

BAP.12800 Inventory System Tracking Criteria**Phase II**

The inventory system tracks, as applicable:

1. Unique identifier
2. Study and study participant identifier
3. Visit identifier, if applicable
4. Specimen material type
5. Preservatives/additives/preservation methods
6. Specimen *parent/child* relationship, if applicable
7. Specimen vial type
8. Specimen volume
9. Date/time of collection
10. Date/time of receipt into inventory
11. Date/time of processing
12. Date/time and location of distribution
13. Number of thaws
14. Number of times sent previously for testing, if applicable
15. Condition warnings (eg, partially frozen upon receipt, micro-clots present, frozen sideways, or any other relevant exceptions to the SOP)
16. Clinical data, as applicable
17. Biospecimen status (eg, reserved or available)
18. Clinical collection site identifier, if applicable

NOTE: If clinical data is not stored at the biorepository in the inventory tracking system, there is a method for linking the physical spec with the clinical information, as needed.

Information regarding some of these elements may not be available to the biorepository for all biospecimen collections, especially those that were procured before recent best practices for biorepositories were published or for legacy collections.

BAP.12900 Inventory System Audit Trail Criteria**Phase II**

The inventory system includes a full audit trail of changes made to the database to include:

1. Original date
2. Changed date
3. Identity of who made the change
4. Reason for change
5. What was changed
6. How the change was made

BAP.12950 Specimen Quantity Warnings**Phase II**

If required by the sponsor, there is a mechanism in place to ensure minimum vial and minimum volume warnings are triggered before quantities fall below collection specified quantities.

NOTE: The warning mechanism may be either manual or automated. The intent of the requirement is inventory based.

BAP.13000 Inventory System Distribution Records**Phase II**

The inventory system keeps full records for specimens after distribution.

BAP.13100 Environmental Storage Areas Identifiers**Phase II**

Environmental storage areas (eg, freezers and refrigerators) have their own unique identifier that includes a defined convention for numbering shelves, racks, boxes, and the location within each container.

BAP.13150 Missing Specimen - Inventory Update

Phase II



If a specimen is missing, inventory is updated to reflect that the specimen cannot be located.

SAMPLE MANAGEMENT

Inspector Instructions:

| | |
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| | <ul style="list-style-type: none"> Sampling of sample distribution records |
| | <ul style="list-style-type: none"> Sample being removed from inventory |
| | <ul style="list-style-type: none"> What is the process if a sample entered into the inventory system cannot be located? What are you looking for when performing a sample pre-distribution quality check? How do you ensure personnel are available to receive shipments? |
| | <ul style="list-style-type: none"> Select a specimen that was shipped and review the audit trail for the specimen |

BAP.13200 Shipment Acceptance Confirmation

Phase II



Recipients are notified before shipping to ensure that appropriate personnel are available to receive the shipment.

BAP.13300 Shipping Tracking Criteria

Phase II

Tracking information for shipment of specimens includes the following, as applicable.

1. Invoice/tracking number
2. Recipient/source
3. Date of shipment or receipt
4. Courier name and ID# for each package
5. Sample description
6. Number of samples shipped/received
7. Study name/number