Sample Management and Specimen Query Resolution

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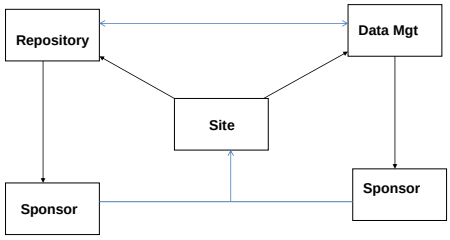
EMBLEM Specimen Mgt



Chain of Custody

- An audit trail that ensures that there is proof of proper storage and that sample integrity can be respected.
  - Biological specimen freezing cycle
- The chain of custody should cater for safety measure at all stages
  - HBV Immunization, proper handling gear,

Labeling

Vital for proper sample identification and verification.

This should be emphasized at all sample management stages,

-Pre- Analytical
-Analytical
-Post Analytical

Specimen transport Shipments

- In EMBLEM, we have used either LN2 or Dry Ice
- LN2: 78% of Atmosphere, Colorless, Odorless, Tasteless and Nontoxic, Boils at -320 ^{0}F (-196^{0}C) and Non-Flammable
  - Handling Precautions: PPE, Avoid use in small enclosed areas, Avoid prolonged breathing of vapors, Avoid rough handling of containers, Provide adequate ventilation.
- Dry Ice: Extremely cold, -109°F (-79°C), Does not melt, but sublimates from solid to gas releasing CO_2 , Displaces air in poorly ventilated areas, causing asphyxiation.

1520 vapor shipper

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Process takes 24Hrs

Specimen in country shipments

- All archived aliquots stored at the local lab must be captured on the Specimen Tracking/ data management Database.
- 2ml cryovials (plasma, saliva, buffy coat, & RBC) should be frozen in 2ml aliquots and stored in 10x10 cardboard or plastic cryoboxes at -70°C.
- Shipments will be scheduled to minimize the number of shipments made and maximize the contents of a shipment

Specimen in country shipments

- Shipment requests will focus on requesting completely filled or close to completely filled – 70°C cryo-boxes to avoid shipping partially empty boxes.
- Prior to a shipment the local lab must generate a shipping manifest for all specimens to be shipped

Specimen in country shipments

- The Specimen Tracking Database generates an electronic and printable copy of the manifest.
- The electronic copy must be saved with the site name and shipment date and emailed to the PI.
- The manifests must represent the actually shipped specimens.

Specimen in country shipments

- These manifests must list all the specimens being shipped, and only specimens that are indeed shipped. The manifests must represent the actual shipped specimens
- The site should have one or more staff members trained how to pack and ship Biological Substances to meet IATA regulations of shipping.

Shipment to central Repositories

- The courier waybill needs to be completed and a pro-forma invoice for customs purposes completed.
- A copy of the shipping export permit should be included in the shipment if applicable.
- Currently, IATA classifies EMBLEM shipments as “Biological substance, category B”.

Specimen Packing

Frozen Vials,

- Each specimen vial must be packed according to IATA requirements packaging instruction 650.
- An elastic band must be secured around the 10 x 10 freezer box containing ~100 vials per box.

Slides

- Twenty slides in cardboard holders with elastic bands secured around are packed in 10x10 freezer boxes. As above,

Shipment Tracking

- After shipment, site should write an email to the consignee indicating the time of pick up, AWB No.
- Inform all relevant Investigators in the same email.
- The team should regularly track/monitor the movement of the shipper until received.
- Keep the shippers indicated phones on- just in case!

Specimen Quality Control and Query resolution

- **Specimen Query Causes**

Means Bad data: due to IMS or Site

1. IMS: Reconciliation completed before inclusion of last shipment hence "ship sample on CRF"

2. Site: -If manifest does not agree with shipped vials hence "ship sample included on manifest but not received"

-If manifest does not agree with Lab Records hence "Update CRF to include aliquot"

Data (IMS) Vs Specimen QC

3. IMS:

Protocol Vs CRF is site doing as expected? Hence remove sample from CRF.

- If for example a slide was collected
  Even though protocol did not prescribe it
- IMS would inquire
- Site may change CRF to reflect no slide
- If then slide was sent to Repository
- IMS would inquire

Response to Specimen QC Reports

- Staff Training to emphasize the importance of the QC process
- An established lab QC system
- Respond on time
- Split/filter similar QCs to efficiency
- Have these activities on schedule
- Identify a contact/lead person
- Have a site deadline
- Updates should be shared in meetings.

Conclusion

- It takes team effort from sample reception to shipment to reduce QC..please be more vigilant.

Lessons

- Wrong box arrangement and wrong box types
- Mix of patient and research samples especially biopsy blocks
- Broken slides at shipment
- Lack of formalized freezer back up
- Power challenges at some sites
- Inability to print electronic manifests

Lessons

- Lack of proper chain of custody
- Lack of sample handling SOPs
- Delayed assessment of sample integrity could be a potential problem
- Lack of temperature monitoring logs
  - Freezer temp logs, sample transportation logs
- Delayed shipments