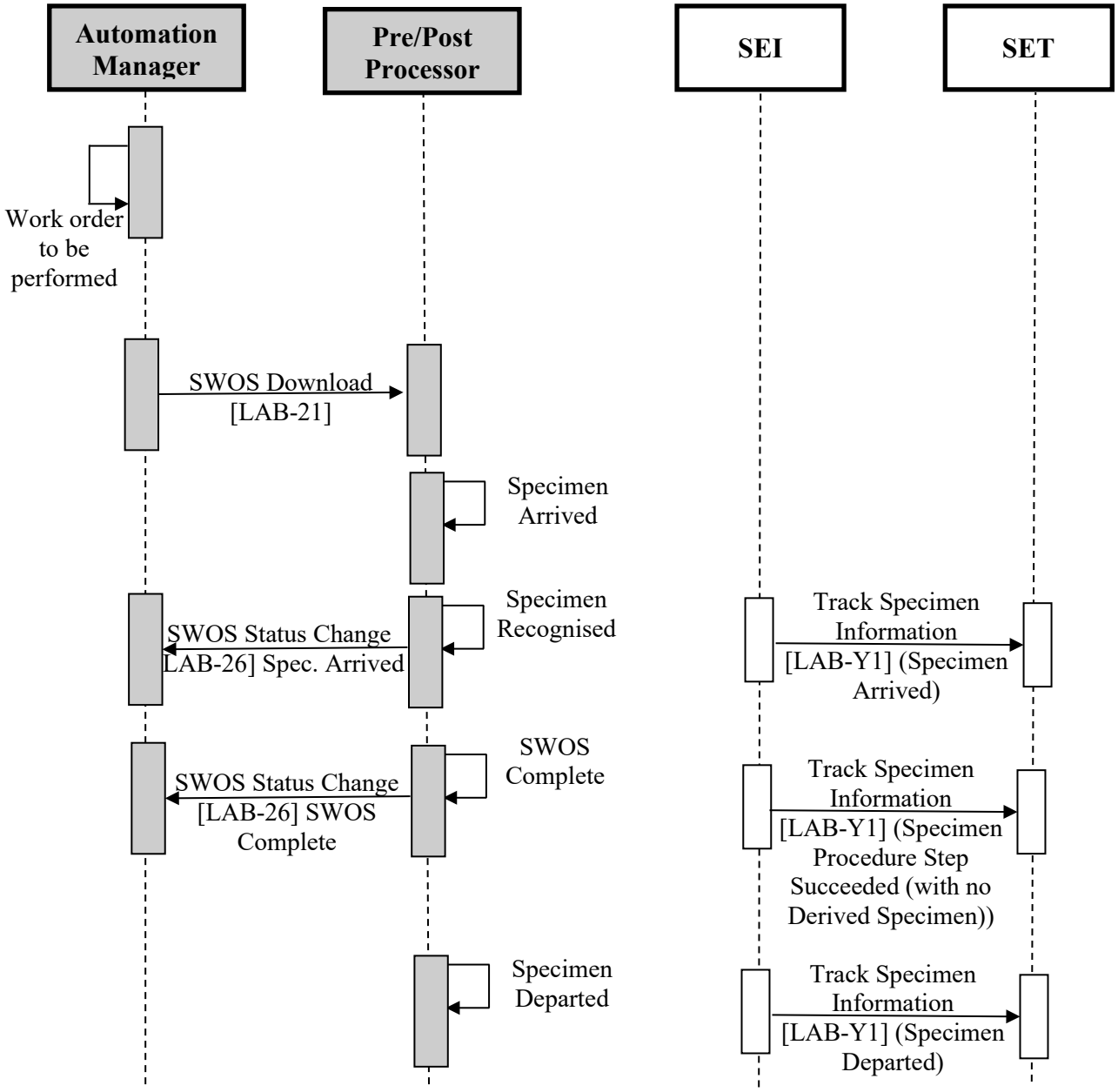
Figure X.4.3.1-1: Use case specialization #1 – Specimen containers production and collection tracking in the context of LBL Profile Basic Process Flow in SET Profile

X.4.3.2 Use Case Specialization #2: Specimen movement and acceptance tracking, in the context of ILW Profile



715 **Figure X.4.3.2-1: Use case specialization #2 – Specimen movement and acceptance tracking, in the context of ILW Profile Basic Process Flow in SET Profile**

X.4.3.3 Use Case Specialization #3: Specimen movement and pre-processing tracking, in the context of LDA Profile



720

Figure X.4.3.3-1: Use case specialization #3 – Specimen movement and pre-processing tracking, in the context of LDA Profile Basic Process Flow in SET Profile

X.5 SET Security Considerations

NA

X.6 SET Cross Profile Considerations

A Label Broker in Laboratory specimen Barcode Labeling (LBL) might be grouped with a Specimen Event Informer (SEI) to track the event of delivery of labeled containers.

An Order Filler in Laboratory Testing Workflow (LTW) might be grouped with a Specimen Event Informer (SEI) to track the event of successful specimen collection.

A Requester in Inter Laboratory Workflow (ILW) might be grouped with a Specimen Event Informer (SEI) to track successful departure of specimens.

A Sub-contractor in Inter Laboratory Workflow (ILW) might be grouped with a specimen event informer to track specimen arrival, acceptance, rejection and identifier changing of specimens.

A Pre/Post-processor in Laboratory Device Automation (LDA) might be grouped with a Specimen Event Informer to track arrival, departure and procedure step successfully executed with or without derived specimen.

An Analyzer in Laboratory Analytical Workflow (LAW) might be grouped with a Specimen Event Informer to track arrival, departure and procedure step successfully executed, without a derivation of the specimen.

An Analyzer Manager in Laboratory Analytical Workflow might be grouped with a Specimen Event Informer to track specimen archiving and final disposure.

Every one of these cross-Actors listed above could potentially play also the role of Specimen Event Tracker. Grouping decisions between SET and other external profiles actors are out of scope for this profile.

Appendices to Volume 1

None

Volume 2 – Transactions

Add Section 3.Y

3.Y Track Specimen Information [LAB-40]

3.Y.1 Scope

This transaction is used to track specimen information events from a Specimen Event Informer (SEI) to a Specimen Event Tracker (SET). Each event reflects a specific macro-activity on the specimen, occurred during its lifecycle.

When one of the macro-activities to be tracked occurs, the SEI creates the related event and sends it to one or more trackers (SETs), depending on how much SETs, in relation to a specific use case, are interested to receive the tracking of this event.

As a response to the tracking message sent by the SEI, the SET sends a positive acknowledgement or a negative acknowledgement in case of error of integration of the received event. In case of negative acknowledgement, the SEI may decide to correct and send again the same message to the SET. A resend is also performed in case of timeout (SET unreachable).

3.Y.2 Actor Roles

Table 3.Y.2-1: Actor Roles

Actor:	Specimen Event Informer
Role:	Provides and sends Specimen Event Tracking events
Actor:	Specimen Event Tracker
Role:	Receives and collects Specimen Event Tracking events

3.Y.3 Referenced Standards

- HL7 Version 2.9 (Change request for new message types)

3.Y.4 Messages

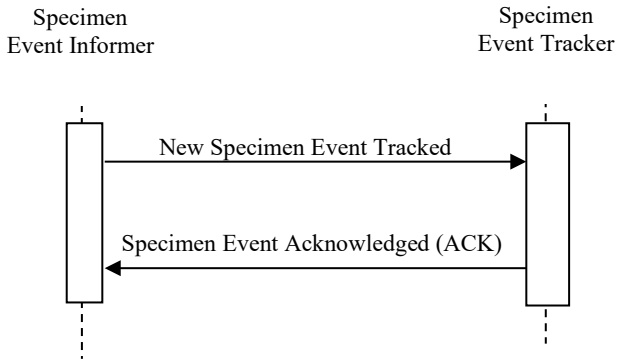


Figure 3.Y.4-1: Interaction Diagram

3.Y.4.1 SET Profile Message and Acknowledgement

All tracking messages sent by a SEI refer to a specific macro activity and a specific event. A complete list of all the events a SEI is able to send, is described in Table X.4.1.1-1. These events differ from one another by their specific event code and by the detailed information associated with the event. For example, information required for the "Specimen Collection Succeeded" event differs from the information required for "Specimen Collection Failed" or from "Specimen Procedure Step Successfully Produced a Derived Specimen".

Each kind of event is mapped to a specific HL7 v2.x message type and trigger event.

3.Y.4.2 SET Events and trigger messages mapping

The following table identifies the trigger events and message types for each of the specimen events listed in Table X.4.1.1-1. Some events have been grouped, as they can refer to the same message structure (almost same metadata to be carried by the message). [1]

Table 3.Y.4.2-1: SET events and triggers summary table

Category of SET Events	SET Events	MSH-9.2 (Trigger Event)	MSH-9.3 (Message Structure)	ACK
Tracking specimen container preparation and specimen collection events	Containers Prepared For Specimen Collection	S38	SET_S38	ACK^S38^ACK
	Specimen Collection Succeeded	S39	SET_S38	ACK^S39^ACK
	Specimen Collection Failed	S40	SET_S40	ACK^S40^ACK
Tracking specimen movements events	Specimen Departed	S41	SET_S41	ACK^S41^ACK
	Specimen Arrived	S42	SET_S41	ACK^S42^ACK
	Specimen Accepted	S43	SET_S41	ACK^S43^ACK

[1] All the messages shown in the table refer to a CR discussed with the HL7 Orders and Observations workgroup.

Category of SET Events	SET Events	MSH-9.2 (Trigger Event)	MSH-9.3 (Message Structure)	ACK
	Specimen Rejected	S44	SET_S41	ACK^S44^ACK
	Specimen Archived	S46	SET_S41	ACK^S46^ACK
	Specimen Retrieved from Archive	S47	SET_S41	ACK^S47^ACK
	Specimen Disposed Of	S48	SET_S41	ACK^S48^ACK
Tracking specimen identification events	Specimen Identifier Changed	S45	SET_S45	ACK^S45^ACK
Tracking specimen processing events	Specimen Procedure Step Successfully Produced a Derived Specimen	S49	SET_S49	ACK^S49^ACK
	Specimen Procedure Step Succeeded (with no derived specimen)	S50	SET_S49	ACK^S49^ACK
	Specimen Procedure Step Failed	S51	SET_S51	ACK^S51^ACK

As this table shows, there are four major categories of events and six different HL7 message structures (MSH-9.3):

1. Tracking specimen container preparation and specimen collection events leverages two message structures:
   a. SET_S38, with trigger events S38 (Containers Prepared for Specimen Collection), S39 (Specimen Collection Succeeded);
   b. SET_S40, with trigger event S40 (Specimen Collection Failed).
2. Tracking specimen movement events, leverages one message structure, SET_S41, with trigger events S41 (Specimen Departed), S42 (Specimen Arrived), S43 (Specimen Accepted), S44 (Specimen Rejected), S47 (Specimen Archived), S48 (Specimen Retrieved from Archive) and S49 (Specimen Disposed Of).
3. Tracking specimen identification events leverages one message structure, SET_S45, with the only one trigger event S45 (Specimen Identifier Changed).
4. Tracking specimen processing events leverages two message structures:
   a. SET_S49, with trigger events S49 (Specimen Procedure Step Succeeded (with derived specimens)) and S50 (Specimen Procedure Step Succeeded (with no derived specimens));
   b. SET_S51, with trigger event S51 (Specimen Procedure Step Failed).

In the following table, are listed all the common metadata for all the structures.

Table 3.Y.4.2-2: SET events common metadata mapping to HL7 v2

SET Event Attribute	Matching HL7 V2 field
Specimen event tracked	MSH-9.1 Message code fixed to "SET"
Event Type	MSH-9.2 Trigger event Snn (starting with first free slot: S38)
Event Registered Timestamp	EVN-2
Effective time of the event	EVN-6
Event Participant	PRT segment(s) following the EVN segment
Event Reason (A reason for this particular occurrence of the event)	EVN-4
Event ID	EVN-8 new element "Event Unique ID" to be added to EVN segment, datatype EI, optional, non-repeatable. Definition: The unique identifier for the occurrence of this event.
Specimen ID	SPM-2/SPM-3
Specimen Type	SPM-4
Specimen Container ID	SAC-3/SAC-4
Sending Organization	MSH-3
Sending Facility	MSH-4
Receiving Organization	MSH-5
Receiving Facility	MSH-6

NOTE: Almost all these fields SHALL be required. Concerning specimens and containers, the fields SPM-3 and SAC-4 refer respectively to the parent specimen and container identifiers. These two fields might not be always provided; they are required, for example, in case of a specimen derivation, because this event splits the chain of custody into several paths, and the information about parent specimen and container is crucial to backwardly reconstruct the chain itself.

Comments on usage of the EVN and PRT segments for tracking specimen events:

- Any event may convey a reason for the event, encoded in EVN-4. Given that table HL7 0062 is user defined, the SET Profile defines a value set of possible reasons for each type of event. For example a usual reason for the event type "Specimen collection succeeded" is 02 "Physician/health practitioner order". Another possible reason is PB "Patient consent to provide a specimen to a biobank". A frequent reason for "Specimen Collection Failed" is PR "Patient refusal".
- Since the HL7 Change Request is for an HL7 version >= 2.9, it plans to use the PRT segment following the EVN to capture event performer related information, which makes this a very flexible approach, as the performer could be a person or a device, and both of these can be associated with an organization.
- A new EVN-8 field has been added, as specified in the table above.

In the following sections, each trigger event is described in detail inside separate sections, keeping the order of the related structures listed above.

As described in Tables X.4.1.2-1 and X.4.1.2-2, each type of event has a set of attributes that are in common with all other events, and a set of specific attributes. Some of the common attributes (e.g., sending and receiving facility, trigger related to the event type) are carried by the MSH segment. The EVN segment is used to carry information specific to the event, for example the occurrence timestamp of the event and its reason.

The PRT segment provides information about the person/device/department responsible for the event. According to the event type, one or more PRT fields shall be required. Check the attribute matrix and the mapping information of each event type for additional information.

The Table 3.Y.4.2.2 reports the mapping between common (header) metadata and the correspondent SET^SXX fields. Logically, these fields are supported by ALL the structures of the message types listed in the table above. The mapping of the specific attributes, instead, is described inside the related subsection dedicated for each single message type, starting from the next section.

3.Y.4.3 SET^S38^SET_S38 (Containers prepared for specimen collection message)

This message tracks that one or more labeled containers have been prepared and delivered (by a human or by an automated device) for the intended collection of one or more specimens related to an order.

3.Y.4.3.1 Trigger Events

The occurrence of the “Containers Prepared for Specimen Collection” event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S38^SET_S38 message.

3.Y.4.3.2 Message Semantics

The structure of this message is the SET_S38, detailed in the following table.

Table 3.Y.4.3.2-1: SET_S38 message structure

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
EVN	Event Type	R	[1..1]	3
{PRT}	Participation (for Event type)	R	[1..*]	7
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen Information	R	[1..1]	7
[{	--- SPECIMEN_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Specimen)	R	[1..1]	7

Segment	Meaning	Usage	Card.	HL7 chapter
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- SPECIMEN_OBSERVATION end			
[{	--- CONTAINER begin	O	[0..*]	
{SAC}	Container Information	R	[1..*]	13
[{	--- CONTAINER_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Container Information)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- CONTAINER_OBSERVATION end			
}]	--- CONTAINER end			
[{	--- ORDER begin	O	[0..1]	
ORC	Order Common	R	[1..1]	4
OBR	Observation Request	R	[1..1]	4
}]	--- ORDER End			
}	--- SPECIMEN End			

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S38^SET_S38.

The containers are described by SAC segments attached to the SPM segments representing the specimens to be collected. PRT segments below the EVN segment provide information about the performer of this delivery.

At least one Specimen shall be carried by the message, while more than one Specimen (and related containers) can be carried for tracking by the same message. If the SEI knows the information about the order that triggered the preparation of the container(s), an ORC-OBR block can be used to track also this information.

When the ORC segment is populated, the ORC-1 field shall be valued with “SC” (Status Changed).

The following table explains the mapping between the metadata related to the Containers prepared for specimen collection events and the mapping SET^S38^SET_S38 message segments/fields.

Table 3.Y.4.3.2-2: Containers prepared for specimen collection event metadata to SET^S38^SET_S38 message segments/fields mapping

Event field	SET_S38 Mapping
Placer Order Number	ORC-2, OBR-2 (Required if Available)
Placer Group Number	ORC-4 (Required if Available)
Filler Order Number	ORC-3, OBR-3 (Required if Available)
Test	OBR-4 (Required if Available)

Event field	SET_S38 Mapping
Producer/Producer Type	It is described in either PRT-5 (Person), PRT-7 (Organization Unit Type), PRT-8 (Organization), PRT-9 (Location), PRT-10 (Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "CPE" (Containers Preparation Entity)
Container Name (Type)	SAC-49 (Required if Available)
Container Material/Additive	SPM-27 (Optional, Change name in progress)
Container Capacity	SAC-21 (Optional)
Number of specimen containers	SPM-26 (Required if Available)
Container Height	SAC-16 (Optional)

3.Y.4.3.3 Expected Actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S38^SET_S38 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.4 SET^S39^SET_S38 (Specimen collection succeeded message)

This message tracks the successful collection of one or more specimens.

3.Y.4.4.1 Trigger Events

The occurrence of a Specimen Collection Succeeded event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S39^SET_S38 message.

3.Y.4.4.2 Message Semantics

The structure of this message is the SET_S38 one. See Table 3.Y.4.3.2.1-1 for details.

The collected specimens and related containers are described by SPM and SAC segments. PRT segments below the EVN segment provide information about the performer of specimen collection.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S39^SET_S38.

At least one Specimen shall be carried by the message, while more than one Specimen (and related containers) can be carried for tracking by the same message. If the SEI knows the information about the order that triggered the preparation of the container(s), an ORC-OBR block can be used to track also this information. When the ORC segment is populated, the ORC-1 field shall be valued with “SC” (Status Changed).

The following table explains the mapping between the metadata related to the Specimen Collection Succeeded event and the mapping SET^S39^SET_S39 message segments/fields.

Table 3.Y.4.4.2-1: Specimen collection succeeded event metadata to SET^S39^SET_S38 message segments/fields mapping

Event field	SET^S42 Mapping
Placer Order Number	ORC-2, OBR-2 (Required if Available)
Placer Group Number	ORC-4 (Required if Available)
Filler Order Number	ORC-3, OBR-3 (Required if Available)
Test	OBR-4 (Required if Available)
Collector	It is described in either PRT-5 (Person), PRT-7 (Organization Unit Type), PRT-8 (Organization), PRT-9 (Location), PRT-10 (Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 Participation), that shall be valued with "CE" (Collection Entity)
Description	SPM-14 (Optional)
Procedure	SPM-7 (Optional)
Coll. Date Range	SPM-17 (Required if Available)
Container Name (Type)	SAC-49 (Required if Available)
Container Material/Additive	SAC-27 (Optional, Change name in progress)
Container Capacity	SAC-21 (Optional)
Number of specimen containers	SPM-26 (Optional)
Container Height	SAC-16 (Optional)
Expiration Time	SPM-19 (Required)

3.Y.4.4.3 Expected Actions

As soon as the “Specimen Collection Successful” event occurs, the SEI Actor will send to the SET Actor a SET^S39^SET_S38 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.5 SET^S40^SET_S40 (Specimen collection failed message)

This message tracks the failed collection of one or more specimens.

3.Y.4.5.1 Trigger events

The occurrence of a “Specimen Collection Failed” event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S40^SET_S40 message.

3.Y.4.5.2 Message semantics

The structure of this message is the SET_S40, defined in the following table:

Table 3.Y.4.5.2-1: SET_S40 message structure

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
EVN	Event Type	R	[1..1]	3
{PRT}	Participation (for Event type)	R	[1..*]	7
{	--- ORDER begin	R	[1..1]	
ORC	Order Common	R	[1..1]	4
OBR	Observation Request	R	[1..1]	4
}	--- ORDER End			

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S40^SET_S40.

In case of failed specimen collection, no information about the involved specimen is provided. This event is the only one where it is not mandatory to provide at least the main information of the specimen (i.e., specimen ID, container ID). The related order will be the only link available to reconstruct the traceability chain.

The PRT segment provides participation information about the performer of the specimen collection. The non-collected specimens and related containers are described by SPM and SAC segments. PRT segments below the EVN segment provide information about the performer of specimen collection.

EVN-4 can be used to track the reason for failed specimen collection.

The ORC segment is mandatory for this message; the ORC-1 field shall be valued with “SC” (Status Changed).

The following table explains the mapping between the metadata related to the Specimen Collection Failed event and the mapping SET^S40^SET_S40 message segments/fields.

Table 3.Y.4.5.2-2: Specimen collection failed event metadata to SET^S40^SET_S40 message segments/fields mapping

Event field	SET^S42 Mapping
Placer Order Number	ORC-2, OBR-2 (At least one Required)
Placer Group Number	ORC-4 (Required)
Filler Order Number	ORC-3, OBR-3 (At least one Required)
Test	OBR-4 (Required)

Event field	SET^S42 Mapping
Collector	It is described in either PRT-5 (Person), PRT-7 (Organization Unit Type), PRT-8 (Organization), PRT-9 (Location), PRT-10 (Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 Participation), that shall be valued with "CE" (Collection Entity)
Missed Reason	EVN-4 (Required)

3.Y.4.5.3 Expected actions

As soon as the “Specimen Collection Failed” event occurs, the SEI Actor will send to the SET Actor a SET^S40^SET_S40 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.6 SET^S41^SET_S41 (Specimen departed message)

This message tracks the departure of specimens from the origin location.

3.Y.4.6.1 Trigger events

The occurrence of a Specimen Departed event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S41^SET_S41 message.

3.Y.4.6.2 Message semantics

The structure of this message is the SET_S41, detailed in the following table.

Table 3.Y.4.6.2-1: SET_S41 message structure

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
EVN	Event Type	R	[1..1]	3
{PRT}	Participation (for Event Type)	R	[1..*]	7
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen Information	R	[1..1]	7
[{	--- SPECIMEN_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Specimen)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- SPECIMEN_OBSERVATION end			
[{	--- CONTAINER begin			
{SAC}	Container Information	R	[1..*]	13
[{	--- CONTAINER_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Container Information)	R	[1..1]	7

Segment	Meaning	Usage	Card.	HL7 chapter
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- CONTAINER_OBSERVATION end			
}]	--- CONTAINER end			
}	--- SPECIMEN end			

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S41^SET_S41.

NOTE: Two different PRT segments shall be used to identify the departure and arrival locations, because in cases when we have no one of the two tracking messages (missing departure or arrival message) it could be useful to identify the counterpart. The value of the PRT-4 field (see mapping table in the next section) identifies the relative role (sender or receiver). As this segment is required, at least PRT information about the receiving facility shall be provided. The field PRT-2 shall be valued with “SP” (Snapshot). At least the PRT segment providing information about the arrival facility shall be provided.

The following table explains the mapping between the metadata related to the Specimen Departed event and the mapping SET^S41^SET_S41 message segments/fields.

Table 3.Y.4.6.2-2: Specimen departed event metadata to SET^S41^SET_S41 message segments/fields mapping

Event field	SET^S41 Mapping
From Entity/Origin/From Location	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "TE" (To Entity) or "FE" (From Entity)
To Entity/Destination/To Location	

Notice that no Order block is present in this message structure, because all information about the order from which the specimen originated can be easily linked by backwardly reconstructing the tracking chain for the current specimen, if any order information had previously been provided by either “Containers Prepared for Specimen Collection” and “Specimen Collection succeeded” messages.

3.Y.4.6.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S41^SET_S41 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.7 SET^S42^SET_S41 (Specimen arrived message)

This message tracks the arrival of specimens at the destination location. As described in several SET Profile use cases, the arrival of the specimen happens after a movement from one location to another one.

3.Y.4.7.1 Trigger events

The occurrence of a Specimen arrived event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S42^SET_S41 message.

3.Y.4.7.2 Message semantics

The structure of this message is the SET_S41 one. See Table 3.Y.4.6.2-1 for details.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S42^SET_S41.

PRT segments below the EVN segment provide information about the departure/arrival facility. At least the PRT segment providing information about the departure facility shall be provided. The PRT-2 field shall be valued with “SP” (Snapshot).

The following table explains the mapping between the metadata related to the Specimen Arrived event and the mapping SET^S42^SET_S41 message segments/fields.

Table 3.Y.4.7.2-1: Specimen arrived event metadata to SET^S42^SET_S41 message segments/fields mapping

Event field	SET^S42 Mapping
From Entity/Origin/From Location	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "TE" (To Entity) or "FE" (From Entity)
To Entity/Destination/To Location	

3.Y.4.7.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S42^SET_S41 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.8 SET^S43^SET_S41 (Specimen accepted message)

This message tracks the acceptance of specimens by the destination location. The specimens and containers listed in the messages are the subset of specimens arrived that have been accepted.

3.Y.4.8.1 Trigger events

The occurrence of a Specimen accepted event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S43^SET_S41 message.

3.Y.4.8.2 Message semantics

The structure of this message is the SET_S41 one. See Table 3.Y.4.6.2-1 for details.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S43^SET_S41.

The PRT segment below the EVN segment provide information about the acceptance facility.

The following table explains the mapping between the metadata related to the Specimen Accepted event and the mapping SET^S43^SET_S41 message segments/fields.

Table 3.Y.4.8.2-1: Specimen accepted event metadata to SET^S43^SET_S41 message segments/fields mapping

Event field	SET^S43 Mapping
Accepting Entity	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "ARE" (Acceptance/Rejection Entity)

3.Y.4.8.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S43^SET_S41 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.9 SET^S44^SET_S41 (Specimen rejected message)

This message tracks the rejection of specimens by the destination location, for a common reason provided in EVN-4. The specimens and containers listed in the messages are the subset of specimens arrived that have been rejected for the same reason (e.g., broken tube).

3.Y.4.9.1 Trigger events

The occurrence of a Specimen Rejected event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S44^SET_S41 message.

3.Y.4.9.2 Message semantics

The structure of this message is the SET_S41 one. See Table 3.Y.4.6.2-1 for details.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S44^SET_S41.

The PRT segment below the EVN segment provides information about the rejection facility.

The following table explains the mapping between the metadata related to the Specimen Rejected event and the mapping SET^S44^SET_S41 message segments/fields.

Table 3.Y.4.9.2-1: Specimen rejected event metadata to SET^S44^SET_S41 message segments/fields mapping

Event field	SET^S44 Mapping
Reject Reason (more granular)	SPM-21 (Specimen level), OR SAC-8 (Container level) (At least one of them required)
Rejecting Entity	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "ARE" (Acceptance/Rejection Entity)

In the event of rejection, EVN-4 gives the reason overall, but SPM-21 can be used to give more detail for each of the rejected specimens; while SAC-8 can be used to give more detail about each specific container related to the rejected specimen.

Examples of EVN-4, SPM-21 and SAC-8 usage: the table below shows some examples of granularity for a rejection, with details at specimen level (specimen ID 1001) or container level (specimen ID 1002):

Specimen ID	Container ID	EVN-4	SPM-21	SAC-8
10001	10001-1	Unusable Specimen	RN^Contamination	
10002	10002-1	Unusable Specimen		X^Container Unavailable
10002	10002-2	Unusable Specimen	RB^Broken Container	X^Container Unavailable

The previous table provides two examples of detailed reject reason for specimen 10001 and for the containers 10002-1 and 10002-2, related to specimen 10002.

Notice that the detailed reject reason could be related to a combination of specimen and container detailed reasons: for example, the unavailability of the specimen collected inside the container 10002-2 is due to a container unavailability caused by a breakage.

3.Y.4.9.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S44^SET_S41 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.10 SET^S46^SET_S41 (Specimen archived message)

This message tracks the archival of one or more specimens.

3.Y.4.10.1 Trigger events

The occurrence of a Specimen Archived event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S46^SET_S41 message.

3.Y.4.10.2 Message semantics

The structure of this message is the SET_S41 one. See Table 3.Y.4.6.2-1 for details.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S46^SET_S41.

The PRT segment below the EVN segment provide information about the archiving facility.

The following table explains the mapping between the metadata related to the Specimen archived event and the mapping SET^S46^SET_S41 message segments/fields.

Table 3.Y.4.10.2-1: Specimen archived event metadata to SET^S46^SET_S41 message segments/fields mapping

Event field	SET^S47 Mapping
Expiration Time	SPM-19 (Required)
Original Quantity	SPM-12 (Required)
Current Quantity	SPM-25 (Required)
Current Status	SAC-8 (Required)
Archiving location	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "AE" (Archiving Entity).

3.Y.4.10.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S46^SET_S41 message to track all the related event information. The SET Actor receives

the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.11 SET^S47^SET_S41 (Specimen retrieved from archive message)

This message tracks the retrieval of one or more specimens.

3.Y.4.11.1 Trigger events

The occurrence of a Specimen Retrieved from archive event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S47^SET_S41 message.

3.Y.4.11.2 Message semantics

The structure of this message is the SET_S41 one. See Table 3.Y.4.6.2-1 for details.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S47^SET_S41.

The PRT segment below the EVN segment provide information about the retrieval facility.

The following table explains the mapping between the metadata related to the Specimen Retrieved from archive event and the mapping SET^S47^SET_S41 message segments/fields.

Table 3.Y.4.10.2-1: Specimen retrieved from archive event metadata to SET^S47^SET_S41 message segments/fields mapping

Event field	SET^S48 Mapping
Expiration Time	SPM-19 (Required)
Original Quantity	SPM-12 (Required)
Current Quantity	SPM-25 (Required)
Retriever Name/Identifier/Location	They are described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "RE" (Retrieval Entity).

3.Y.4.11.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S47^SET_S41 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.12 SET^S48^SET_S41 (Specimen disposed of message)

This message tracks the final disposal of one or more specimens.

3.Y.4.12.1 Trigger Events

The occurrence of a Specimen disposed of event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S48^SET_S41 message.

3.Y.4.12.2 Message semantics

The structure of this message is the SET_S41 one. See Table 3.Y.4.6.2-1 for details.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S48^SET_S41.

The PRT segment below the EVN segment provide information about the specimen disposure facility.

The following table explains the mapping between the metadata related to the Specimen Disposed of event and the mapping SET^S48^SET_S41 message segments/fields.

Table 3.Y.4.12.2-1: Specimen disposed of event metadata to SET^S48^SET_S41 message segments/fields mapping

Event field	SET^S48 Mapping
Disposure Location	It is described in either PRT-5 (Participation Person), PRT-7(Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "DE" (Disposure Entity).

3.Y.4.12.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S48^SET_S41 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.13 SET^S45^SET_S45 (Specimen identifier changed message)

This message tracks the change of a specimen identifier during its lifecycle.

3.Y.4.13.1 Trigger events

The occurrence of a Specimen re-identified event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S45^SET_S45 message.

3.Y.4.13.2 Message semantics

The SET_S45 message structure supports tracking of information related to a change of identifier in one or more specimens.

Such operation may happen, for example, when the specimen departs from a sending to a receiving location, and the latter has to re-identify the specimen for internal usage. Another common situation occurs when the specimen is sent to a Biobank and a de-identification of the specimen is required. According to the scope of the SET Profile, this message does not carry the old specimen identifier, but only the "current identifier" that has to be tracked. Consequently, SET events are not enough to reconstruct the overall specimen chain of custody. The chain can be reconstructed by querying a third party (e.g., an honest broker preserving the link between the old and the new identifiers).

The SET_S45 message structure is detailed in the following table.

Table 3.Y.4.13.2-1: SET_S45 message structure

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
EVN	Event Type	R	[1..1]	3
{PRT}	Participation (for Event type)	R	[1..*]	7
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen Information	R	[1..1]	7
[{	--- SPECIMEN_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Specimen)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- SPECIMEN_OBSERVATION end			
[{	--- CONTAINER begin	O	[0..*]	13
{SAC}	Container Information	R	[1..*]	
[{	--- CONTAINER_OBSERVATION begin	O	[0..*]	7
OBX	Observation (for Container Information)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- CONTAINER_OBSERVATION end			
}]	--- SPECIMEN_CONTAINER end			
}	--- SPECIMEN end			

Specimen de-identification occurs in the context of a biobank: when there is no authorization to know the original identifier of the specimen, the biobank de-identifies it, by assigning a new identifier to the specimen and dropping the link between the new identifier and the original one. In this case, the message carries only the new specimen identifier, and not the original one.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S45^SET_S45.

The PRT segment below the EVN segment provides information about the entity responsible for specimen ID changes.

The following table explains the mapping between the metadata related to the Specimen re-identified event and the mapping SET^S45^SET_S45 message segments/fields.

Table 3.Y.4.13.2-2: Specimen identifier changed event metadata to SET^S45^SET_S45 message segments/fields mapping

Event field	SET^S45 Mapping
Specimen Identifier Changing Entity	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "IE" (Identification Entity).

Notice that no Order block is present in this message structure, because all information about the order from which the specimen originated can be easily linked by backwardly reconstructing the tracking chain for the current specimen, if any order information had previously been provided by either “Containers Prepared for Specimen Collection” and “Specimen Collection succeeded” messages.

3.Y.4.13.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S45^SET_S45 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.14 SET^S49^SET_S49 (Specimen Procedure Step Successfully Produced a Derived Specimen)

This message structure supports tracking of information related to processing operation of the specimen that lead to the derivation of a child specimen from a parent one. Example of derivations include aliquoting, slide preparation from a tissue block or dice, isolation of a pure colony from a microbiology specimen. The derivation is often itself been obtained from some kind of processing, for this reason this trigger event has the same structure of the “Specimen procedure step performed (with no derived specimens)” one.

3.Y.4.14.1 Trigger events

The occurrence of a Child Specimen Derived from Parent event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S49^SET_S49 message.

3.Y.4.14.2 Message semantics

1160 The SET_S49 message structure is detailed in the following table.

Table 3.Y.4.14.2-1: SET_S49 message structure

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
EVN	Event Type	R	[1..1]	3
{PRT}	Participation (for Event Type)	R	[1..*]	7
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen Information	R	[1..1]	7
[{	--- SPECIMEN_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Specimen)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- SPECIMEN_OBSERVATION end			
OBR	Observation Request (Specimen Processing)	R	[1…1]	4
[{	--- CONTAINER begin	O	[0..*]	
{SAC}	Container Information	R	[1..*]	13
[{	--- CONTAINER OBSERVATION begin	O	[0..*]	
OBX	Observation/Result (for Container)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- CONTAINER_OBSERVATION end			
}]	--- CONTAINER end			
[{	--- DERIVED SPECIMEN begin	O	[0..*]	
SGH	Segment Group Header	R	[1..1]	2
SPM	Specimen Information	R	[1..1]	7
[{	--- SPECIMEN_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Specimen ID)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- SPECIMEN_OBSERVATION end			
[{	--- CONTAINER begin	O	[0..*]	
SAC	Container Information	R	[1..1]	13
[{	--- CONTAINER_OBSERVATION begin	O	[0..*]	
OBX	Observation (for Container Information)	R	[1..1]	7
[{PRT}]	Participation (Observation Participation)	O	[0..*]	7
}]	--- CONTAINER_OBSERVATION end			
}]	--- CONTAINER end			
SGT	Segment group trailer	O	[1..1]	2
}]	------ DERIVED SPECIMEN end			
}	--- SPECIMEN end			

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S49^SET_S49.

The PRT segment below the EVN segment provides information about the specimen derivation entity/facility.

The following table explains the mapping between the metadata related to the Child specimen derived from parent event and the mapping SET^S49^SET_S49 message segments/fields.

Table 3.Y.4.14.2-2: Specimen procedure step succeeded (with derived specimens) event metadata to SET^S45^SET_S45 message segments/fields mapping

Event field	SET^S50 Mapping
Parent Identifier	SPM-3 (Required)
Procedure Name	OBR-4 (Required)
Processing Additive	SPM-6 (Optional)
Temperature	SAC-31 (Optional)
Current Quantity	SPM-25 (Optional)
Original Quantity	SPM-12 (Optional)
Specimen Child Role	SPM-29 (Optional)
Procedure Step Entity	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "PE" (Procedure Entity).

Notice that no Order block is present in this message structure, because all information about the order from which the specimen originated can be easily linked by backwardly reconstructing the tracking chain for the current specimen, if any order information had previously been provided by either “Containers Prepared for Specimen Collection” and “Specimen Collection succeeded” messages.

3.Y.4.14.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S49^SET_S49 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.15 SET^S50^SET_S49 (Specimen procedure step succeeded (with no derived specimens) message)

This message is sent to track a positive procedure step operation performed on a specimen. This trigger event is used to track all that procedures that do not lead to a derivation of the specimen.

3.Y.4.15.1 Trigger events

The occurrence of a Specimen retrieved event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S50^SET_S49 message.

3.Y.4.15.2 Message semantics

The SET^S50 structure is the same as the SET^S49_SET^S49 one. See Table 3.Y.4.14.2-1 for details.

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S50^SET_S49.

SPM and PRT segments carry important information about the procedure performed on specimen.

The following table explains the mapping between the metadata related to the Specimen procedure step performed event and the mapping SPM^S50^SPM_S49 message segments/fields.

Table 3.Y.4.15.2-1: Specimen procedure step succeeded (with no derived specimens) event metadata to SET^S50^SET_S49 message segments/fields mapping

Event field	SET^S51 Mapping
Procedure Name	OBR-4 (Required)
Processing Additive	SPM-6 (Optional)
Temperature	SAC-31(Optional)
Procedure Step Entity	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "PE" (Procedure Entity).

3.Y.4.15.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^S49^SET_S49 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.4.16 SET^S51^SET_S51 (Specimen procedure step failed)

This message is sent to track the failure of a procedure step on a specimen, due to a related reason.

3.Y.4.16.1 Trigger events

The occurrence of a “Specimen Procedure Step Failed” event will trigger the Specimen Event Informer to send to the Specimen Event Tracker a SET^S51^SET_S51 message.

3.Y.4.16.2 Message semantics

The structure of the SET^S51^SET_S51 is detailed in the following table.

Table 3.Y.4.16.2-1: SET_S51 message structure

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R		2
EVN	Event Type	R		3
{PRT}	Participation (for Event type)	R		7
{	--- SPECIMEN begin	R		
SPM	Specimen Information	R		7
[{	--- SPECIMEN_OBSERVATION begin	O		
OBX	Observation (for Specimen ID)	R		7
[{PRT}]	Participation (Observation Participation)			7
}]	--- SPECIMEN_OBSERVATION end			
[{	--- CONTAINER begin			
SAC	Container Information			
[{	--- SPECIMEN_OBSERVATION begin			
OBX	Observation (for Patient ID)			7
[{PRT}]	Participation (Observation Participation)			7
}]	--- SPECIMEN_OBSERVATION end			
}]	--- CONTAINER end			
OBR	Order (Specimen Processing)			7
}	--- SPECIMEN end			

Field MSH-9 (Message Type) shall have its three components valued as follows: SET^S51^SET_S51.

In case of failure of specimen processing it may happen that some pieces of information about specimen and containers are not available.

This tracking only aims to link the unsuccessful procedure to the order that generated the specimens and containers, with the information of OBR and ORC segments, and the reason for processing failure, carried on EVN-4.

A single OBR represents the procedure step that was performed (OBR-4). The table below maps to the message structure the event attributes defined for this use case.

Table 3.Y.4.16.2-2: Specimen procedure step failed event metadata to SET^S51^SET_S41 message segments/fields mapping

Event field	SET^S52 Mapping
Procedure Name	OBR-4 (Required)
Processing Additive	SPM-6 (Optional)

Event field	SET^S52 Mapping
Temperature	SAC-31(Optional)
Unsuccessful procedure reason	EVN-4 (Required)
Procedure Step Entity	It is described in either PRT-5 (Participation Person), PRT-7 (Participant Organization Unit Type), PRT-8 (Participation Organization), PRT-9 (Participant Location), PRT-10 (Participation Device). At least one of these fields shall be provided, together with the PRT-2 (Action Code), that shall be valued with "SP" (Snapshot) and the PRT-4 (Participation), that shall be valued with "PE" (Procedure Entity).

As it happens for the specimen rejection use case, EVN-4 is used to track the unsuccessful procedure reason overall.

Notice that no Order block is present in this message structure, because all information about the order from which the specimen originated can be easily linked by backwardly reconstructing the tracking chain for the current specimen, if any order information had previously been provided by either “Containers Prepared for Specimen Collection” and “Specimen Collection succeeded” messages.

3.Y.4.16.3 Expected actions

As soon as the mapped event occurs, the SEI Actor will send to the SET Actor a SET^51^SET_S51 message to track all the related event information. The SET Actor receives the message and answers notifying with a positive or negative acknowledgement the result of the tracking operation.

3.Y.5 Protocol Requirements

NA

3.Y.6 Security Considerations

NA

3.Y.6.1 Security Audit Considerations

NA

3.Y.6.(z) <Actor> Specific Security Considerations

NA

Appendices to Volume 2

Appendix A – EVN Segment

Add this section to the list of common segments in 2.x volume

This segment provides some generic information about a specific type of event triggered in the SET Profile, as for example its timestamp of occurrence, the specific event type, a unique identifier and so on.

SEQ	LEN	DT	Usage	Card.	TBL	ITEM	Element Name
1	0	ST	X	[0..0]		00099	Event Type/Code
2	0	DTM	R	[1..1]	00100		Recorded Date/Time
3	0	DTM	X	[0..0]	00101		Date/Time Planned Event
4	0	CWE	R	[1..1]	0062		Event Reason Code
5	0	XCN	X	[0..0]	6188		Operator Id
6	0	DTM	R	[1..1]	01278		Event Occurred
7	0	HD	X	[0..0]	01534		Event Facility
8	0	EI	R	[1..1]		XXXX	Event Unique Id

EVN-1 Event/Type code (EI), not supported.

This field is present only for backward compatibility and it is not supported.

EVN-2 Recorded Date/Time (DTM), required.

In the context of SET Profile, this field reports the date and time when the event has been recorded by the tracking system

EVN-3 Planned Date/Time (DTM), not supported.

This field contains the Date/Time when the event is planned. In the context of the SET Profile it is not supported.

EVN-4 Event Reason Code (CWE), required.

This field contains the reason for an event. In the context of SET Profile, this field is mandatory; the SET Profile has a user-defined custom table of suggested events, as shown below.

Table A-1: EVN-4 customized values table for SET Profile

EVN-4 code	EVN-4 Description
IHE-SET-01	Specimen collection operation
IHE-SET-02	Specimen containers production
IHE-SET-03	Specimen check-in
IHE-SET-04	Patient unavailable/refusal

EVN-4 code	EVN-4 Description
IHE-SET-05	Container unavailable/missing
IHE-SET-06	Specimen inter-facility movement
IHE-SET-07	Order subcontract
IHE-SET-08	Specimen unavailable/refusal
IHE-SET-09	Additional tests to be performed
IHE-SET-10	Research test purposes
IHE-SET-11	Archiving/Final disposition
IHE-SET-12	Specimen unavailable after usage
IHE-SET-13	Patient/order anonymization
IHE-SET-14	Generic IVD/Anatomic Pathology operation
IHE-SET-15	Anatomic Pathology grossing operation
IHE-SET-16	Anatomic Pathology staining operation
IHE-SET-17	Anatomic Pathology digital slides creation
IHE-SET-18	IVD aliquoting operation
IHE-SET-19	IVD centrifugation operation

Note: This table shows a proposed set of additional codes to define all the main event reasons addressed by SET Profile use cases. While this table is extensible, if needed, additional custom reason codes may be added to this list.

EVN-5 Operator Id (XCN), not supported.

This field identifies the individual responsible for the event. In the context of SET Profile this field is not supported, because such information is provided by the PRT segment.

EVN-6 Event Occurred (DTM), required.

In the context of SET Profile, this field reports the date and time when the event effectively occurred. This might be different from the EVN-2 one.

EVN-7 Event Facility (HD), not supported.

This field identifies the facility responsible for the event. In the context of SET Profile this field is not supported, because such information is provided by the PRT segment.

EVN-8 Event Unique Id (EI), required.

This field provides a unique identifier for the specific event instance. It has been introduced as an extension to the HL7 2.9 standard by the SET Profile. It is required and very important in order to reconstruct and distinguish the event tracking chain of a specific specimen.

Appendix B – PRT Segment

Add this section to the list of common segments in 2.x volume

This segment provides information of the participant(s) responsible for events/message triggering.

1290

SEQ	LEN	DT	Usage	Card.	TBL	ITEM	Element Name
1	4	EI	O	[0..1]		02379	Participation Instance ID
2	2	ID	R	[1..1]	0287	00816	Action Code
3	0	CWE	O	[0..1]		02380	Action Reason
4	0	CWE	R	[1..1]	0912	02381	Participation
5	0	XCN	C	[0..*]		02382	Participation Person
6	0	CWE	O	[0..1]		02383	Participation Person Provider Type
7	0	CWE	C	[0..1]	0406	02384	Participant Organization Unit Type
8	0	XON	C	[0..*]		02385	Participation Organization
9	0	PL	C	[0..*]		02386	Participant Location
10	0	EI	C	[0..*]		02348	Participation Device
11	0	DTM	X	[0..1]		02387	Participation Begin Date/Time (arrival Time)
12	0	DTM	X	[0..1]		02388	Participation End Date/Time (departure Time)
13	0	CWE	X	[0..1]		02389	Participation Qualitative Duration
14	0	XAD	X	[0..*]		02390	Participation Address
15	0	XTN	X	[0..*]		02391	Participant Telecommunication Address

PRT-1 Participation Instance ID (EI), optional.

This field contains a unique identifier of the specific participation, in the context of a SET Profile event occurrence.

1295 **PRT-2 Action Code (ID),** required.

This field reveals the intent of the message; as it is used in the context of SET Profile it reveals the intent of a traceability message; it shall be valued to “SP (Snapshot)”.

PRT-3 Action Reason (CWE), optional.

This fields indicates the reason why the person, organization, location or device is assuming (or changing) the role.

PRT-4 Participation (CWE), conditional.

This field indicates the functional involvement with the activities being transmitted. It is required in all of the Specimen Event Tracking Profile messages, to carry the participation role. The SET Profile defines a set of customized values, as listed in the following table:

Table B-1: PRT-4 customized values table for SET Profile

PRT-4 code	PRT-4 Description
CPE	Containers Preparation Entity
CE	Collecting Entity
FE	From Entity
TE	To Entity
ARE	Acceptance/Rejection Entity
AE	Archiving Entity
RE	Retrieval Entity
DE	Disposure Entity
IE	Identification Entity
PE	Procedure Entity

PRT-5 Participation Person (CWE), conditional.

This field contains the identity of the person who is represented in the participation that is being transmitted. It is required in some of the Specimen Event Tracking Profile messages, to carry the information about the person responsible for a certain event activity, in pair with the correspondent role (PRT-4).

PRT-6 Participation Person Provider Type (CWE), optional.

This field contains a code identifying the provider type for the participating person.

PRT-7 Participant Organization Unit Type (CWE), conditional.

This field identifies the environment in which the participant acts in the role specified. It is required in the context of the SET Profile to generically identify the entity responsible for the occurrence of some events to a specimen

PRT-8 Participation Organization (XON), conditional**.**

This field identifies the organization that is involved in the participation. It is required in the context of the SET Profile to generically identify the entity responsible for the occurrence of some events to a specimen.

PRT-9 Participant Location (PL), conditional.

This field specifies the physical location that is participating. It is required in the context of SET Profile to carry the information where the specimen has been archived or disposed of.

PRT-10 Participation device (EI), conditional.

The identifier of the device participating. It is required in some of the Specimen Event Tracking Profile messages, to carry the information about the device responsible for a certain event activity, in pair with the correspondent role (PRT-4).

PRT-11 Participation Begin Date/Time (arrival time) (DTM), not supported.

This field contains the Date/Time when the participation began. The Technical Framework does not constrain the usage of this field yet.

PRT-12 Participation End Date/Time (departure time) (DTM), not supported.

This field contains the Date/Time when the participation ended. The Technical Framework does not constrain the usage of this field yet.

PRT-13 Participation Qualitative Duration (CWE), not supported.

This field contains the qualitative length of time form participation. The Technical Framework does not constrain the usage of this field yet.

PRT-14 Participation Address (XAD), not supported.

This field contains addresses associated with the participation. The Technical Framework does not constrain the usage of this field yet.

PRT-15 Participant Telecommunication Address (XTN), not supported**.**

This field carries telecommunication addresses for the waypoint. The Technical Framework does not constrain the usage of this field yet.

Appendix C – SET Messages Examples

Add This section to the list of messages examples (volume 2.x)

C.1 – S38 (Containers Prepared for Specimen Collection)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S39^SET_S38|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE-SET-02^Specimen Containers
Production||20210207154759||SET_000002
PRT||SP^Snapshot||CPE^Containers preparation entity||||||LB^Automatic Labeler|
SPM|1|100189470101||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Specimen_Description|||20210207164759^20210207164905||20210217000000|||||||1
|001_Red_Cap
SAC|||||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||0001^XXX_cont_mod
ORC|NW|84392|84392|18946|SC||||20131211154702|TEST1^^||TEST1^^|||||
OBR||84392|84392|FT3^FT3 (FREE TRIIODOTHYRONINE)^^FT3||||||||||||TEST1^^
ORC|NW|84393|84393|18946|SC||||20131211154702|TEST1^^||TEST1^^|||||^
OBR||84393|84393|FT4^FT4   (FREE THYROXINE)^^FT4||||||||||||TEST1^^
```

C.2 – S39 (Specimen Collection Succeeded)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S38^SET_S38|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE-SET-01^Specimen collection
operation||20210207154759||SET_000001
PRT||SP^Snapshot||CE^Collecting entity|COLL_1^Collector|||||
SPM|1|100189470101||WB^Blood,whole|||||||PSN^Human Patient||||||||||||||1|001_Red_Cap
SAC|||||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||0001^XXX_cont_mod
ORC|NW|84392|84392|18946|SC||||20131211154702|TEST1^^||TEST1^^|||||
OBR||84392|84392|FT3^FT3 (FREE TRIIODOTHYRONINE)^^FT3||||||||||||TEST1^^
ORC|NW|84393|84393|18946|SC||||20131211154702|TEST1^^||TEST1^^|||||^
OBR||84393|84393|FT4^FT4 (FREE THYROXINE)^^FT4||||||||||||TEST1^^
```

C.3 – S40 (Specimen Collection Failed)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S40^SET_S40|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE-SET-04^Patient
unavailable/refusal||20210207154759||SET_000003
PRT||SP^Snapshot||CE^Collecting entity|COLL_1^Collector|||||
ORC|NW|84392|84392|18946|SC||||20131211154702|TEST1^^||TEST1^^|||||
OBR||84392|84392|FT3^FT3 (FREE TRIIODOTHYRONINE)^^FT3||||||||||||TEST1^^
ORC|NW|84393|84393|18946|SC||||20131211154702|TEST1^^||TEST1^^|||||^
OBR||84393|84393|FT4^FT4 (FREE THYROXINE)^^FT4||||||||||||TEST1^^
```


C.4 – S41 (Specimen Departed)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S41^SET_S41|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE-SET-06^Specimen inter-facility movement
||20210207154759||SET_000004
PRT||SP^Snapshot||FE^From Entity||||CARD^Cardiology Facility|||
PRT||SP^Snapshot||TE^From Entity||||LAB^Laboratory Facility|||
SPM|1|100189470101||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Spec_Description|||20210207164759^20210207164905||20210217000000|||||||1|001
_Red_Cap
SAC|||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||0001^XXX_cont_mod
```

C.5 – S42 (Specimen Arrived)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S42^SET_S41|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759|IHE-SET-06^Specimen inter-facility movement
|||20210207154759||SET_000005
PRT||SP^Snapshot||FE^From Entity||||CARD^Cardiology Facility|||
PRT||SP^Snapshot||TE^From Entity||||LAB^Laboratory Facility|||
SPM|1|100189470101||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Spec_Description|||20210207164759^20210207164905||20210217000000|||||||1|001
_Red_Cap
SAC|||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||0001^XXX_cont_mod
```

C.6 – S43 (Specimen Accepted)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S43^SET_S41|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE-SET-03^Specimen check-in||20210207154759||SET_000006
PRT||SP^Snapshot||ARE^Acceptance/Rejection
Entity|||LAB_ORG^Laboratory_Organization|LAB^Laboratory Facility|||
SPM|1|100189470101||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Spec_Description|||20210207164759^20210207164905||20210217000000|||||||1|001
_Red_Cap
SAC|||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||0001^XXX_cont_mod
```

C.7 – S44 (Specimen Rejected)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S44^SET_S41|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE_SET_08^Specimen
Unavailable/Refusal||20210207154759||SET_000007
PRT|| SP^Snapshot||ARE^Acceptance/Rejection Entity
|||LAB_ORG^Laboratory_Organization|LAB^Laboratory Facility|||
SPM|1|100189470101||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Spec_Description|||20210207164759^20210207164905||20210217000000||RB^Broken
Container|||||1|001_Red_Cap
SAC|||||||||X^Container
Unavailable|||||||||5^cm|||||10^ml|||||||||||||||||||||||||||0001^XXX_cont_mod
```


C.8 – S45 (Specimen Identifier Changed)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S45^SET_S45|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE-SET-03^Specimen check-in||20210207154759||SET_000007
PRT||SP^Snapsot||IE^Identification
Entity|||LAB_ORG^Laboratory_Organization|LAB^Laboratory Facility|||
SPM|1|100189470101_LAB_001||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Spec_Description|||20210207164759^20210207164905||202102170000000|||||||1|001
_Red_Cap
SAC|||||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||||0001^XXX_cont_mod
```

C.9 – S51 (Specimen Procedure, not Resulting in a Derived Specimen)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S51^SET_S50|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE_SET_19^IVD Centrifugation
Operation||20210207154759||SET_000009
PRT||SP^Snaphot||PE^Procedure Entity|||LAB_ORG^Laboratory_Organization|LAB^Laboratory
Facility||CENT^Centrifugation Device|
SPM|1|100189470101||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|10^ml||Spec_Description|||20210207164759^20210207164905||202102170000000||||||1
0^ml|1|001_Red_Cap
OBR|1|1||CENT^Specimen Centrifugation|
SAC|||||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||||0001^XXX_cont_mod2
```

C.10 – S49 (Specimen Procedure, Resulting in a Derived Specimen)

```
MSH|^~\&|SET_SET|SPEC_EVN_TRCK|SEI|SPEC_EVN_INF|20210207154759||SET^S49^SET_S50|633513
355095980900|D|2.9|||||IT|UTF-8|EN
EVN||20210207154759||IHE-SET-18^IVD Aliquoting Operation||20210207154759||SET_00000811
PRT||SP^Snapshot||PE^Procedure Entity
|||LAB_ORG^Laboratory_Organization|LAB^Laboratory Facility||ALIQ^Aliquoting Device|
SPM|1|100189470101||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|10^ml||Spec_Description|||20210207164759^20210207164905||202102170000000||||||1
0^ml|1|001_Red_Cap
OBR|1|1||ALI^Specimen Aliquoting|
SAC|||||||||||||||||5^cm|||||10^ml|||||||||||||||||||||||||||||0001^XXX_cont_mod
SGH|1|Specimen Derivation
SPM|1|100189470101_ALI1||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Spec_Description|||20210207164759^20210207164905||202102170000000|||||||1|001
_Red_Cap
SAC|||||||||||||||||5^cm|||||5^ml|||||||||||||||||||||||||||||0001^XXX_cont_mod
SPM|2|100189470101_ALI2||WB^Blood,whole|||VENIP^Venipuncture||||PSN^Human
Patient|||Spec_Description|||20210207164759^20210207164905||202102170000000|||||||1|001
_Red_Cap
SAC|||||||||||||||||5^cm|||||5^ml|||||||||||||||||||||||||||||0001^XXX_cont_mod
SGT|1|Specimen Derivation
```

