

SET Profile

Volume 1 to Volume 2

IHE PaLM Face to Face meeting – Cagliari
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Agenda

- Where we left off?
- SET - Overview and Use Cases Review
- SET - From Volume 1 to Volume 2
 - Events Traceability matrix review
 - Specimen DAM model review/coverage
 - Candidate messaging standards analysis
 - How to map events with messaging standard?
 - How to move from DAM to DAM-based messages?
 - Real examples of messages exchange in SET

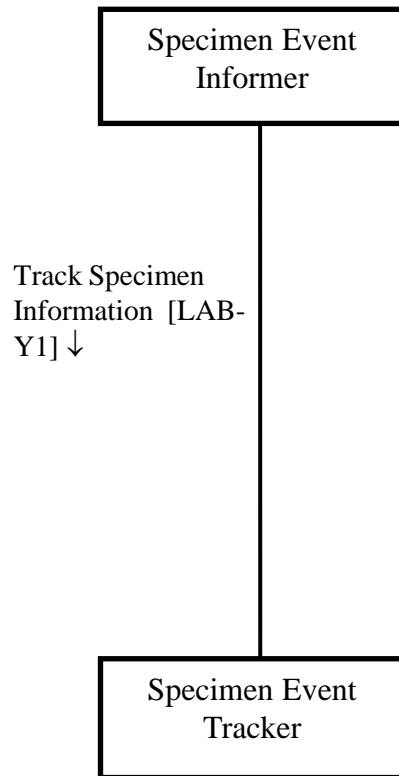
Where we left off?

- Identified five different use cases
- List of all specimen tracking events
- Events metadata matrix: to be carefully reviewed during this F2F
- New issues (to be also faced here in Cagliari)
 - Specimen DAM model coverage
 - Discussion about best message structure to adopt
 - Volume 2 implementation plan

SET Profile overview (1/2)

- The Specimen Event Tracking (SET) profile covers use cases, workflows and transactions related to the tracking of the specimen during all its lifecycle
- The scope of the SET profile involves tracking from a point of view of macro activities focused on specimens, such as collecting, shipping, receiving, accepting and so on. Micro operations composing a macro activity are not tracked, that is out of scope for this profile

SET Profile overview (2/2)



- **Specimen Event Informer(SEI):** Per the specific use case, this actor will trigger a LAB-Y1 transaction, whose message will carry all tracking information describing a specific event. In the context of a single use case, the SEI actor triggers one message on LAB-Y1 transaction for each event tracked in this use case (i.e., “Specimen collected in ward”, “Specimen sent to Laboratory”).
- **Specimen Event Tracker (SET):** Receives and/or stores/forwards Specimen tracking information received by SEI. Usage and way of collection of this information are out of scope for SET

SET Use Cases Overview

- #1 Specimen containers production and collection tracking
- #2 Specimen inter and intra organization transfer
 - Specimen transferred, no re-identification by receiver
 - Specimen transferred and re-identified by receiver
 - Specimen rejected by receiver
- #3 Intra-laboratory IVD testing specimen tracking
- #4 Specimen biobank transfer
 - Specimen collected in Laboratory and then shipped to Biobank
 - Specimen retrieved from Biobank for immediate testing
 - Specimen retrieved from Biobank for testing preparation
- #5 Specimen derived tracking

SET Events list

Event	Description
Specimen Collected	The specimen has been collected by an operator (phlebotomist, physician, nurse, etc.) in a ward or in a collection room. Specimen collection action includes specimen identification.
Specimen Containers Prepared	The containers where specimens will be collected have been prepared: the appropriate containers have been selected and labeled.
Specimen Shipped	The specimen has been delivered from a location to another, which could be a different location in the same institution, or even a remote location. The specimen container could be part of a box, as many containers are transported all together to the receiving location.
Specimen Received	This event identifies the check-in of the specimen, when it arrives from an external location, and registers the successful arrival.
Specimen Accepted	This event reports the acceptance of the specimen after its check-in, meaning the specimen has passed all quality checks needed to be processed inside 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 Re-identified	This event is tracked when the specimen needs to be re-identified by the receiving facility or institution.
Specimen Archived	The specimen has been archived in a storage system or biobank.
Specimen Retrieved	The specimen has been retrieved from a storage system or biobank, for further usage.
Specimen Derived	The specimen has been derived from a previous one. The event is useful, for example when some blocks are derived from a tissue specimen, or some slides are derived from a block. The event is also useful for biobanks, where a parent specimen is processed to create new ones for further testing.
Query for Specimens Retrieval	A query has been executed in a storage system/biobank to retrieve one or more specimens, for further usage (i.e., testing).
Specimen Sent for Testing	The specimen has been shipped to automation, or to a testing location, if no automation is present in the laboratory.
Specimen Processing Start	Specimen processing started on the referred Device
Specimen Processing End	Specimen processing ended on the referred device
Specimen Arrived at Laboratory Device	The specimen has been taken in charge by a Laboratory Device
Specimen left Laboratory Device	The specimen left a Laboratory Device
Specimen Discarded	The specimen has been discarded after all IVD tests have been performed

Specimen Tracking Events

- Common structure (for all events)

Event	Description
Event Type	Type of the Event (“Event” column of table X.1-2)
Event Registered Timestamp	Timestamp of event creation
Effective time of the event	
Event Performer	Operator/Machine/Device responsible for the event
Event ID	Unique identifier of 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
Sending Organization	Identifier of the organization sending the tracking message
Sending Facility	Identifier of the facility sending the tracking message
Receiving Organization	Identifier of the organization receiving the tracking message
Receiving Facility	Identifier of the facility receiving the tracking message

Event	Attribute	Data type	Description	Card.	Usage	DAM Mapping
Specimen Collected	Placer Group Number	String	PGN as usual in HL7 V2	0...1	RE	To be dropped
	Placer Order Number	String	PON as usual in HL7 v2	0...*	RE	Check FHIR specimen resource
	Associated Tests	String	List of ALL tests performed on the specimen	0...*	RE	To be Dropped
	Collector	String /ID	Person responsible of Specimen Collection	1...1	R	Performer.identifier
	Type	String/Code	Specimen Type as usual in HL7 V2	0...1	O	Specimen.typeCode
	Form	String/Code	Material nature (i.e., liquid, gas)	0...1	O	Specimen.formCode
	Description	String	Additional specimen information	0...1	O	Specimen.description
	Procedure	String	Activity performed for collection (i.e., venipuncture, biopsy)	0...1	O	SpecimenCollectionProcedure.ProcedureCode
	Reason	String/Code	Motivation for collection	0...1	O	SpecimenCollectionProcedure.ReasonCode
	Coll. Date Range	Timestamp (range)	Time range of collection duration	0...1	C	SpecimenCollectionProcedure.actualCollectionDateRange
	Missed Reason	String	Reason of collection not completed	1...1	C	SpecimenCollectionProcedure.missedReason
	Status	String/Code	Status of specimen collection	1...1	R	SpecimenCollectionProcedure.statusCode
	Container Name	String	Name (model?) of the container	1...1	R	SpecimenContainer.name
	Container Material	String/Code	Material of the specimen container	0...1	O	SpecimenContainer.containerMaterialCode
	Container Capacity	Number/Code	Capacity of the specimen Container	0...1	O	SpecimenContainer.Parameters.capacity
	Container Additive	String/Code	Additive of the specimen Container	0...1	O	SpecimenContainer.additive
	Container Number	Number	Overall number of containers where the specimen has been collected	0...1	RE	
	Container Length	Number	Length of the specimen container	0...1	O	SpecimenContainerParameters.length
Container Width	Number	Width of the specimen container	0...1	O	SpecimenContainerParameters.width	
Container Height	Number	Height of the specimen container	0...1	O	SpecimenContainerParameters.height	
Expiration Time	Timestamp	Date after the specimen is no longer viable	1...1	R	Specimen.expirationTime	

Event	Attribute	Data type	Description	Card.	Usage	DAM Mapping
Specimen Containers Prepared	Placer Group Number	String	PGN as usual in HL7 V2	0..1	RE	To be dropped
	Placer Order Number	String	PON as usual in HL7 v2	0..*	RE	Check FHIR resource
	Associated Tests	String	List of ALL tests performed on the specimen	0..*	RE	To be dropped
	Producer	String /ID	Person or robotic system responsible of Specimen labeled containers production	1..1	R	No mapping, use HL7 v2 instead?
	Producer Type	String	Prodycer type (Human, Robotic System)	1..1	R	Performer.typeCode
	Container Name	String	Name (model?) of the container	1..1	R	SpecimenContainer.name
	Container Material	String/Code	Material of the specimen container	0..1	O	SpecimenContainer.containerMaterialCode
	Container Capacity	Number/Code	Capacity of the specimen Container	0..1	O	SpecimenContainer.Parameters.capacity
	Container Additive	String/Code	Additive of the specimen Container	0..1	O	SpecimenContainer.additive
	Container Number	Number	Rank of the container collecting the specimen (1=first, 2= second, and so on)	0..1	RE	
	Container Length	Number	Length of the specimen container	0..1	O	SpecimenContainerParameters.length
	Container Width	Number	Width of the specimen container	0..1	O	SpecimenContainerParameters.width
Container Height	Number	Height of the specimen container	0..1	O	SpecimenContainerParameters.height	

Event	Attribute	Data type	Description	Card.	Usage	DAM Mapping
Specimen Accepted	Accept Entity	String/ID	Location where the specimen has been accepted	1...1	R	SpecimenMoveActivity.toEntity
	Accept Timestamp	Timestamp	Timestamp of acceptance	1...1	R	Moved to common event attributes
Specimen Rejected	Reject Entity	String/ID	Location where the specimen has been rejected	1...1	R	SpecimenMoveActivity.toEntity
	Reject Timestamp	Timestamp	Timestamp of rejection of the specimen	1...1	R	Moved to common event attributes
	Reject Reason	String	Reason why the specimen has been rejected	1...1	R	SpecimenMoveActivity.varianceReasonCode
Specimen Re-identified	New Specimen identifier	String/ID	New specimen identifier	1...1	R	Specimen.specimenIdentifier
	New Container Identifier	String/ID	New container identifier	1...1	R	SpecimenContainer.containerIdentifier
	Re-identification Entity	String/ID	Location where the specimen has been re-identified	1...1	R	SpecimenMoveActivity.toEntity
	Re-Identification Timestamp	Timestamp	Timestamp of re-identification	1...1	R	Moved to common event attributes
	Is De-identified	Boolean	Boolean that explains a de-identification	1...1	R	

Event	Attribute	Data type	Description	Card.	Us age	DAM Mapping
Specimen Archived	Expiration Time	Timestamp	Date after the specimen is no longer viable	1...1	R	Specimen.expirationTime
	Original Measurement	Number	Initial volume (i.e., container capacity) of the specimen	1...1	R	Specimen.originalSpecimenMeasurement
	Current Measurement	Number	Current volume of the specimen	1...1	R	Specimen.currentSpecimenMeasurement
	Archive Timestamp	Timestamp	Timestamp of specimen archiving	1...1	R	
	Current Status	String	Status of the specimen at the time of archiving	1...1	R	SpecimenCollectionProcedure.statusCode
Specimen Retrieved	Expiration Time	Timestamp	Date after the specimen is no longer viable	1...1	R	Specimen.expirationTime
	Original Measurement	Number	Initial volume (i.e., container capacity) of the specimen	1...1	R	Specimen.originalSpecimenMeasurement
	Current Measurement	Number	Current volume of the specimen	1...1	R	Specimen.currentSpecimenMeasurement
	Retrieve Timestamp	Timestamp	Timestamp of specimen retrieve	1...1	R	Moved to event common attributes
	Retriever Name	String	Name of the person responsible for retrieve	1...1	R	
	Retriever Identifier	String/ID	Identifier of the person responsible for retrieve	1...1	R	
	Retriever Location	String	Location where the retrieve has been performed	1...1	R	
	Reason Retrieve	String	Reason for specimen retrieve	1...1	R	
	Involved Specialty?	String/Code	Specialty related to specimen retrieve	0...1	O	No mapping, use HL7 v2 instead?
	Involved Diagnosis?	String/Code	Diagnosis related to specimen retrieve	0...1	O	No mapping, use HL7 v2 instead?
Specimen Derived	Parent Identifier	String/ID	Parent ID of the specimen from where the specimen has been derived	1...1	R	Specimen.specimenIdentifier
	Type	String	Specimen Type as usual in HL7 V2	1...1	R	Specimen.typeCode
	Current Measurement	Number	Volume of the derived specimen	1...1	R	Specimen.currentSpecimenMeasurement
	Original Measurement?	Number		1...1	R	Specimen.originalSpecimenMeasurement
	Specimen Child Role	String	Role of the derived specimen (i.e., aliquot, block for tissue)	1...1	R	Specimen.childRole
	Derivation Timestamp	Timestamp	Timestamp of derivation of the specimen	1...1	R	Moved to event common attributes

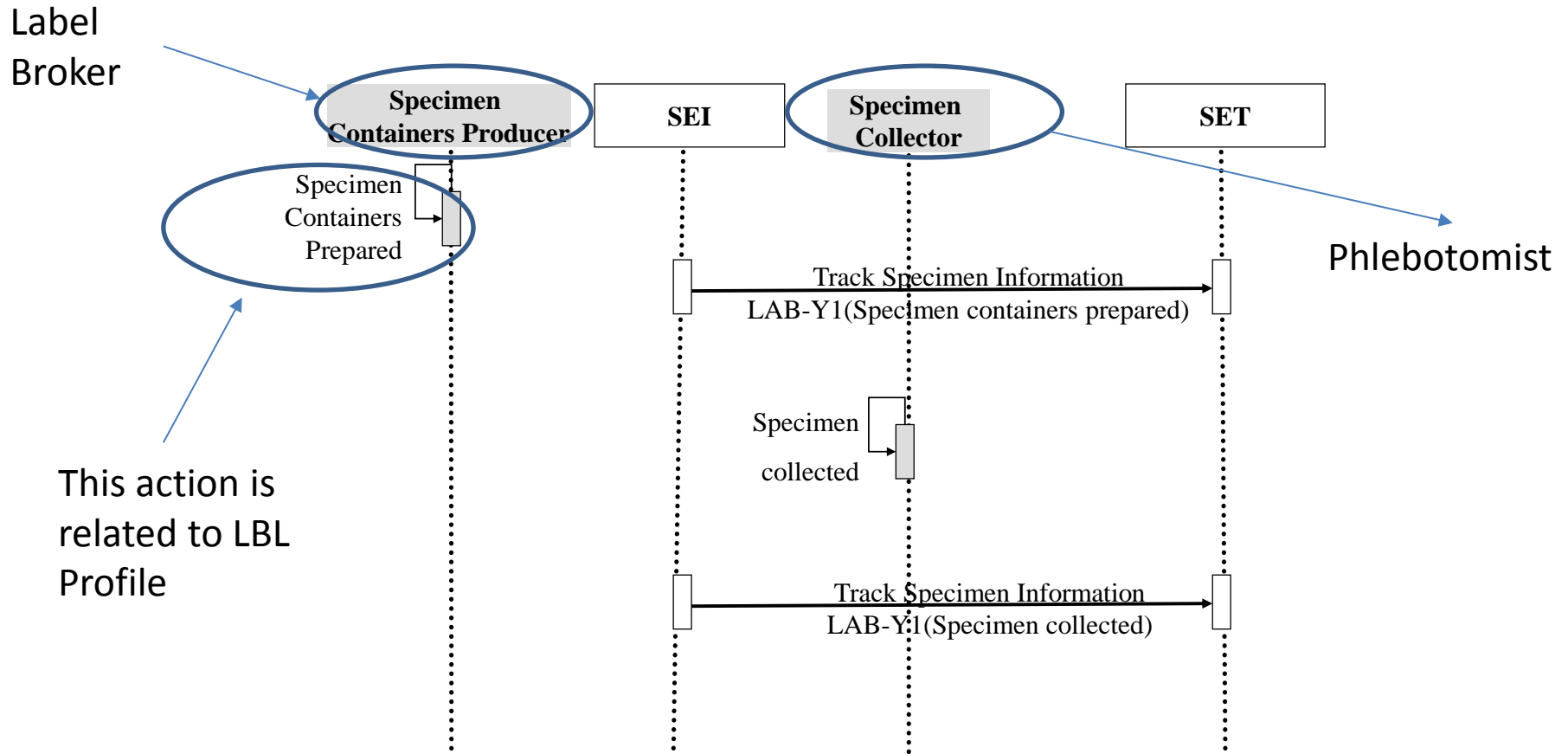
Event	Attribute	Data type	Description	Card.	Usage	DAM Mapping
Specimen Processing Start	Processing Timestamp	Timestamp	Timestamp of specimen processing start	1...1	R	Moved to event common attributes
	Processing Procedure	String	Description of the processing step started	0...1	O	SpecimenProcessingActivity.processingProcedure
	Processing Additive	String	Substance required and added to the specimen for processing	0...1	O	SpecimenProcessingActivity.processingAdditive
	Temperature	Number	Temperature at which the processing occurred	0...1	O	SpecimenProcessingActivity.Temperature
Specimen Processing End	Processing Timestamp	Timestamp	Timestamp of specimen processing end	1...1	R	Moved to event common attributes
	Processing Procedure	String	Description of the processing step ended	1...1	R	SpecimenProcessingActivity.processingProcedure
	Processing Additive	String	Substance required and added to the specimen for processing	0...1	O	SpecimenProcessingActivity.processingAdditive
	Temperature	Number	Temperature at which the processing occurred	0...1	O	SpecimenProcessingActivity.Temperature
Specimen Arrived at Location	To Entity	String/ID	Location where the specimen arrived	1...1	R	SpecimenMoveActivity.toEntity
	Arrival Timestamp	Timestamp	Timestamp of arrival of the specimen	1...1	R	Moved to event common attributes
	Box Identifier (If any)	String/ID	ID of the box where the specimen container could be stored for transfer	0...1	O	
	Position In Box (If any)	String	Position of the specimen container in the box	0...1	O	
	Tray Identifier (If any)	String/ID	ID of the tray where the specimen container could be stored for transfer	0...1	O	
	Position in Tray (If any)	String	Position of the specimen container in the tray	0...1	O	
	Number of Containers	Number	Overall number of containers related to the specimen (reported here for check purposes)	1...1	R	

Event	Attribute	Data type	Description	Card.	Usage	DAM Mapping
Specimen Left Location	From Entity	String/ID	Location from where the specimen has been transferred	1...1	R	SpecimenMoveActivity.FromEntity
	Transfer Timestamp	Timestamp	Timestamp of transfer of the specimen	1...1	R	Moved to common event attributes
	Box Identifier (If any)	String/ID	ID of the box where the specimen container could be stored for transfer	0...1	O	No mapping, use HL7 v2 instead?
	Position In Box (If any)	String	Position of the specimen container in the box	0...1	O	No mapping, use HL7 v2 instead?
	Tray Identifier (If any)	String/ID	ID of the tray where the specimen container could be stored for transfer	0...1	O	No mapping, use HL7 v2 instead?
	Position in Tray (If any)	String	Position of the specimen container in the tray	0...1	O	No mapping, use HL7 v2 instead?
	Number of Containers	Number	Overall number of containers related to the specimen (reported here for check purposes)	1...1	R	No mapping, use HL7 v2 instead?
Specimen Discarded	Discarding Timestamp	Timestamp	Timestamp of specimen discarding	1...1	R	Moved to common event attributes
	Discarding Reason	String	Reason for specimen discarding	1...1	R	

From V1 to V2 : From matrix to messages

- Main issues
 - Fields in the matrix that are not covered by Specimen DAM Model
 - Timestamps (fixed yesterday)
 - Orders reference (fixed yesterday)
 - How to (genererically) cover a traceability event?
 - Possible choices:
 - DAM -> V3?
 - DAM -> Specimen FHIR? (Issue: coverage with DAM)
 - DAM -> Something of “Directly derived?”

#1 : Use case real example



“Specimen containers prepared” example message

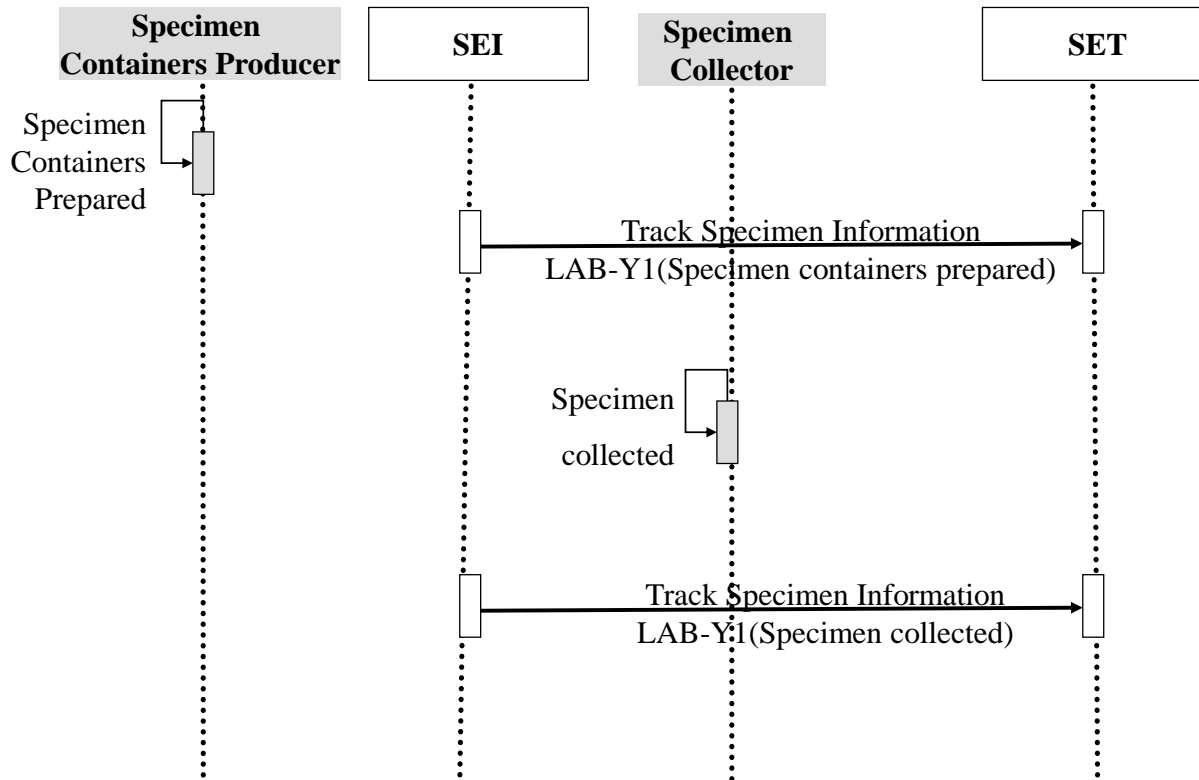
```
{ "event_type" : "Specimen containers prepared",  
  "event_timestamp" : "20171110090000",  
  "event_performer" : "LB Machine 001",  
  "event_id" : "djekwjfehfhorjgkr5gkello5poy5k6r",  
  "specimen_id" : "1001",  
  "specimen_container_id" : "1001-01",  
  "sending_organization" : "Hospital XYZ",  
  "sending_facility" : "Specimen Event Informer Company XYZ",  
  "receiving_organization" : "Hospital XYZ",  
  "receiving_facility" : "Specimen Event Tracker Company XYZ",  
  "producer" : "LB Robotic System",  
  "producer_type" : "Machine",  
  "associated_tests" : "HDL, LDL",  
  "preparation_timestamp" : "20171110070000",  
}
```

“Specimen collected” example message

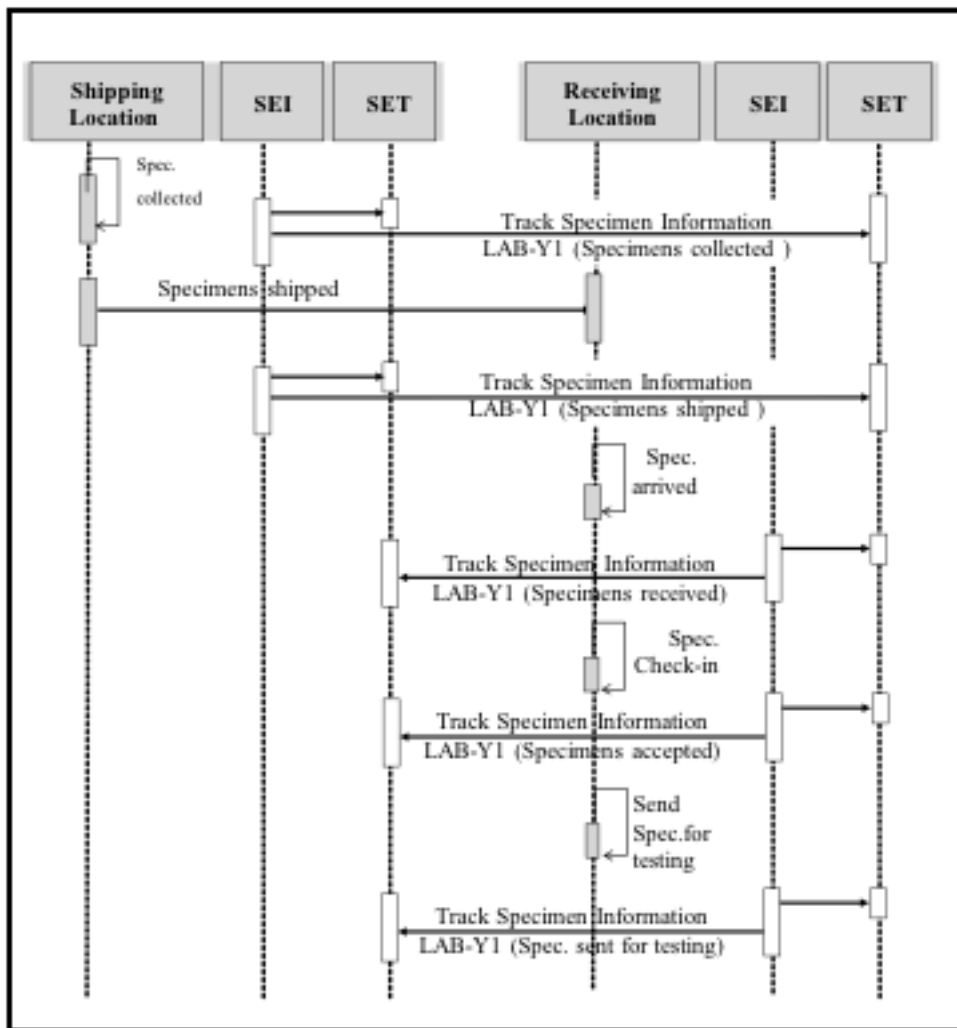
```
{ "event_type" : "Specimen collected",  
  "event_timestamp" : "20171110090415",  
  "event_performer" : "Phlebotomist 001",  
  "event_id" : "ruiteirergjerjgpoktrlghlhtyhlyhlot",  
  "specimen_id" : "1001",  
  "specimen_container_id" : "1001-01",  
  "sending_organization" : "Hospital XYZ",  
  "sending_facility" : "Specimen Event Informer Company XYZ",  
  "receiving_organization" : "Hospital XYZ",  
  "receiving_facility" : "Specimen Event Tracker Company XYZ",  
  "producer" : "Phlebotomist 001",  
  "producer_type" : "Human",  
  "associated_tests" : "HDL, LDL",  
  "collector" : "Phlebotomist 001",  
  "collection_date_range" : {"start" : "20171110090115",  
                             "end" : "20171110090205"}  
  "container_type" : "VC-143892"  
}
```

Appendix – Use Cases Flow diagrams

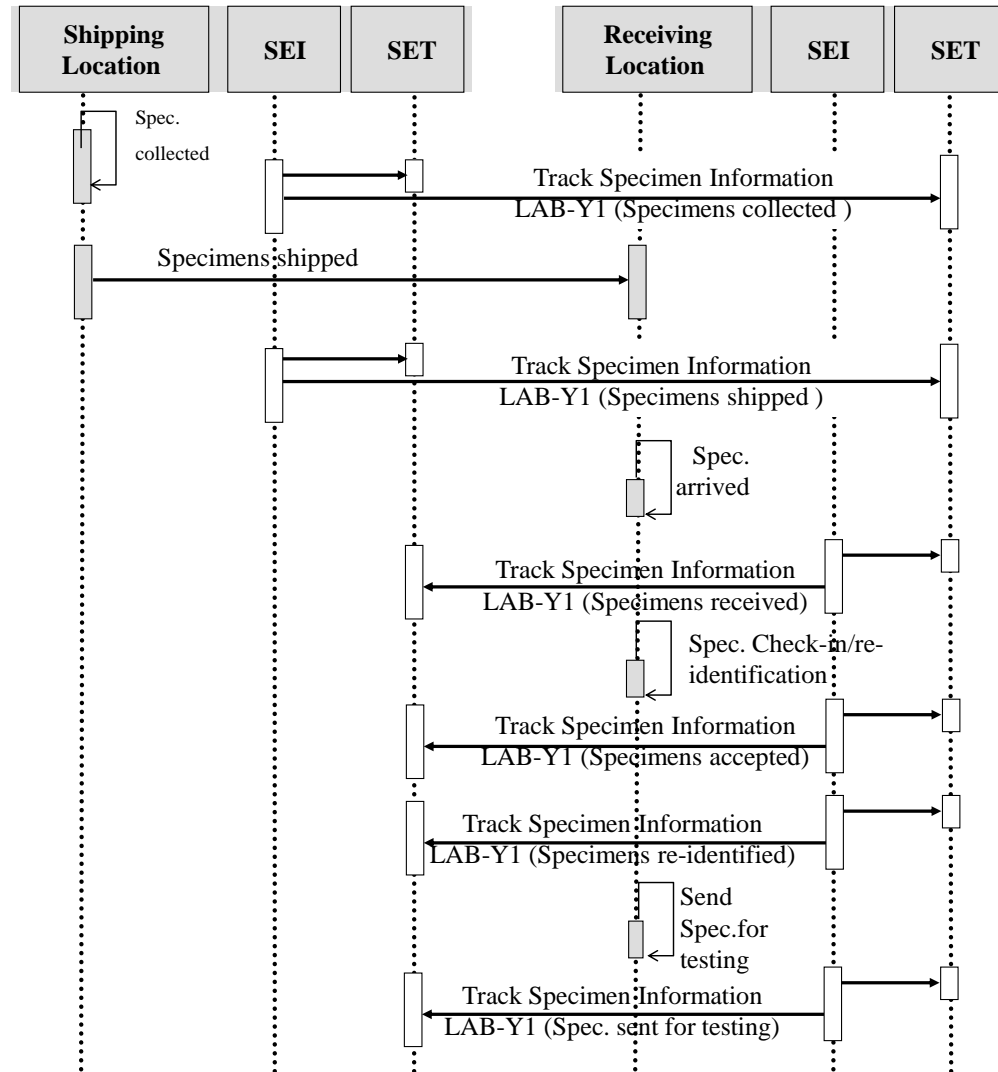
#1 - Specimen containers production and collection tracking



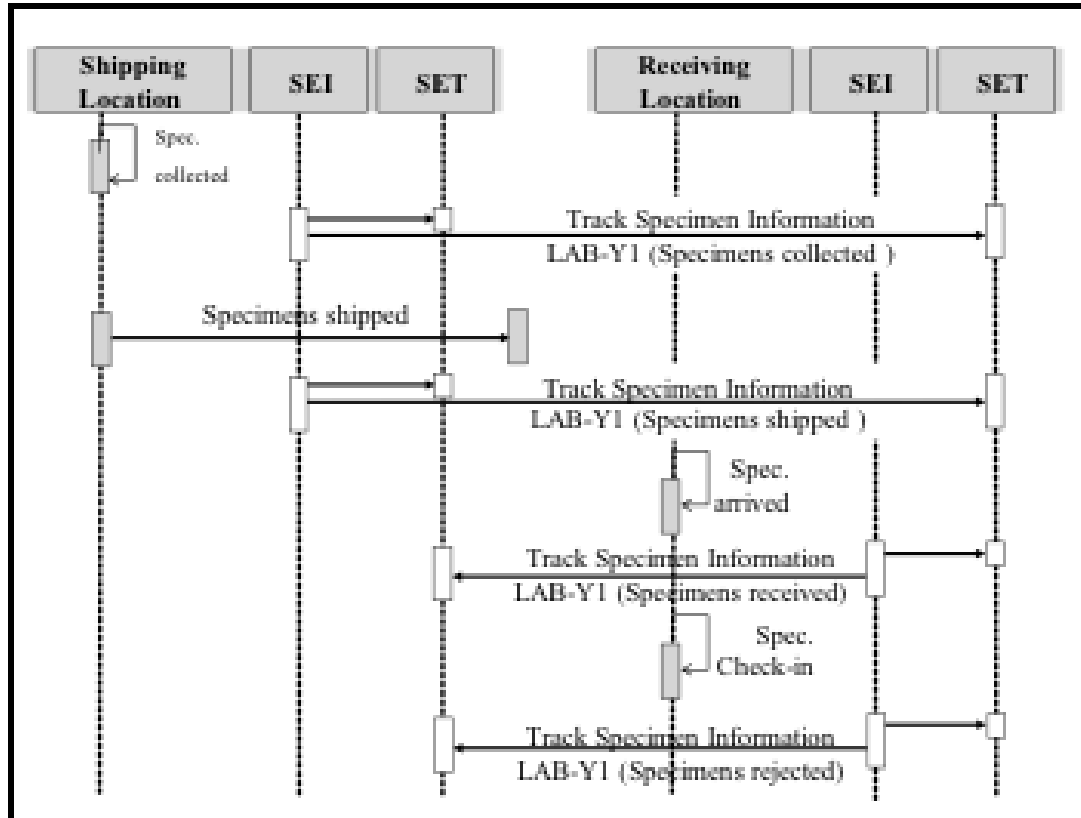
#2 - Specimen inter and intra organization transfer (1/3) – No re-identification by receiver



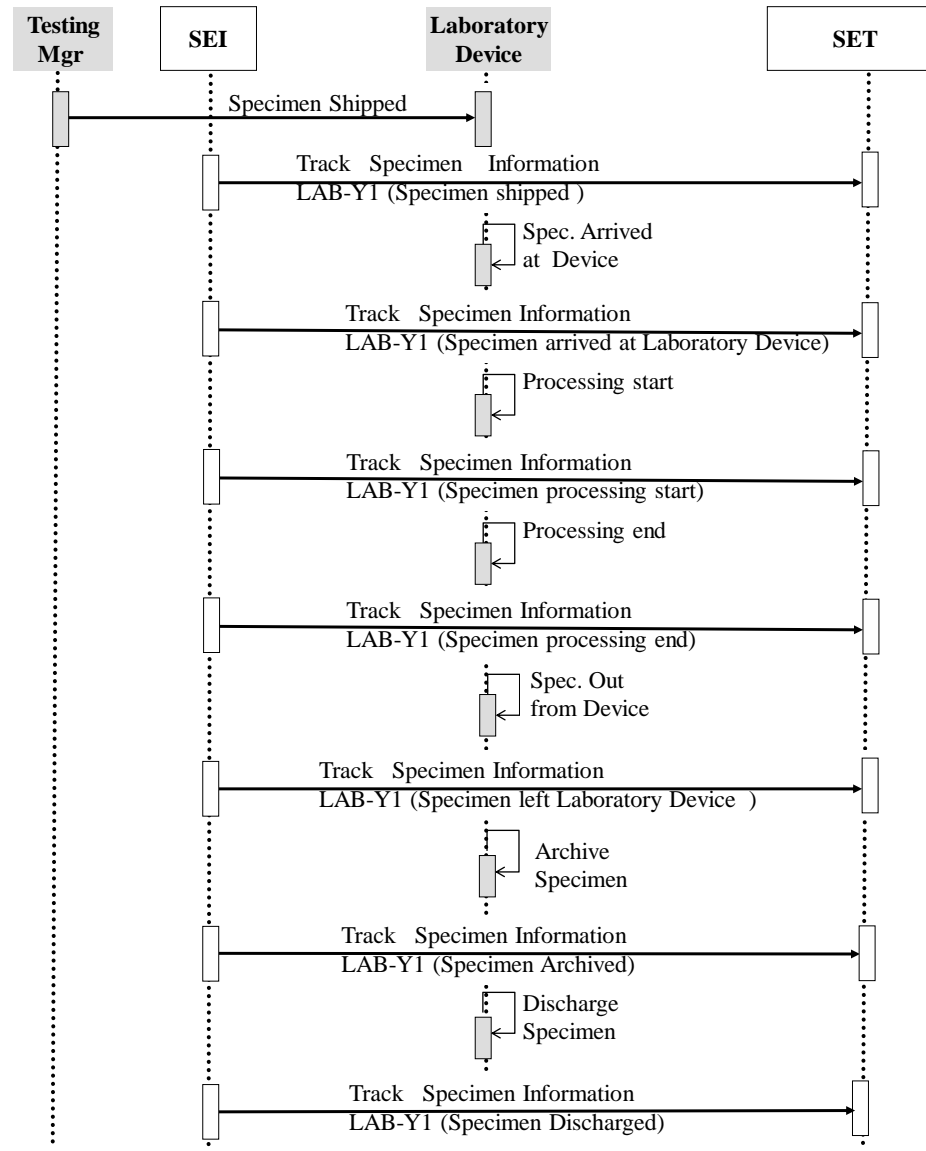
#2 - Specimen inter and intra organization transfer (2/3) – Re-identification by receiver



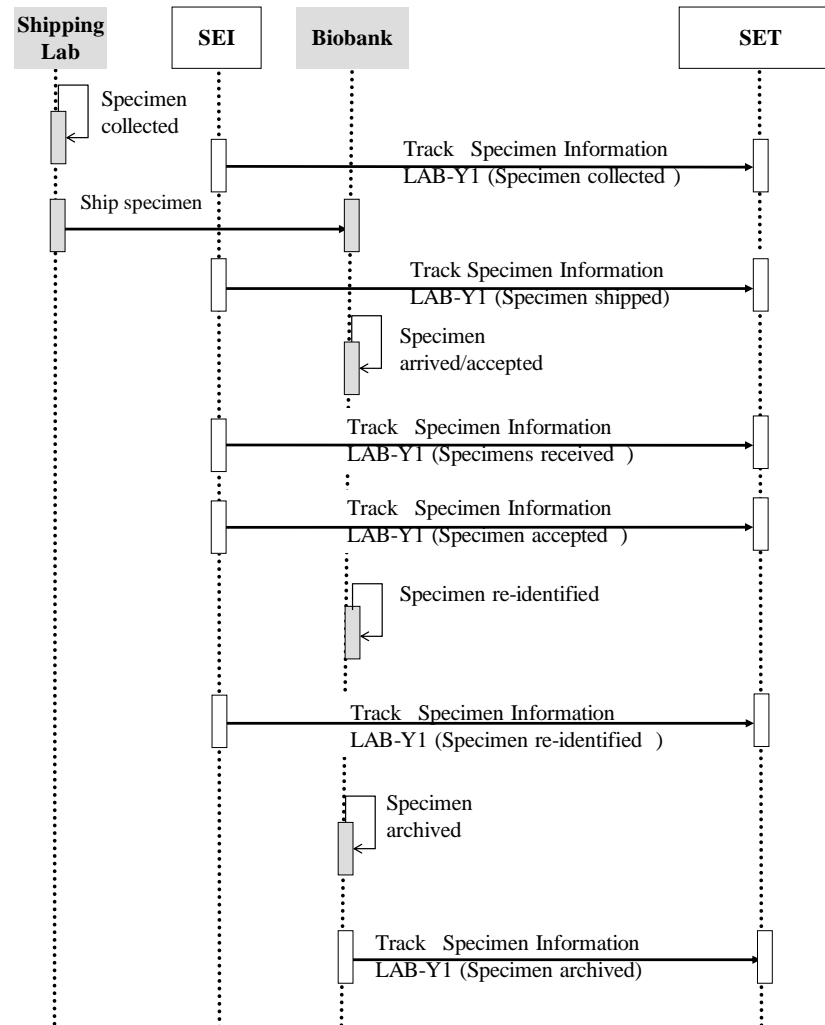
#2 - Specimen inter and intra organization transfer (3/3) – Rejected by receiver



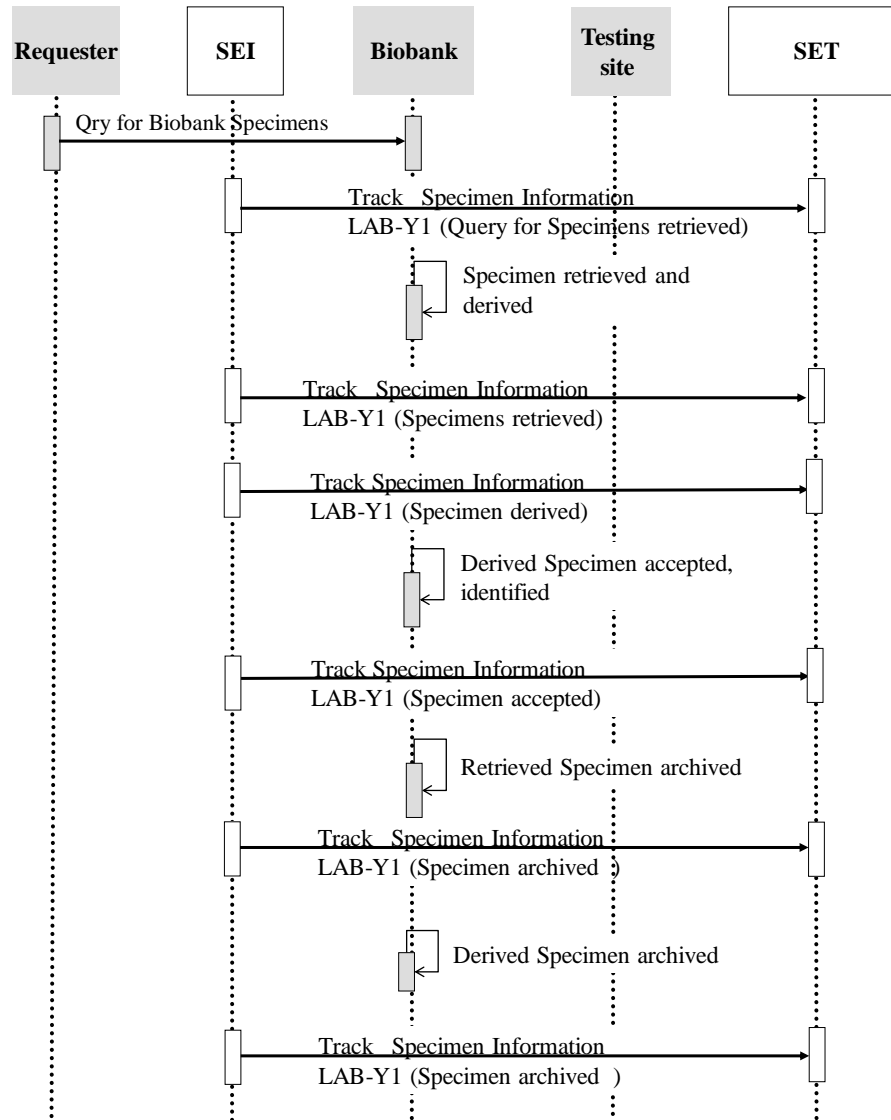
#3 - Intra-laboratory IVD testing



#4 - Biobank specimen tracking (1/3) – Spec. collected in Lab and then shipped to Biobank



#4 - Biobank specimen tracking (3/3) – Spec. Retrieved from Biobank for testing preparation



#5 - Specimen derivation tracking

