



THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

Timely Accurate Diagnostics for a TB-Free Africa

Training on Proficiency Testing Scheme (Microscopy PT)

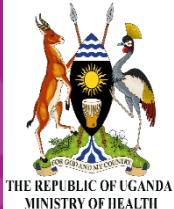
Module 8: Packaging of PT materials

Date

Uganda Supranational Reference
Laboratory

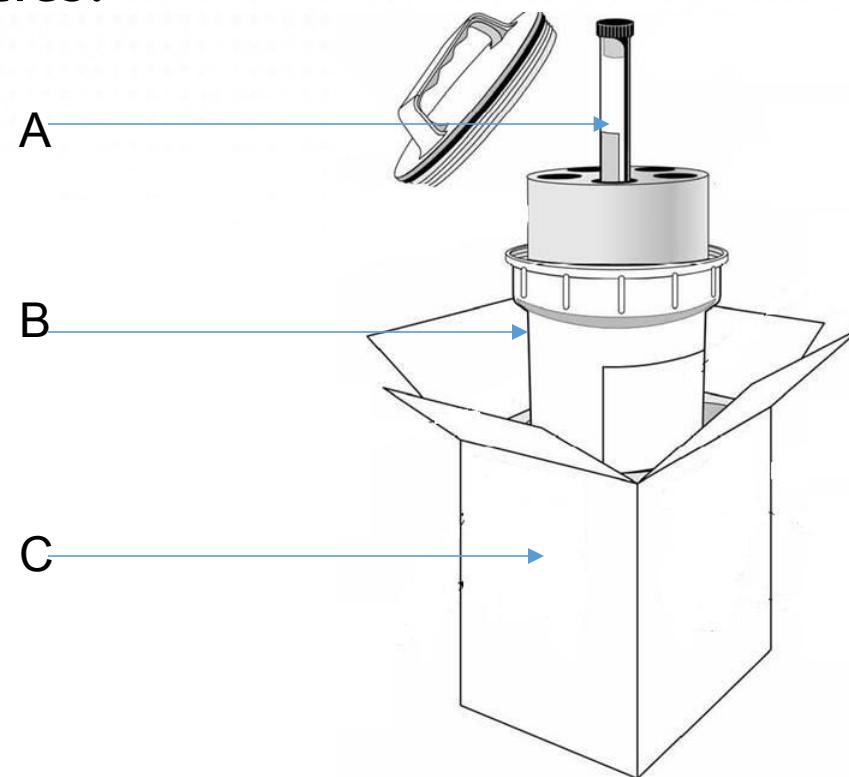
Content outline

- Overview
- Triple Packaging
- Packaging Category A Infectious Substances (PI620)
- Packaging Category B Biological Substances (PI650)
- Packaging Limitations
- Packaging Exercise



Exercise

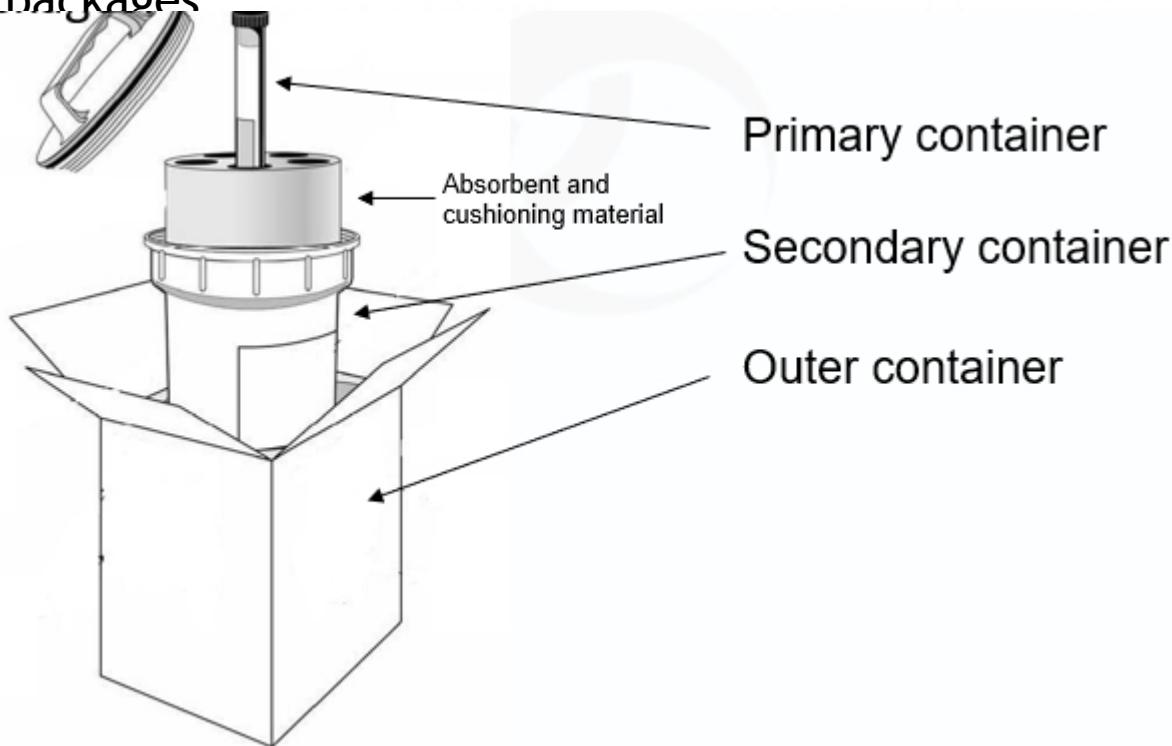
Identify the different container levels A, B and C and list their characteristics.



Packaging of Infectious Substances

Triple Packaging

Triple packaging provides three layers of containment to protect the substances being shipped. These layers are primary, secondary, and outer containers. The following diagram shows the basic concept of triple packages.



Packaging of Infectious Substances

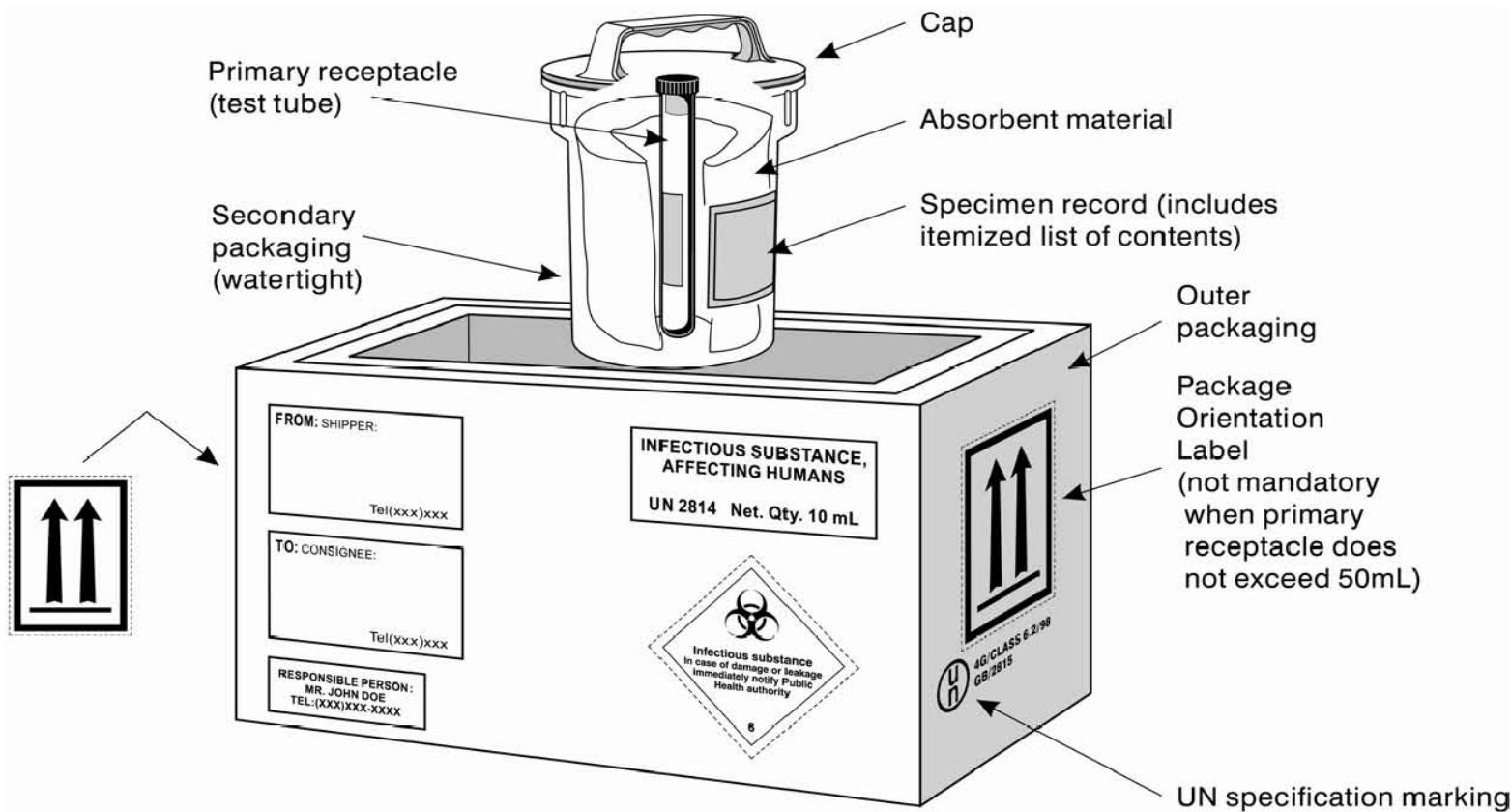
Category A Packaging Requirements

- Primary container is leakproof
- Secondary container is leakproof
- Outer container is rigid
- UN specification marking:
 - Pressure tested at 95kPa
 - Drop tested from 9m
 - Puncture tested at 7kg
 - Stacking tested
- Shipper must be trained



Packaging of Infectious Substances

Category A Packaging Requirements



Packaging of Infectious Substances

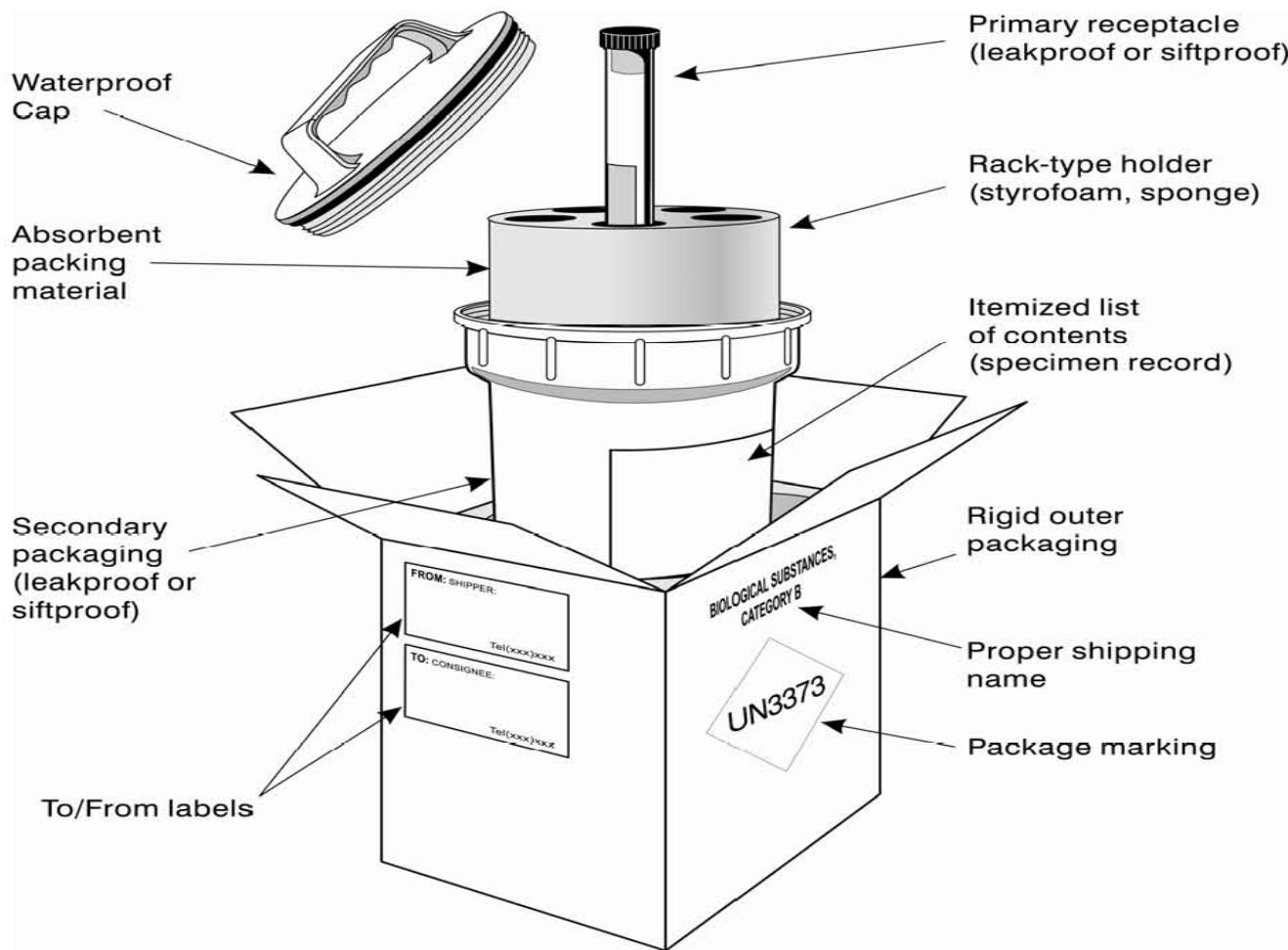
Category B Packaging Requirements

- Primary container is leakproof
- Secondary container is leakproof
- Either the primary or the secondary container must be pressure tested at 95kPa
- Either secondary or outer container is rigid
 - If the shipment is transported by air, the outer container must be rigid.
- Drop tested from 1.2m



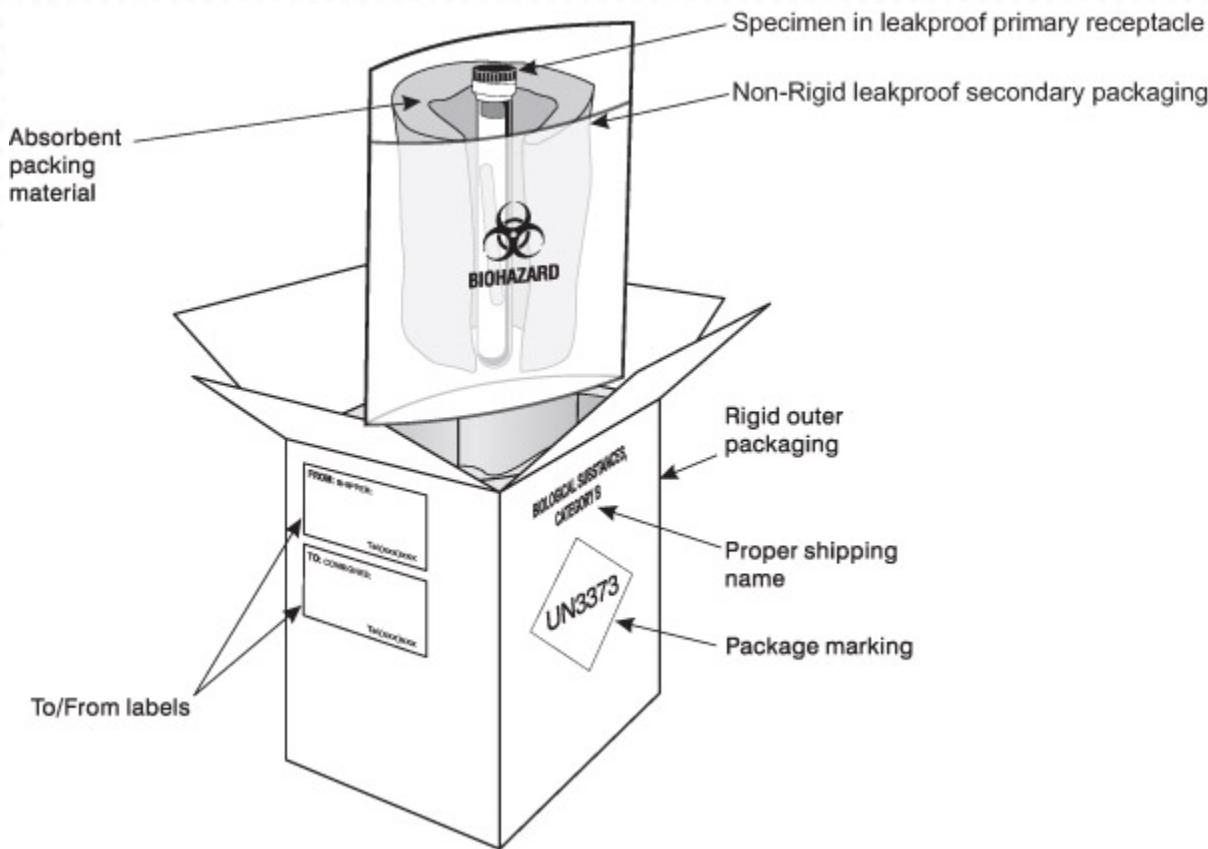
Packaging of Infectious Substances

Category B Packaging Requirements



Packaging of Infectious Substances

Category B Packaging Requirements



Marking and labeling packages of infectious substances

UN Specification Marking

This symbol means the packaging has passed a series of tests.
UN approved packaging is required for PI620.



**4G/CLASS 6.2/05
GB/2470**

Improper Marking and Labelling

- Package should not be accepted (by carrier)
- Courier refusal
- Package may be returned to shipper
- Package may be delayed
- Package may be destroyed
- Customs retention



Category A Markings and Labels

- **Markings**

- Shipper's name and address
- Receiver's name and address
- Name and tel. of responsible person
- UN Specification Marking
- UN 3373
- Proper Shipping Name
- UN Number

- **Labels (hazard and handling)**

- Infectious substance label
- Package orientation label

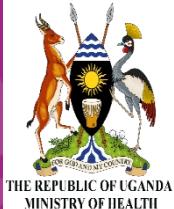
Cargo aircraft only label



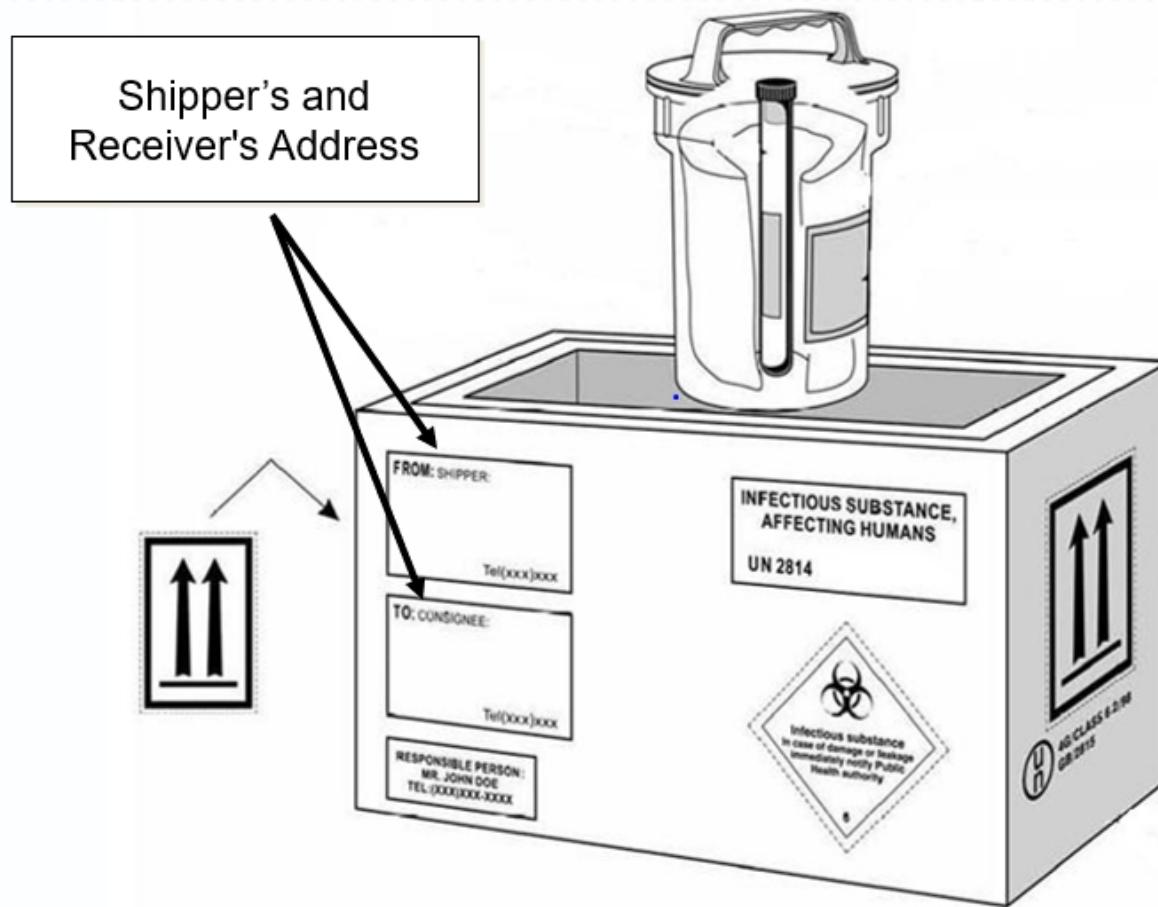
MARKINGS	
SHIPPER PINCO PALLINO TIMELY LOGISTICS BP 102 ERAGNY/OISE F-95613 CERGY PONTOISE	RECEIVER AB NORMAL LAB PASTEUR CERBA RUE DE L'EQUERRE F-44567 FORT DE FRANCE
EMERGENCY CONTACT 24H/24H Dr RED PEPPER: +67 56 45 34 23	
	4G/CLASS 6.2/02 F/BVT 312103
	INFECTIOUS SUBSTANCE, AFFECTING HUMANS UN2814
LABELS	

Category A Markings and Labels

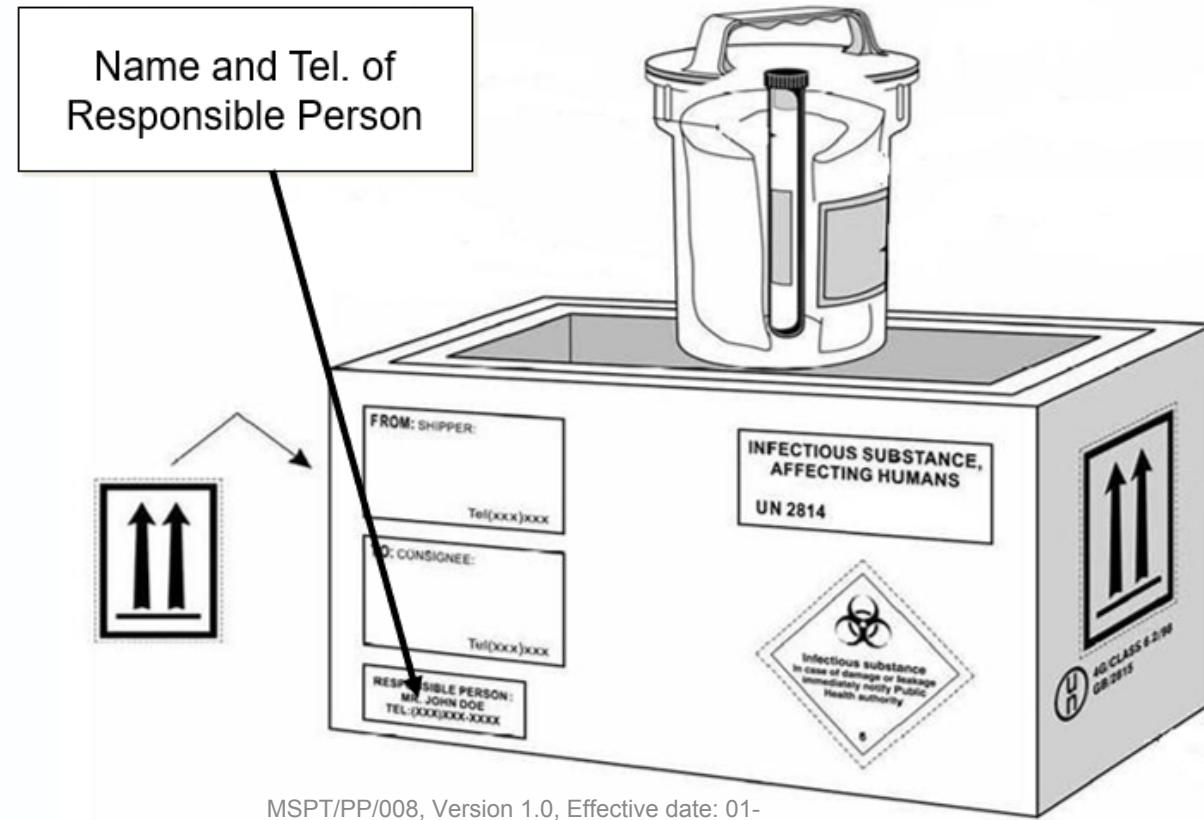
- **Markings**
 - Shipper's name and address
 - Receiver's name and address
 - Name and telephone of responsible person (who is available 24 hours a day until shipment arrives)
 - Proper Shipping Name
 - UN Number
 - UN Specification Marking
- **Labels (hazard and handling)**
 - Infectious substance label
 - Package orientation label (mandatory only when primary container exceeds 50ml)
 - Cargo Aircraft Only (when the package may only be transported on a cargo aircraft)



Category A Markings and Labels



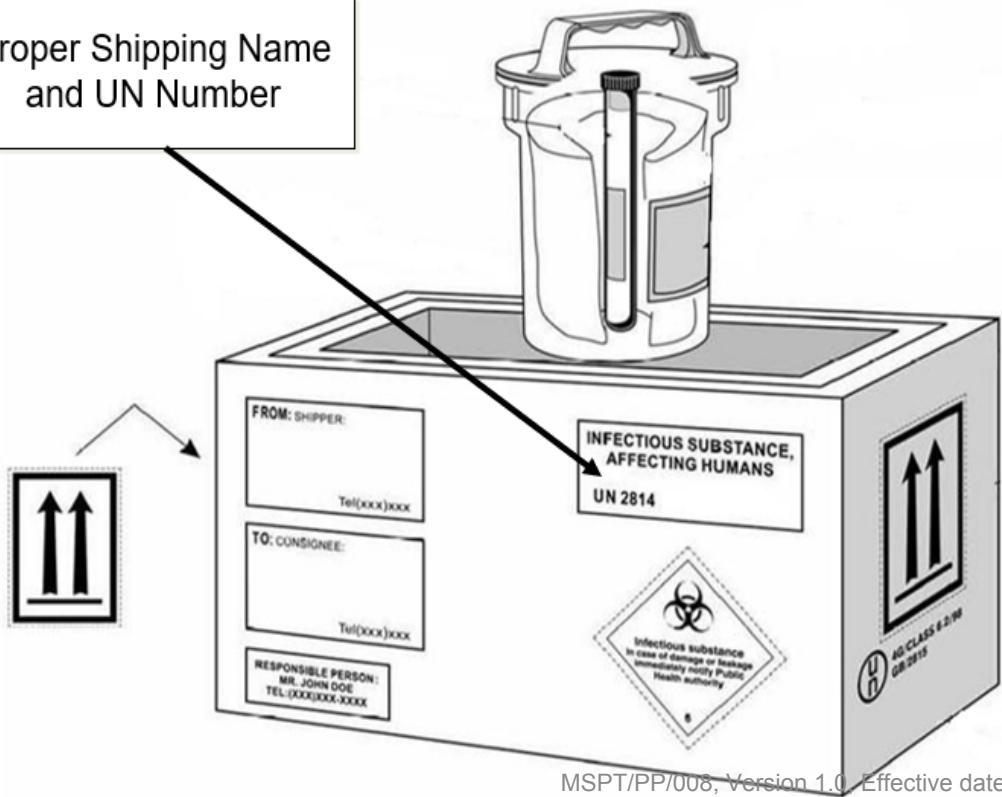
Category A Markings and Labels



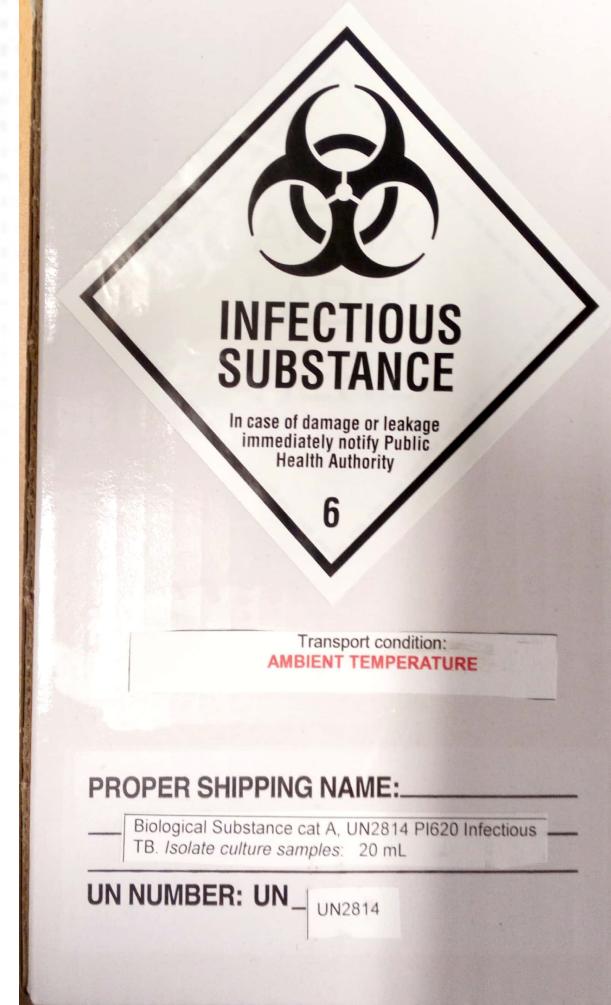
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Category A Markings and Lab

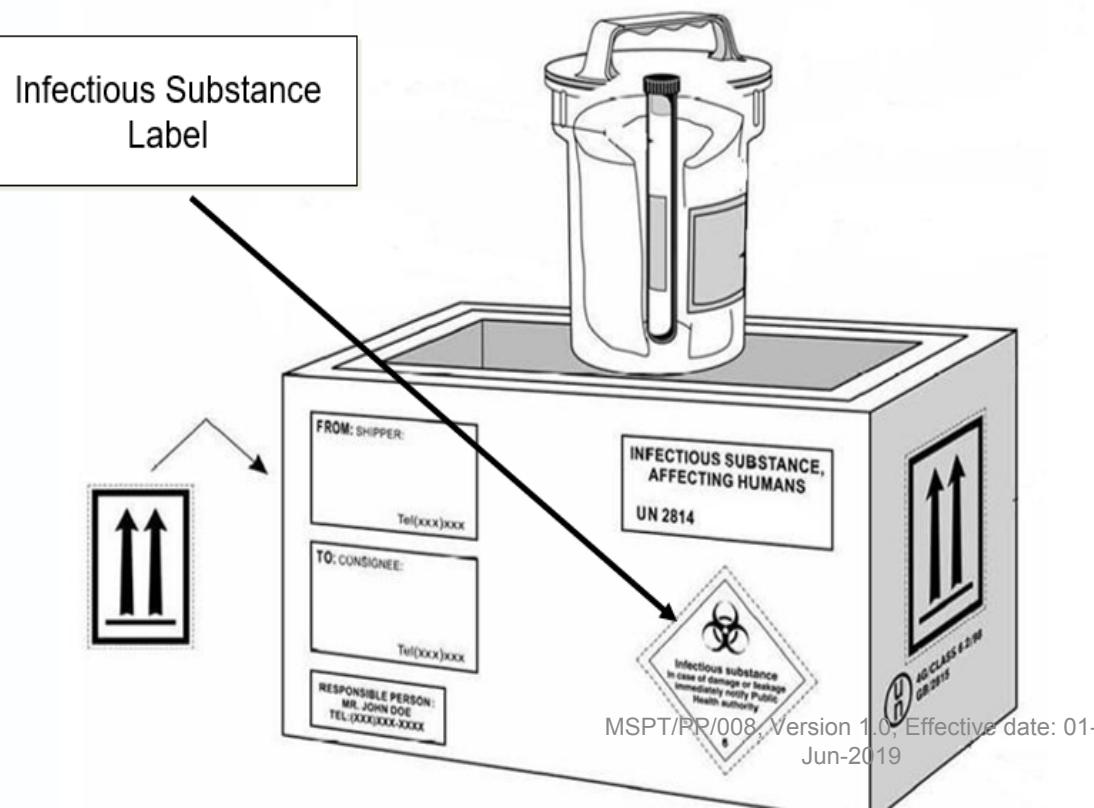
Proper Shipping Name
and UN Number



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Category A Markings and Labels



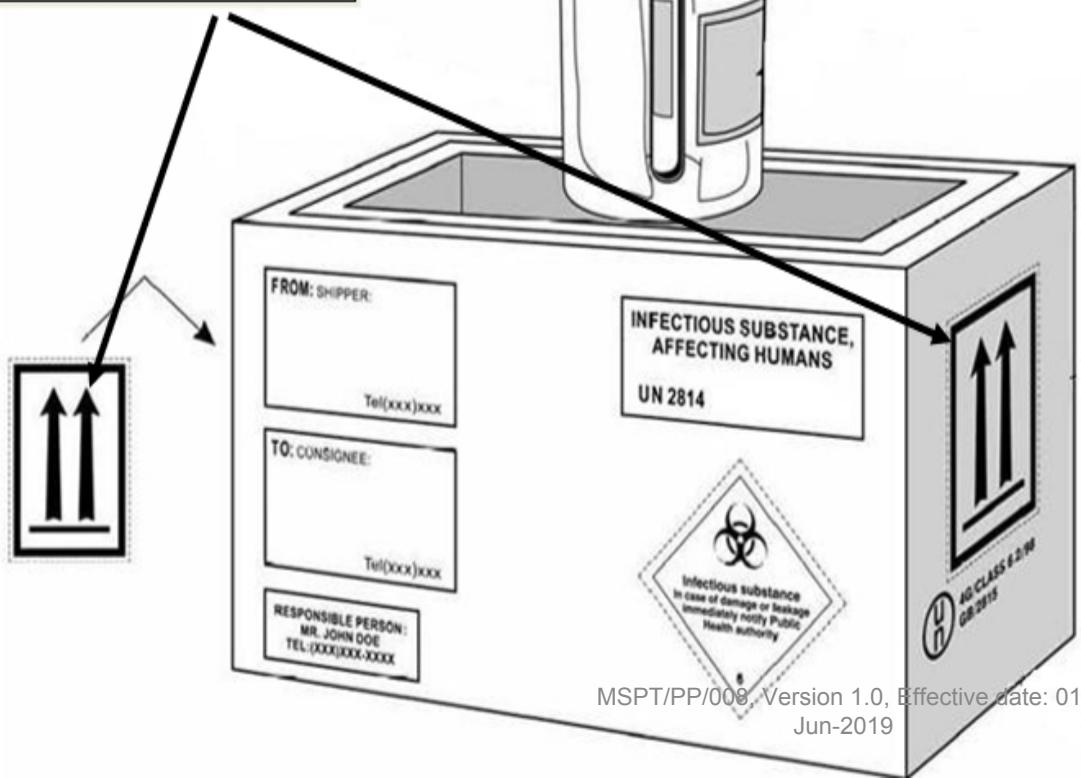
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Category A Markings and Labels

Orientation Labels

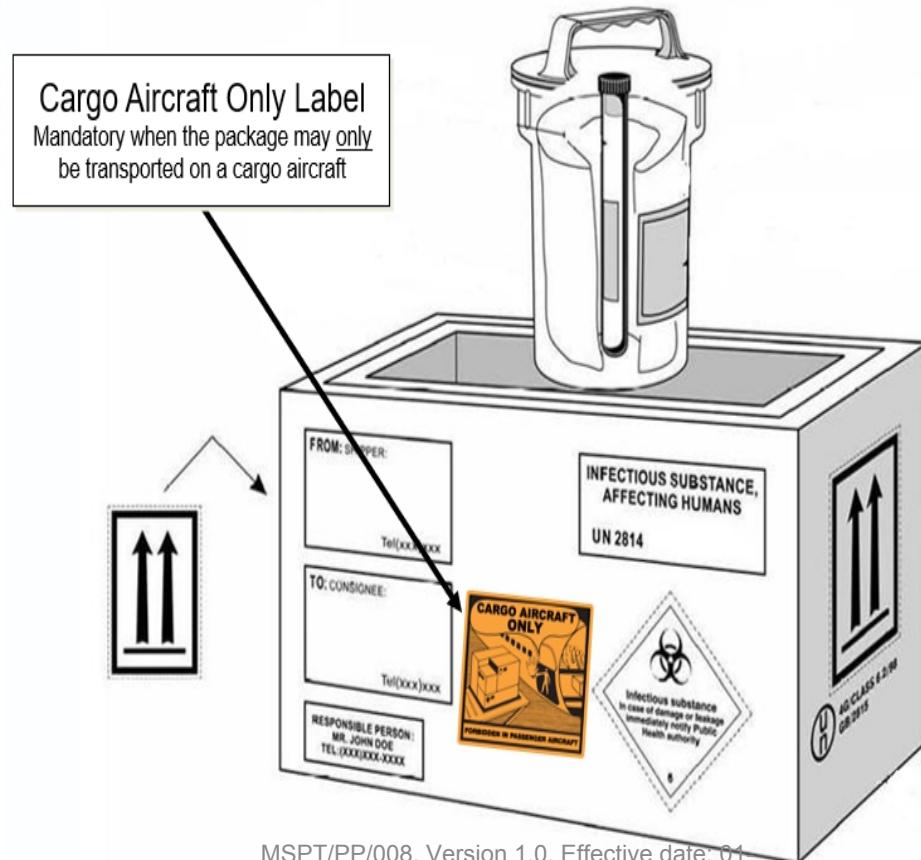
Mandatory on opposite sides when total volume of infectious substance exceeds 50 ml



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Category A Markings and Labels



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Category B Markings and Labels

Markings

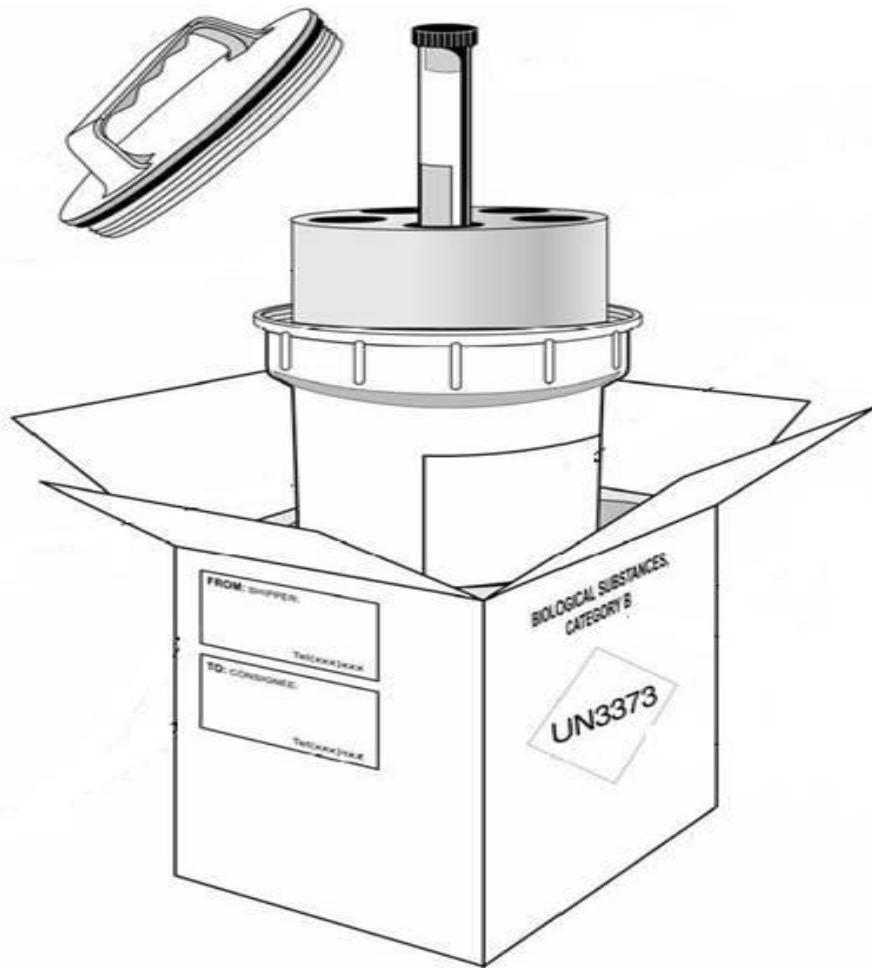
- Shipper's name and address
- Receiver's name and address
- Proper Shipping Name
- UN Number

Labels (hazard and handling)

- None are required (unless shipping with dry ice)



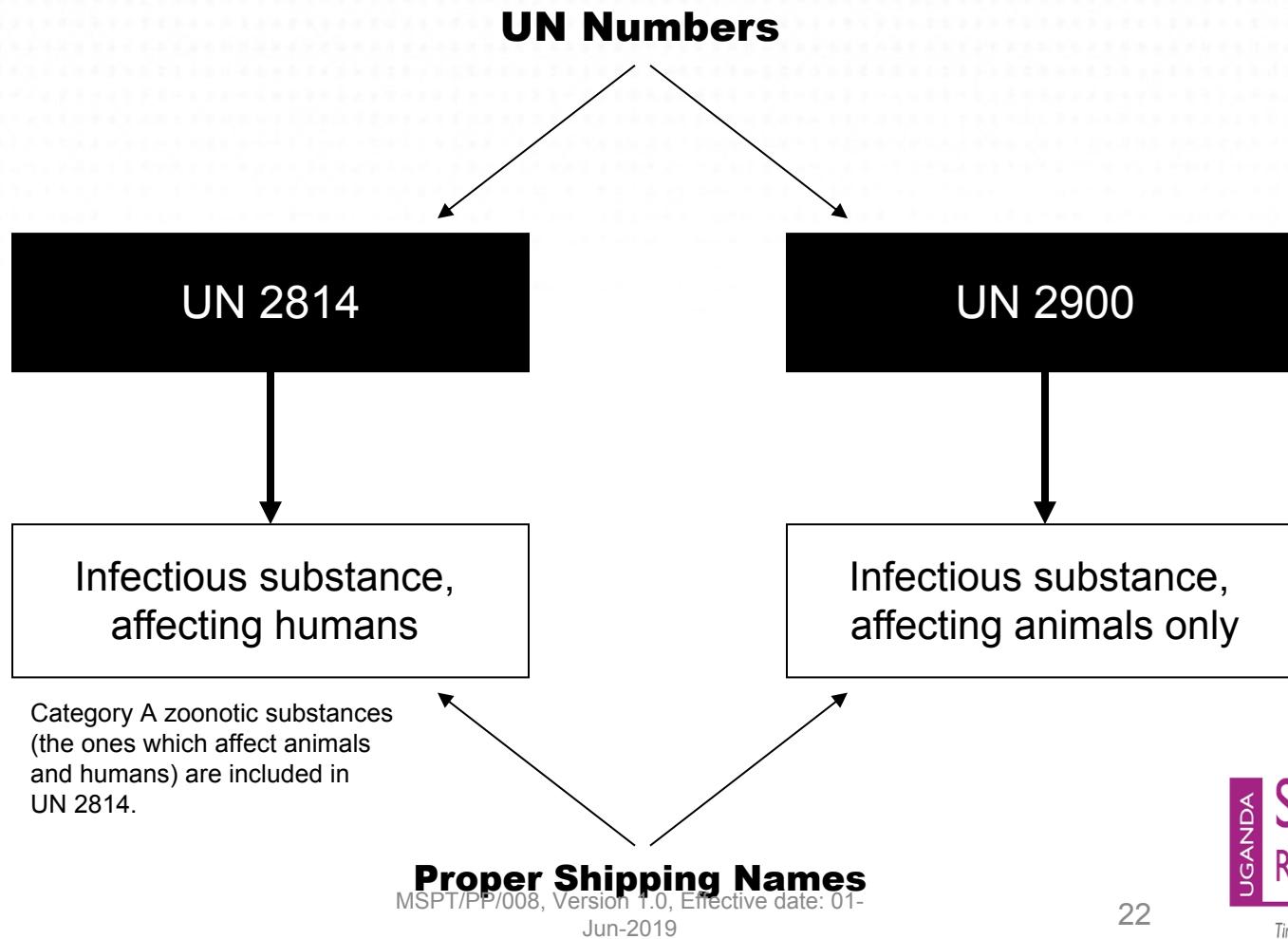
Category B Markings and Labels



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Category A – Infectious Substances



Category B – Biological Substances

MICROSCOPY PT
PANELS FALL HERE

UN Number

UN 3373

Biological substance,
Category B

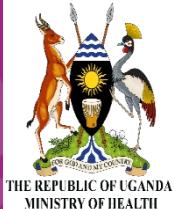


Proper Shipping Name



Labelling of Panels

- Labelling can be done through the use of
 - Permanent markers
 - adhesive tube labels (38.1 x 8mm labels)
- Type of numbers/ID to use
 - Can be random numbers for same strain but different for each participant
 - *NB: Good documentation and record keeping required for traceability*
 - Same ID for each strain for each participant e.g. T1, T2, T3.....T20



Exercise II

Categorization and Identification

Please complete the table below by classifying and listing the shipping name and number for each situation.

Situation	Categorization	Proper Shipping Name	UN Number
Patient presents with suspected case of Hepatitis B virus and blood samples are sent			
Sending a culture of <i>Mycobacterium tuberculosis</i> to a reference laboratory			
The Ebola virus has been found in bats and samples which have not been cultured are being shipped			
A medical professional declares that samples collected for a human drug test have only minimal likelihood of containing pathogens			



Exercise II

Categorization and Identification

Please complete the table below by classifying and listing the shipping name and number for each situation.

Situation	Categorization	Proper Shipping Name	UN Number
Patient presents with suspected case of Hepatitis B virus and blood samples are sent	Category B	Biological Substance, Category B	UN 3373
Sending a culture of <i>Mycobacterium tuberculosis</i> to a reference laboratory	Category A	Infectious Substance, Affecting Humans	UN 2814
The Ebola virus has been found in bats and samples which have not been cultured are being shipped	Category A	Infectious Substance, Affecting Humans	UN 2814
A medical professional declares that samples collected for a human drug test have only minimal likelihood of containing pathogens	Exempt	Exempt Human Specimen	

Steps labelling and packaging Microscopy PT materials

- Use pre-labelled adhesive slide labels
- Pick one slide at a time for labelling
- Pack 5 slides in one slide mailer (T1 upto T5) and T1 upto T10 in another slide mailer
- Label slide mailers with round name & number, year, stained/unstained
- Pack the mailers into Ziplock bags with cottons to prevent movement within the box during transit.
- Pack the Ziplock bags into pre-labelled slide transportation box (UN 3373)

Repeat above steps for another participant
laboratory

Steps labelling and packaging Microscopy PT materials

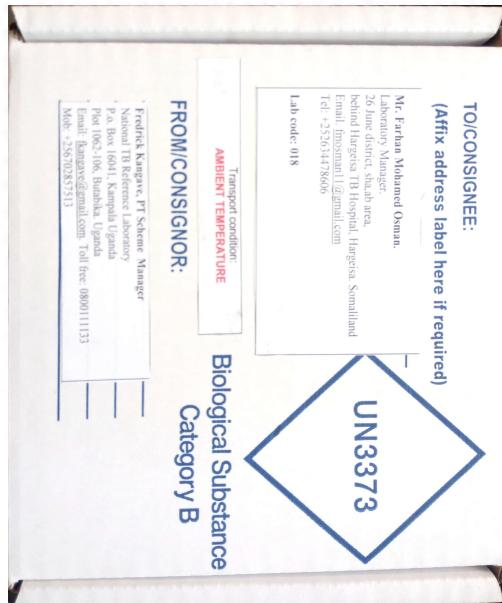
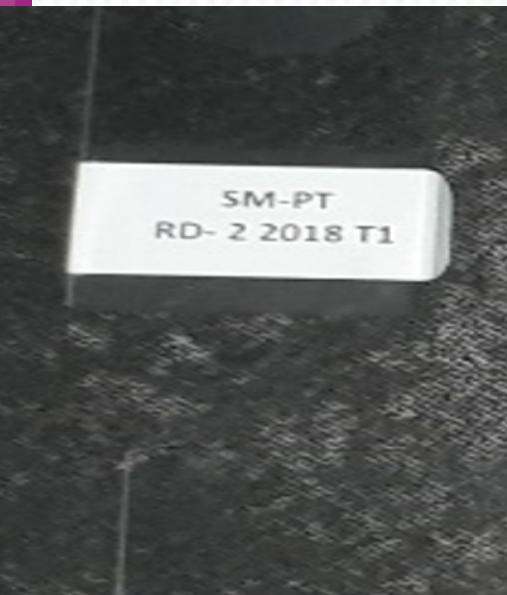
Quality control checks of packaging

- After packaging, ensure a second person rechecks packaging status
 - Checks labels
 - checks slides T1 to T10 are in the slide
 - checks documents
 - checks labelling of transport box i.e. consignee and consigner details
- Checks availability of documentation
 - instructions and result form E.t.c
- Insert a “safety tamper seal” to ensure that the consigner does not use the package once the seal is tampered with





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PARTICIPANTS INSTRUCTION MANUAL

ROUND No: PILOT DEC 2017

MICROSCOPY PROFICIENCY TESTING SCHEME - PILOT

FINAL PARTICIPANT REPORT

Laboratory Name: Laboratory Code: Date Sent:
Date panel received: Date Results Returned: PT ROUND:

Slide code	Technique	Result	Expected result	Error Type	Score
T1					
T2					
T3					
T4					
T5					
		MSPT/PP/008, Version 1.0, Effective date: 01-Jun-2019			

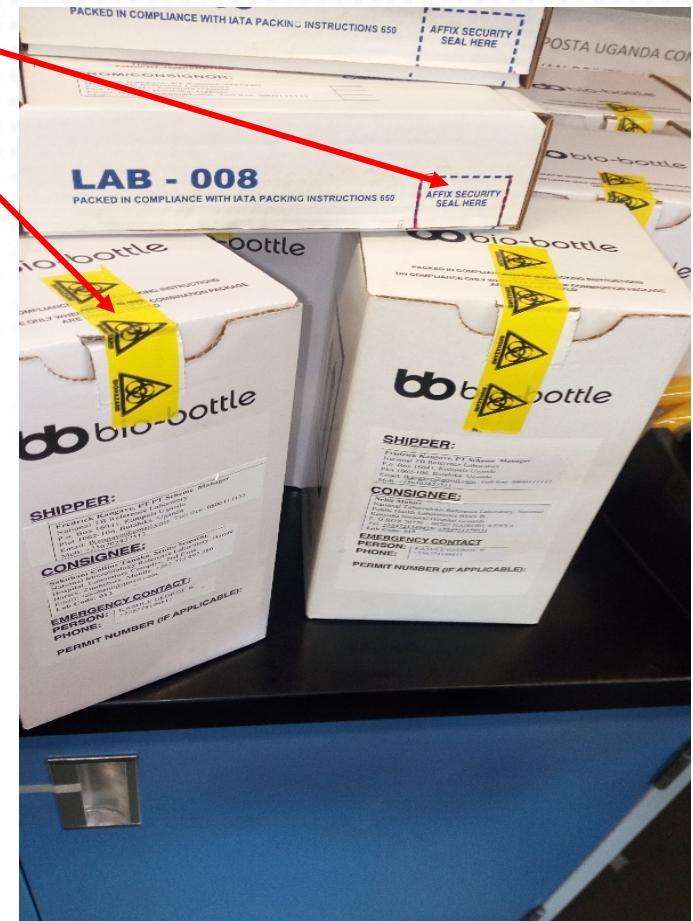
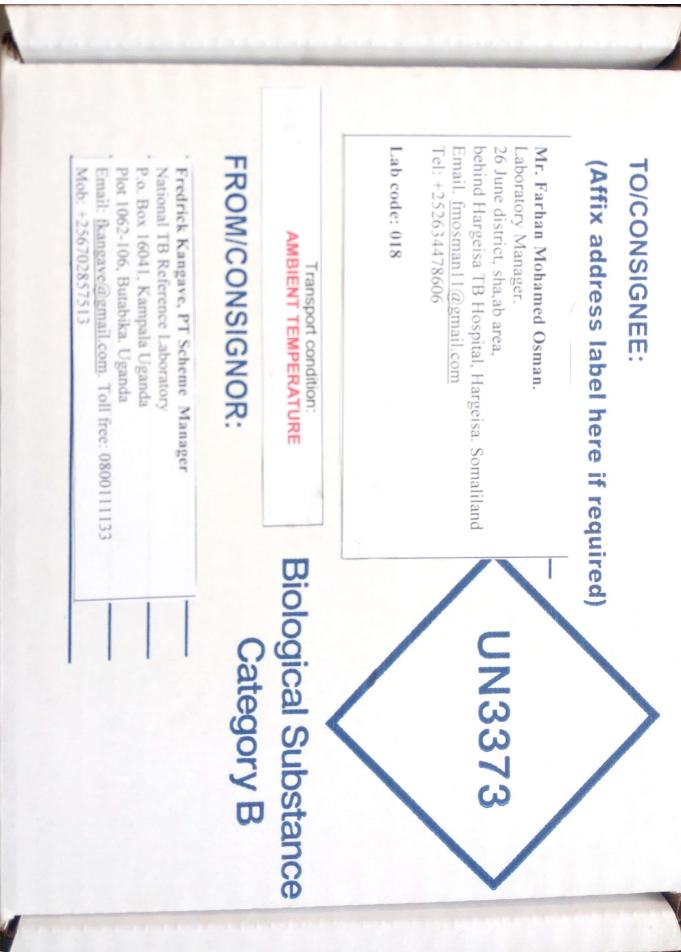
1.0 Introduction

Dear Participants, welcome to this PILOT-round of the microscopy PT panel scheme. The panels are prepared and distributed by the Malawi NTRL to all selected diagnostic facilities performing microscopy. You are encouraged to test the PT panel slides using the routine method of your choice.

The package contains 10 TB microscopy slides (05 stained with ZN technique and 05 unstained) labelled T1 to T10. Examine and treat the specimens as you would normally treat routine clinical

Pictorial

Anti tamper
security seal



Demonstrate Packaging Process of Microscopy PT materials.....



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Limitations for Shipping

Weight and volume (excluding overpacks) Module II slide 16 columns 13 & 15

- **Category A Substances**
maximum 50ml or 50g per package for passenger aircraft
maximum 4litres or 4kg per package for cargo aircraft
- **Category B Substances**
maximum 4litres or 4kg per package for passenger or cargo aircraft
maximum 1litre per primary container for passenger or cargo aircraft

Multiple samples

Multiple primary containers can be placed in the same package and must be individually wrapped or separated to prevent contact

Package dimensions

PI620 packages:

the smallest external dimension shall not be less than 10cm

PI650 packages:

at least one surface of the outer packaging must have a minimal dimension of 10cm x 10cm



References

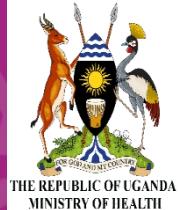
- IATA shipping guidelines
- Ministry of Health (2015); CPHL Biosafety and Biosecurity Manual
- Public Health Agency of Canada (2012); Biorisk Management Notes
- Sandia (2015); Global Biorisk Management Curriculum



Acknowledgments



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