Sample Receipt, Handling, Storage and Inventory

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OBJECTIVES

- Describe the importance of specimen management and sample chain of custody.
- Define the specimen management process for collection, transport, receipt, acce ptance/rejection, accessioning, storage/archiving and disposal
- Explain the importance of maintaining sample integrity and chain of custody and potential impact to sample analysis and reporting

Sample Management

The result of any laboratory examination is only as good as the sample received in the laboratory

Sample Management and Chain of Custody

- Control of sample Chain of Custody (CoC) and management ensures minimal impact to sample integrity throughout the three (03) phases of laboratory analysis (i.e., pre-examination, examination and post-examination phases) and sample storage.

- The tracking of CoC is an essential part of any operational and analytical process to ensure the identity and integrity of the sample from collection through data reporting and provide the necessary traceability and accountability for procured specimens.

Sample Management Involves

Sample management and chain of custody begin with sample acquisition and end with a final result report. Variables impacting sample integrity may include:

- Sample collection/acquisition
- Sample transport
- Sample receipt
- Sample handling
- Sample storage
- Sample disposal

Sample Management

Collection of Samples

- Sample collection sites (e.g., phlebotomy clinics, clinical research units, field or collaborating sites) should have processes established to ensure that sample collection methods are well defined and that respective personnel are trained, and such training is documented.

- In addition, collection methods for each sample type should be defined (e.g., whole blood, serum, plasma, urine, stool, microbiological samples etc.) to ensure the pre-examination phase of sample analysis is not impacted.

- The laboratory should also ensure that appropriate container and collection supplies are available in all sample collection sites

Sample Management

Sample Processing

- Whole Blood, Serum and Plasma Collection - Select the appropriate vacutainer (or similar) tube (e.g., Polymerase Chain Reaction - light blue or yellow top, Hematological – lavender top (containing crystalline K_2 EDTA, etc.) for blood collection

- Blood, serum and plasma samples should be evaluated for interfering substances at the time of collection (if possible) or at the time of sample aliquoting prior to freeze-down the samples. This information should be recorded if potential interferences are identified (e.g., samples are hemolyzed, Icteric, and Lipemic/Turbid)

- Collection of other sample types (e.g., urine, stool, sputum, etc.) should be managed by pre-defined and approved process at the site of acquisition.

Note: on analytic interference / interfering substances – care should be taken to choose acceptable collection vessels as specified by manufactures recommendations and as defined by peer driven literature (e.g., Clinical and Laboratory Standards Institute (CLSI). CLSI standards are available on the IVI intranet).

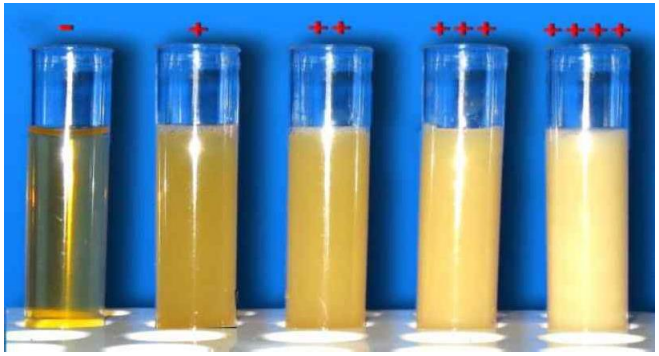
Sample Management

Examples of common interfering substances

Hemolyzed (red)

Icteric (yellow)

Lipemic (turbid)



Sample management

Sample Labeling

- **Samples should be labelled with at minimum the following identifiers:**
  - *Identification Number*
  - *Date of Collection*
  - *Time of Collection*
  - *Sample Type (e.g., blood, urine, etc.)*
  - *Sample storage temperature*

Sample Transport

SAMPLE TRANSPORATION

Specimen packaging

- All samples should be shipped in appropriate packaging, containment vessels associated with appropriate labelling as defined in the World Health Organization Requirements for Shipment of Infectious Substances (*Note: WHO requirements meet United Nations and IATA requirements for shipping of infections and potentially infectious substances, e.g., use of UN 3373 labeling*).

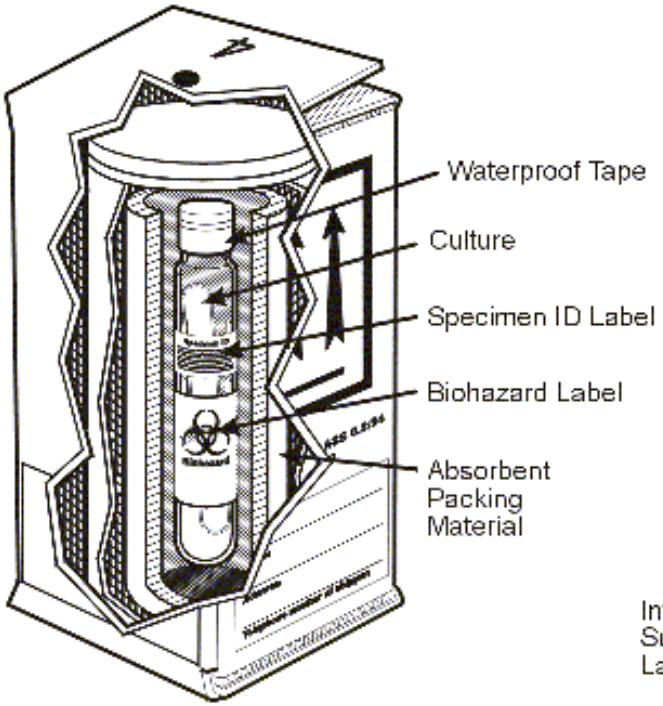
- Samples should be associated with a temperature logger (e.g., Temp tale or equivalent temperature monitor) which should be placed within the internal shipping container in close proximity to samples. *Note: CoC requires that appropriate transport temperatures be maintained and monitored during the shipping process.*

- Place each sample containment vessel (e.g., vacutainer tube, Croyvials, freezer box, etc.) into a separate Zip-Lock bag - multiple containment vessels of the same type may be placed in one Zip-Lock bag, with each tube individually wrapped in absorbent paper which contains moisture or spills and provides protection to guard against breakage.

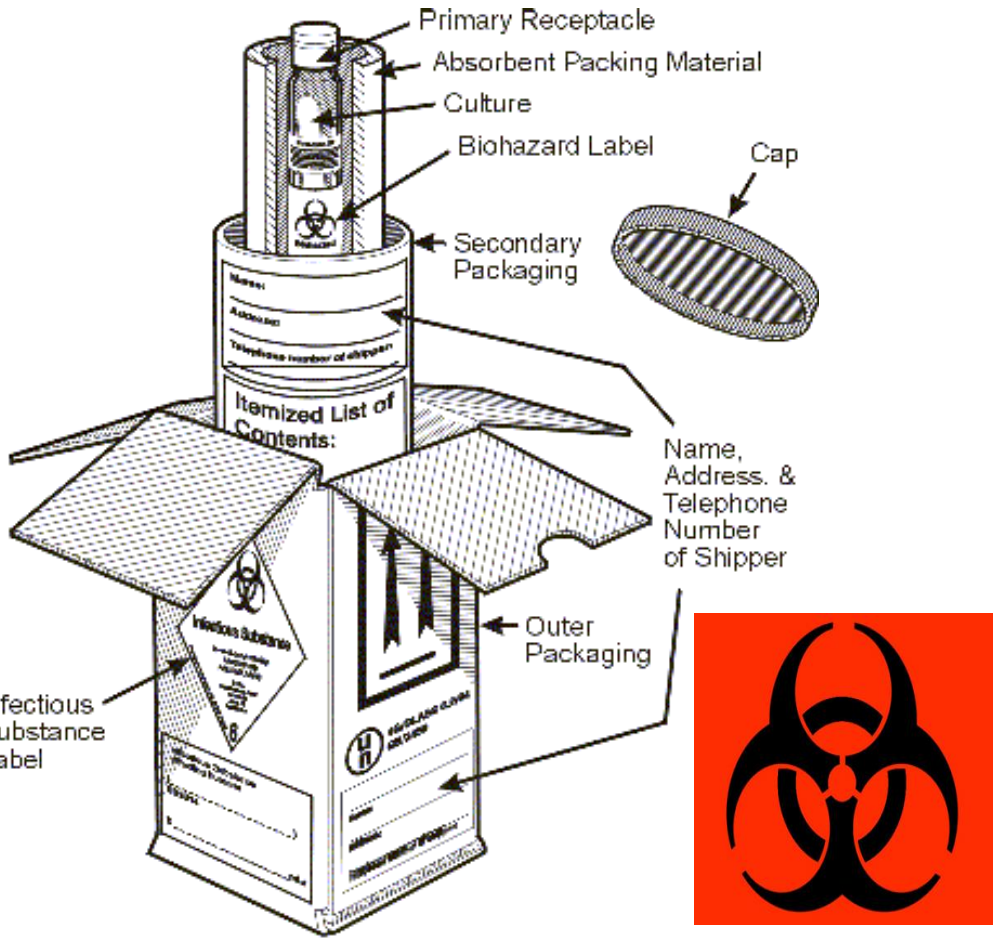
Note: Always place extra absorbent material exterior to the sample chamber within the shipment container in the event that breakage should occur.

Sample Transport

Diagrams of PACKING and LABELLING of INFECTIOUS SUBSTANCES FOR SHIPMENT



Cross Section of Proper Packing



Packing and Labeling of Infectious Substances

Sample Receipt

RECEIVING SPECIMENS:

- Since the potential exists during transportation for tampering, accidental destruction, and/or physical or chemical action to occur within the sample container or kit, an inspection upon receipt will be performed.
- The specimen package should be opened for inspection ***under a biosafety hood*** and contents should be evaluated for damage, leakage, insufficient quantity etc. The lab should have a sample acceptance/rejection criteria established to document unacceptable samples upon receipt
- The contents should be inspected for against the Shipping Manifest
- Temperature readings of the shipments should be obtained upon receipt. This can be accomplished by using a NIST-calibrated thermometer (or equivalent) or utilizing a calibrated data logger within the shipment. a calibrated data logger within the shipment. Sufficient dry ice, if used, upon receipt may also be recorded in lieu of a temperature recording. This information should be This information should be recorded. This will provide further support that the package has been shipped within the targeted temperature range.

Note: Prior to opening box and handling specimen containers (vials/tubes), Observe Universal Precautions wear gloves, laboratory coat, and protective eyewear if there is a risk of splashes or aerosols

Criteria for specimen rejection

- Unlabeled sample/ mislabeled
- Broken or leaking tube/container
- Hemolyzed sample
- Sample collected in a wrong tube, wrong preservative,
- Inadequate volume for the required preservative
- Insufficient for the test requested
- Prolonged transport time
- Incorrect temperature when received

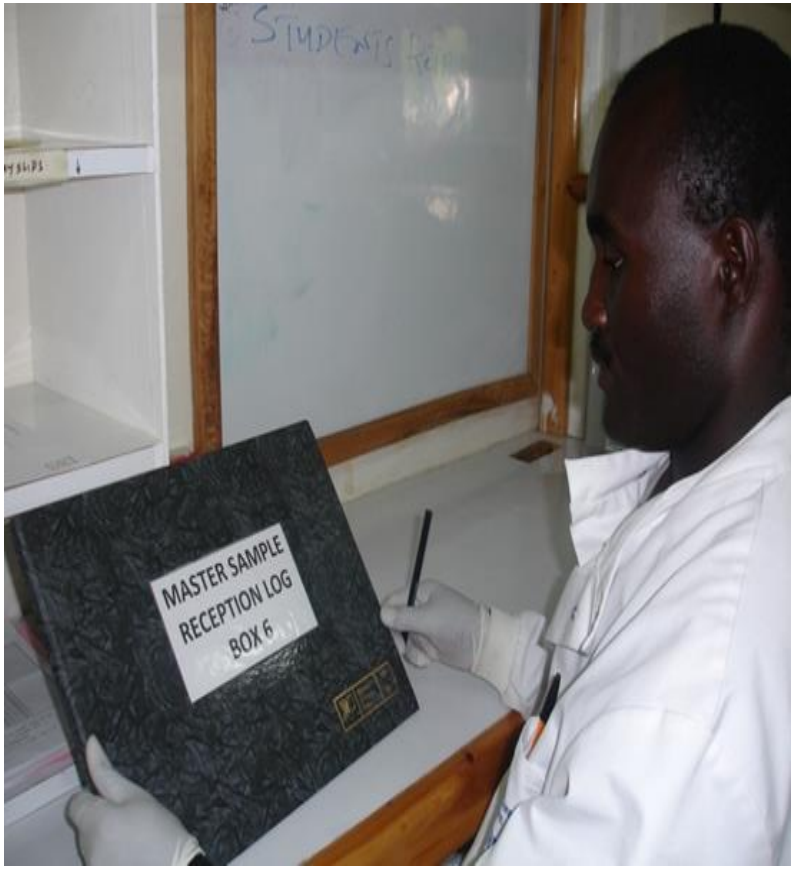
Actions for Rejected Samples

Develop a process for managing rejected samples to include:

- Informing an authorized person
- Request another sample
- Record rejected samples
- Retain rejected sample until final decision for disposition
- Extraordinary circumstances may require testing suboptimal samples

Sample Register or Log

- A register should include:
- date and time of collection
- date and time of receipt
- sample type
- patient name
- demographics as required
- laboratory assigned identification
- tests to be performed



Sample Receipt

Summary:

- ✓ Treat shipping package and specimens as potentially infectious material.
- ✓ Open containers within a Biological Safety Cabinet.
- ✓ Examine incoming specimens and paperwork. Document date and time received and receiver's initials on Requisition Form.
- ✓ Develop/Complete a Specimen Tracking Log to be used as a means of tracking the sample after receipt.

Sample Handling

Sample CoC must be retained throughout all phases of sample analysis:

- Laboratory should develop a process to track samples based upon sample type, storage conditions, retention time (shelf-life) and analysis method. All sample tracking activities must be documented.

- Samples not analyzed upon receipt should be archived/stored and such storage location should reflect a secure and controlled environment (Sample archiving may be achieved by use of hard-copy or electronic systems)

Handle all samples as if infectious

Universal Precautions

Sample storage and Retention

- The laboratory should set a written policy that include description of what samples to be stored, retention time for samples that may be retained for extended periods (e.g., serum samples), location for easy of access,
- Monitor stored samples (temperature and environment), including freeze/thaw cycles
- Maintain an organized, accessible system using a hard-copy or electronic system
- Establish a schedule to review all stored samples to determine when they should be discarded
- Establish tracking procedures

Disposing of Samples

- Establish policies for disposal of medical wastes
  - Comply with local or country regulations regulation for disposal
  - Establish and follow disinfection procedure
  - Include policy for disposal for rejected samples
- If any specimens are discarded, update the information in the electronic/hard copy Specimen Tracking Log.
  - Discard Date
  - Discard By

Summary

- Always follow universal precautions when handling samples or sample containment and shipment vessels
- Develop and implement a sample management process
- Ensure sample acceptance and rejection criteria and subsequent actions are defined
- Have a system for tracking/documenting samples as they move through the laboratory
- Establish and implement a policy for sample archiving/storage and sample disposal
- Assure that all transport regulations and requirements are met (e.g., IATA, UN 3373)

Questions ?

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Case Study

1. **Your laboratory has received a sample referred from the peripheral hospital. The physician indicated that most of the samples they sent have been returned with no results. In most of the cases, it is indicated on the sample request form *"Sample rejected, please re-draw".* The lack of laboratory result is adversely affecting the initiation of treatment for the patient.**

- **How would you handle such a problem?**

Answer 1

1.1 State the problem

•There has been an increased number of complaints from the customer regarding no results available due to the lab rejecting unsatisfactory samples for testing

1.2 Review specimen rejection logbook

The main reasons for the rejection of samples could be;

- Mislabeled samples or unlabeled
- Hemolyzed samples
- Samples collected with the wrong container
- Insufficient samples etc.

Answer

1.3 The possible cause could be:

- Poor sample collection techniques
- High staff turnover due to reassignment at collection sites

1.4 Propose possible solutions:

- Resend instructions on proper sample collection and transportation to all sites
- Train staff at problem sites

References

- International Organization for Standardization. ISO15189 : 2012 Requirements for quality and competence .https://www.iso.org/standard/56115.htm
- Laboratory Quality Management System (LQMS) training toolkit https://www.who.int/ihr/training/laboratory_quality/introduction/en/
- Global health laboratories www.GlobalHealthLaboratories.org
- **IATA Dangerous Goods Regulations, 58th Ed., 2017 Class 6.2 – Infectious Substances**
- **https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substanceclassification-DGR56-en.pdf**
- **Packing Instruction 650 https://www.iata.org/whatwedo/cargo/dgr/Documents/packing-instruction-650-DGR56- en.pdf**
- **Transportation of Dangerous Goods, TDG Bulletin Shipping Infectious Substances, Transport Canada, September 2016.**
- **https://www.tc.gc.ca/media/documents/tdg-eng/Shipping_Infectious_Substances_NEW.pdf**
- **World Health Organization, Guidance on regulations for the Transport of Infectious Substances 2017-2018, January 2017.**
- **http://www.who.int/ihr/publications/WHO-WHE-CPI-2017.8/en/**
- **SafTPaK, Compliance Training Reference Manual for the Safe Transport of Division 6.2 Infectious Substances, Clinicalal Specimens, Dry Ice, and Related Materials, 2017**
- **2012 Best Practices for Repositories: Collection, Storage, Retrieval, and Distribution of Biological Materials for Research BIOPRESERVATION AND BIOBANKING, Volume 10, Number 2, 201**

Sample Management and Chain of Custody