



Laboratory Quality Management System

Module 9: Process Control: Sample Management

Venue:

Presenter:

Date:

Introduction

- Sample management is a part of process control
- Handling of samples in order to ensure accurate and reliable testing.



Learning Objectives

At the end of this activity, participants will be able to:

- name sample collection errors that could lead to incorrect laboratory examination results;
- list contents that should be included in a handbook designed for people who collect samples off-site;



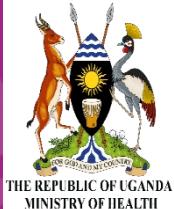
provide a rationale for rejecting unsatisfactory

Module Outline

- Laboratory handbooks
- Collection and preservation
- Sample processing
- Sample storage, retention and disposal
- Sample transport



- describe a system for sample handling, including collection, transport, storage, and disposal;
- Explain the importance of maintaining sample integrity and assuring that all regulations and requirements are met when transporting samples.



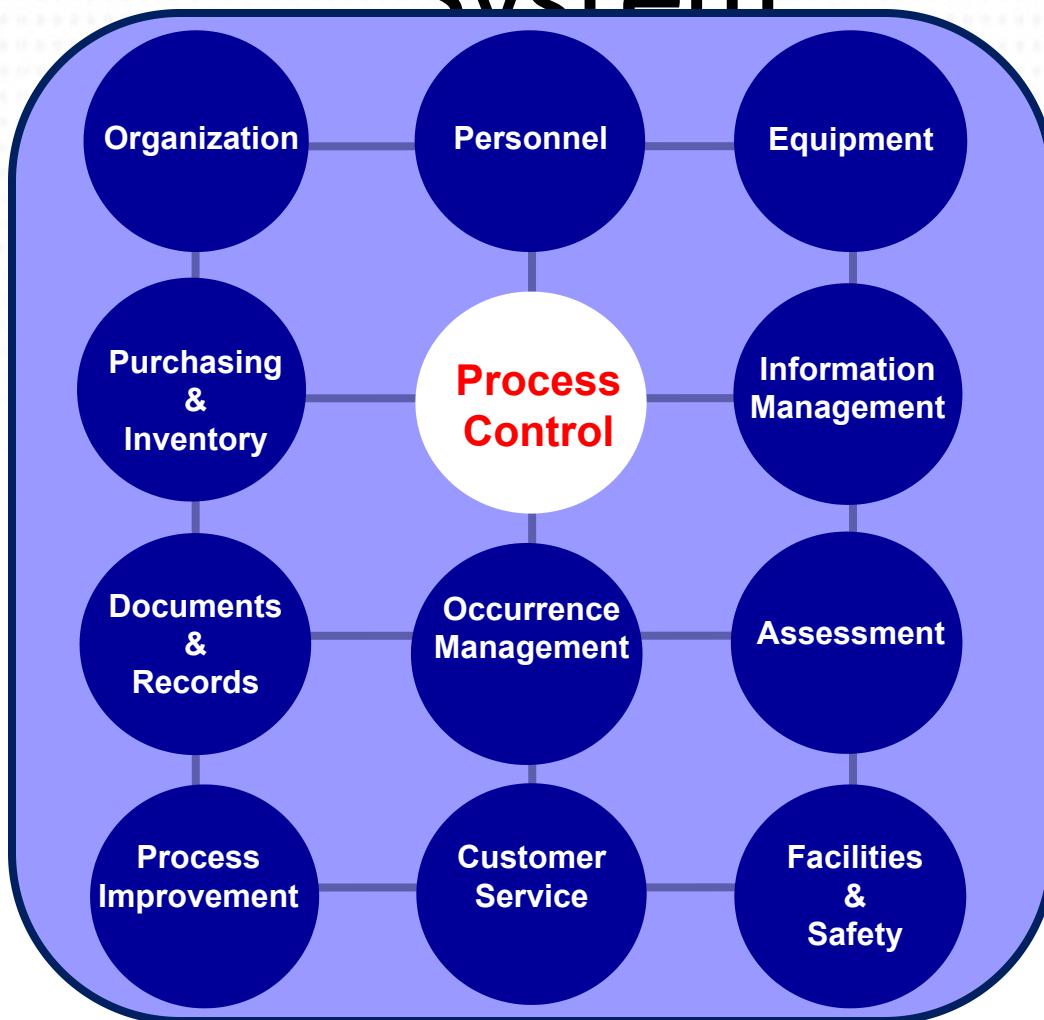
Scenario:

Your Laboratory has performed PCR for influenza virus on patient samples from ‘Clinic A’. Most of these results are negative. The medical staff from ‘Clinic A’ tells you that their patients present all the clinical signs of influenza.

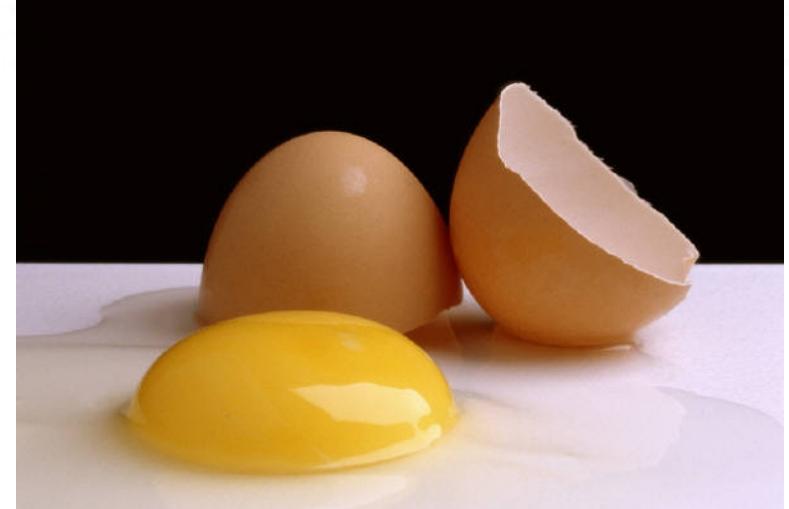


**What are you going to check?
What will you do?**

The Quality Management System



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





**Essential to
accurate
laboratory
diagnosis**

**Influences
laboratory
efficiency**

**Good
sample
management**

**Influences
therapeutic
decisions**

**Directly
affects
patient care
and outcome**



**International
Science Laboratory**

Sample management components



2. The Laboratory Handbook

- contains information needed by those who collect samples
- available to all sample collection areas
- must be understood by all laboratory staff
- referenced in the quality manual



Laboratory Handbook

Contents

- ─ name and address of laboratory
- ─ contact names and telephone numbers
- ─ hours of operation
- ─ list of tests that can be ordered
- ─ sample collection procedures
- ─ sample transport procedures
- ─ expected turn around times (TAT)
- ─ how urgent requests are handled



3. Collection and Preservation: The Laboratory's Responsibilities

Provide sample collection information
What- When- How



Provide appropriate containers and supplies



Assess all samples - preexamination



Define a good labeling system

Test Requisition

- patient ID
- tests requested
- time and date of sample collection
- source of sample, when appropriate
- clinical data, where indicated
- contact information of requesting physician or authorized individual



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**TEST CENTER FOR
NEONATAL HYPOTHYROIDISM**

Address _____

Card No. **16911**

Infant's Name _____ Date and Time
Home Address _____ of Specimen Collection

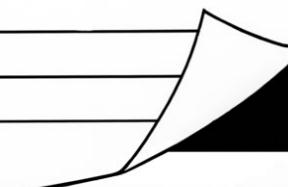
Patient's ID No. _____

Birth Date _____
Birth Weight _____ lbs. _____ oz.

Hospital _____
Address _____

Infant's Physician _____
Address _____

Phone No. _____



Field Data Collection Form

General patient information

Name:
Address:
Country:
County:
City/town/village:

Tracking record number

Date of Birth (dd/mm/yyyy):
Sex: M F
Nationality:
Occupation:

Date of onset of illness (dd/mm/yyyy):

Clinical specimens

Unique ID No.	Type	Date of collection	Clinical diagnosis	Health status when specimens collected	Remarks

Post-mortem specimens

Date of death(dd/mm/yyyy): / /

Name of person completing form: _____

Institutional affiliation: _____

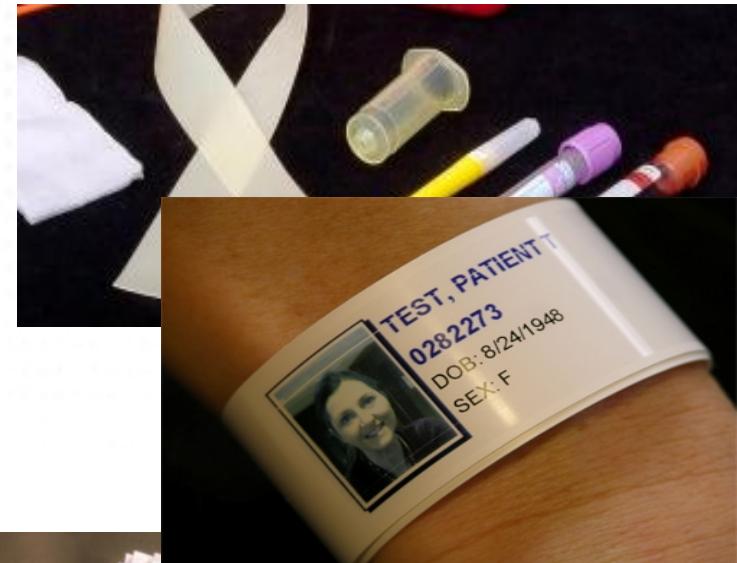
Contact details: _____

Date(dd/mm/yyyy): ____ / ____ / ____



Collection Requirements

- patient preparation
- patient identification
- type of sample required
- type of container needed
- labeling
- special handling
- safety precautions



Provide sample collection information

Finger Prick

Always use universal safety precautions.



1. Collect supplies.



2. Position hand palm-side up. Choose whichever finger is least calloused.



3. Apply intermittent pressure to the finger to help the blood to flow.



4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.



5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip.



6. Firmly press the lancet to puncture the fingertip.



7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball.



8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.



9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops.

10. Properly dispose of all contaminated supplies.



Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2005).



Labeling

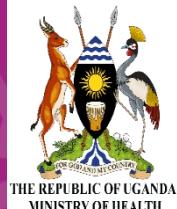
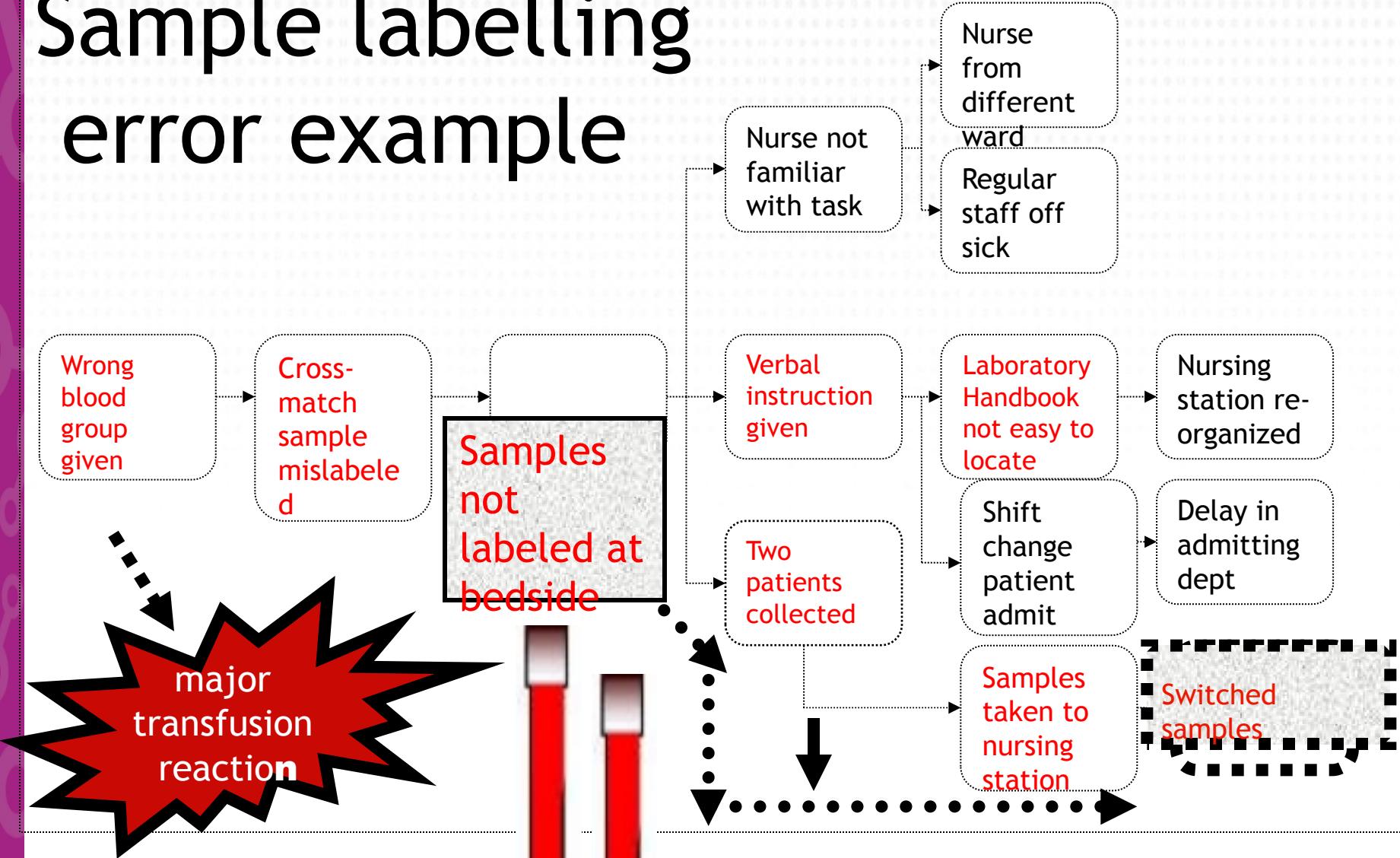
Each sample should be labeled with:

- patient's name
- patient's unique ID number
- test ordered
- time and date of collection
- collector's initials



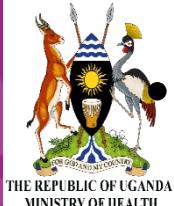
Use computer-generated bar codes when possible

Sample labelling error example



Outcomes of Improper Collection

- delays in reporting test results
- unnecessary re-draws/re-tests
- decreased customer satisfaction
- increased costs
- incorrect diagnosis / treatment
- injury
- death



4. Sample Processing

Pre-examination Steps

- Verify
 - completeness of test request
 - appropriateness of sample
 - information on label
- Record in register or log
- Enforce sample rejection criteria





Labeled samples,
completed requisitions



Spilled urine sample,
a cause for rejection

Actions for Rejected Samples

- inform authorized person
- request another sample
- record rejected samples
- retain rejected sample based on preset criteria
- extraordinary circumstances may

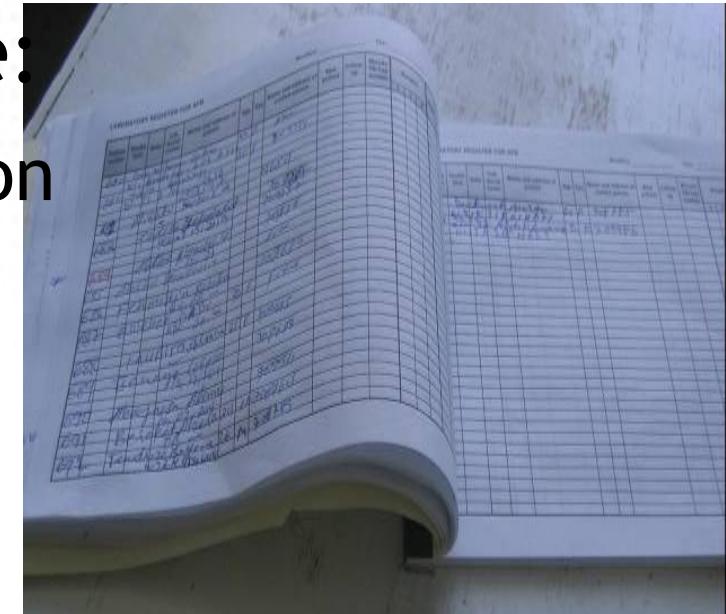
require testing suboptimal samples



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



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Sample Tracking-Manual

- cloud confirm receipt of samples, include date and time
- cloud label samples appropriately; keep with the test requisition until laboratory ID is assigned
- cloud track aliquots-traceable to the original sample

<input checked="" type="checkbox"/>	*****QUALITY LAB*****
<input checked="" type="checkbox"/>	Test order form
<input checked="" type="checkbox"/>	Patient name:
<input checked="" type="checkbox"/>	DOB
<input checked="" type="checkbox"/>	Address/Ward:
<input checked="" type="checkbox"/>	Doctor:
<input checked="" type="checkbox"/>	Sample:
<input checked="" type="checkbox"/>	Date: _____
	Time: _____



Sample Tracking-Computer

Database entries include:

- identification number
- patient information
- collection date and time
- type of sample
- tests to be performed
- name of health care provider
- location of patient, e.g., ward, clinic, outpatient
- diagnostic test results
- time and date results are reported



Sample Handling

Handle all samples as Potentially infectious

Universal Precautions



5. Sample Storage, Retention and Disposal

Sample Storage-Written Policy

- describe samples to be stored
- determine retention time
- determine location
- describe proper conditions
- establish method of organizing samples



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Sample Retention

- set policy for retention
- monitor stored samples, including freeze/thaw cycles
- maintain an organized, accessible system
- establish a schedule to review all stored samples
- establish tracking procedures



Sample Referral

- Record:
 - samples referred
 - date of referral
 - name of person referring to..
- Monitor / Track, and Record:
 - turnaround time
 - results delivery (from referral laboratory, to requestor)
 - problems with referral



Sample Disposal

- ❑ set policy for sample disposal
- ❑ compliance with local and country regulations
- ❑ disinfection procedures



6. Sample Transport

─ Maintain integrity of sample:

- temperature
- preservation of sample
- special transport containers
- time limitations

─ Assure safety regulations
are met



Transport Regulations

- Where do they come from?
- Who develops them?

- ✓ National transport regulations
- ✓ ICAO/IATA transport regulations (air)
- ✓ Rail, road, and sea traffic agencies
- ✓ Postal services
- ✓ Private couriers



Transport Regulations

Mandatory Compliance

Violation ||



Deal with accidents and spills
– reduce biohazards



Safety: couriers, laboratory staff, passengers, carriers

Classification of Infectious Substances

New Classification in 2005: based on two transport categories

**Category A: infectious substances capable of causing permanent disability
life-threatening or fatal disease to humans or both human and animals**

Packaging: most durable triple packaging with full dangerous goods documentation

Training of transport staff

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UGANDA Supranational Reference Laboratory

Timely Accurate Diagnostics for a TB-Free Africa

Classification of Infectious Substances

Category B: Infectious substances not included in Category A

- less stringent triple packaging
- no dangerous goods documentation required



Exemptions

- ❑ substances that do not contain infectious substances
- ❑ substances containing organisms that are non-pathogenic
- ❑ substances containing neutralized or inactivated pathogens
- ❑ environmental samples that pose no risk of infection
- ❑ blood or blood components collected for transfusion
- ❑ tissues or organs cleared for transplantation
- ❑ dried blood spots and fecal occult blood screening tests

Triple Packaging (UN 2007)

Category A

- leakproof primary
- leakproof secondary
- 95 kPa pressure test
- rigid outer
- minimum 100 mm
- absorbent material
- 9 meter drop test
- 7 kg penetration test
- UN marks and labels
- full DG documentation
- training



UN
4G/CLASS 6.2/98
CAN&2 SAF-T-PAK



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Category B

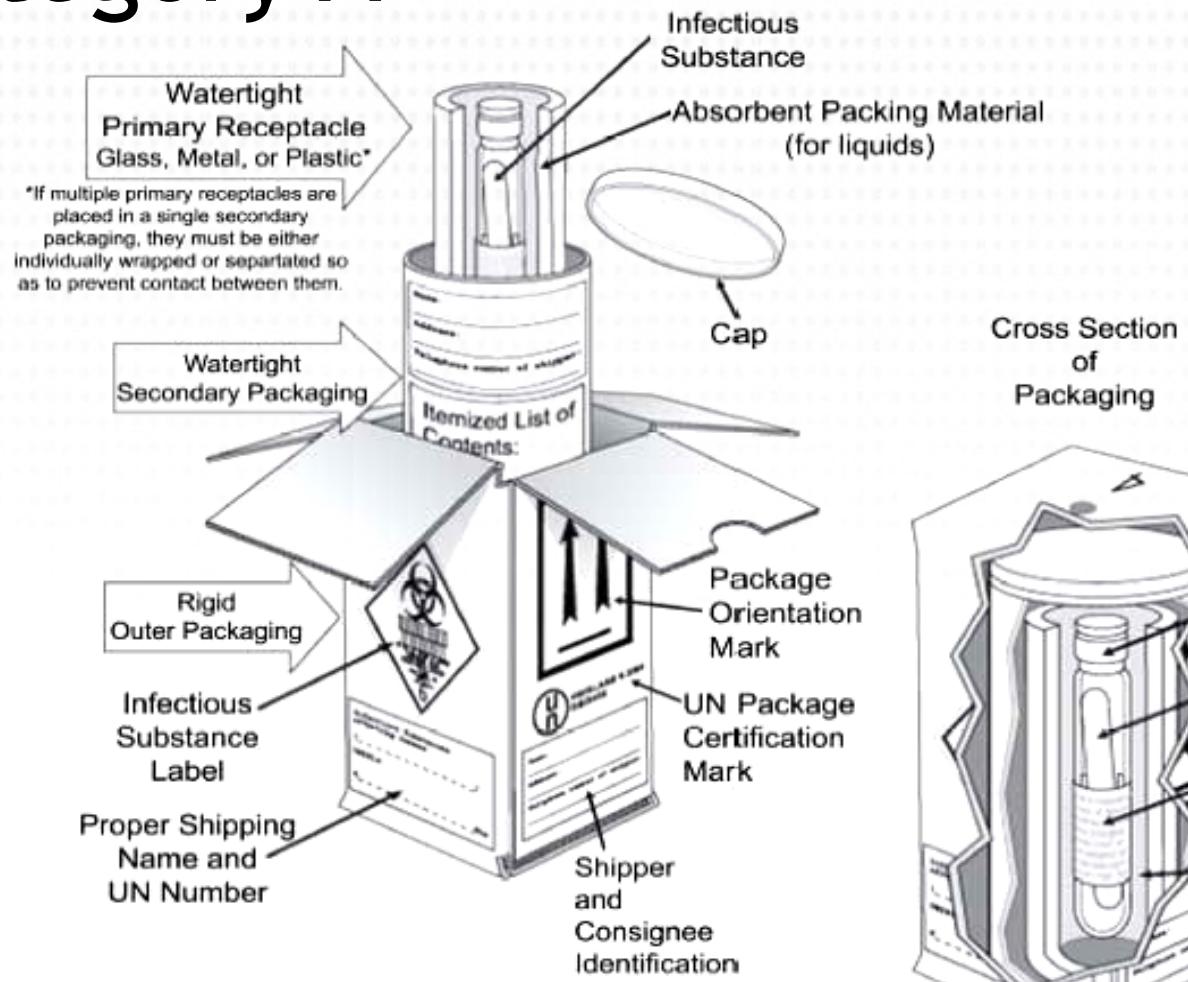
- leakproof primary
- leakproof secondary
- 95 kPa pressure test
- rigid outer
- minimum 100 mm
- absorbent material
- 1.2 meter drop test
- 3373 label



Exempt human or animal specimens

- leakproof primary
- leakproof secondary
- adequate outer
- minimum 100 mm
- absorbent material

Category A



Managing Sample Transport

- Meet all applicable regulations
- Train personnel in all transport procedures
- Assure sample is protected:
 - temperature
 - transport time
 - packaging and preservation



Assessment

- What are some of the sample collection errors that could lead to incorrect laboratory examination results?
- List contents of a handbook designed for people who collect samples off-site.
- What are some of the reasons for sample rejection in the Laboratory.
- explain the importance of maintaining sample integrity and assuring that all regulations and requirements are met when transporting samples.



Summary

- provide a laboratory handbook with collection information to all users
- have a system for tracking samples as they move through the laboratory
- establish and implement a policy for sample storage and sample disposal
- maintain sample integrity
- assure that all transport regulations and requirements are met

Always follow universal precautions



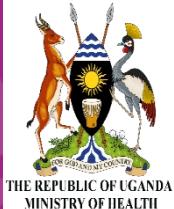
Key Messages

- The laboratory must have good samples in order to ensure accuracy and reliability of testing and confidence in results
- Sample management directly affects patient care and outcome

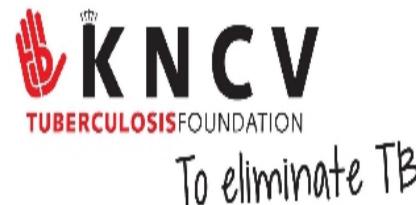


References

- ☁ ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence
« Clause 5.6.2, 5.6.3 & 5.6.4»
- ☁ CLSI
- ☁ ASLM



Acknowledgement



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