

Training on Proficiency Testing Scheme (GeneXpert DTS)

Module 12: Packaging, Labelling and Distribution

Venue

Facilitator's name

Date

Introduction

Prepared Pt items are package according to local and international standards and the best means of transport are decided on to maintain the integrity of the panels.

Objectives

By the end of this module participants should be able to

- Understand the standard way of packaging and labelling PT materials
- To understand the regulations associated with transportation of PT panels
- Understand the quality Assurance procedures in packaging , transportation and distribution of these materials

Module outline

- Packaging guidelines
- workflow of packaging
- Storage of PT panels
- Shipment of PT panels

Guidelines on packaging

Infectious un-inactivated items:

- Cultures of MTB are considered Category B Biological substances (UN3373); and should be packaged according to the requirement for Category B substances (IATA Regulations), particularly when transporting by air,
- Category B means, an infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals in the event of exposure

Guidelines on packaging

- Cultures may be classified as Category B infectious substances when the cultures are intended for diagnostic or clinical purposes ;need urgent transportation

Inactivated materials:

- Inactivated panels can be transported at ambient temperature or at 2-8 °C. These may not require transport in accordance with requirements for the transport of infectious material.
- Transportation at ambient temperature, try to prevent direct sunlight and extreme temperatures.

Group Exercise

- In a group of 3 mention items used in packaging of GeneXpert DTS materials



Packaging of PT Items

- Materials needed
 - Adhesive cryobaby labels
 - Ziplock bags
 - Envelopes
 - Transport boxes
 - Accompanying paperwork

Packaging cont'd

Workflow of packaging

- Print adequate labels according to the number of participants(label is detailed as item code i.e Q4, with GXP for GeneXpert, round number and year
- Label one cryovial at a time from each batch
- Pack each tube in a small ziplock
- Transfer 05 packed tubes to big ziplock bag
- Transfer accompanying work and panel items to transport box

Workflow of packaging cont'd

- Label transport box with consignor and consignee details plus transportation conditions

CONSIGNEE

Lab Contact person: XXXXXXXXX

Position of contact person: xxxxxx

Lab Name: xxxxxxxx

Physical address: xxxxxxxxxxxxxx

Email:xxxxx

Tel:xxxxx

Mobile:xxx

Packed and Transported at:

Ambient Temperature _____

CONSIGNER

EOA scheme Manager Name:xxxxxx

National TB Reference Laboratory

P.o. Box 16041, Kampala Uganda



Handling of Liquid Panels

- Storage:
- label cryo-box for a set of PT items which have been transferred to cryovials with Name of PT, ID of strain, Round number of PT material.
- Stores those pending shipment at -20°C
- Keep the properly labeled excess cryovials of the PT material in cryo-boxes and store at -80°C freezer.
- For retrieval purposes, add 200ul of isolate to 800ul of 7H9 media containing glycerol and kept at -80°C

Handling of DTS Panels

Storage:

- label cryo-box for a set of PT items which have been dried in tubes with Name of PT, ID of strain, Round number of PT material.
- Store those pending shipment at Room temperature under darkness.

Shipment of PT panels

- Delivery system based on services, regulations, resources available:
 - mail/post
 - courier
 - supervisory visit
- Turnaround time
- Safe package to prevent breakage/damage of PT materials:
 - strong plastic slide holders

Documents for shipment

- Documents may include:
 - Customs invoices template
 - Awb template
 - DG Form template
- Others if needed
 - Certificate of origin and analysis template
 - Donation letter template
 - Material transfer agreement template

Documents for shipment

- Exercise on filling custom invoice; **distribute blank invoice**

Telephone: General Lines:
Permanent Secretary's Office:
Fax:

340874/231563/9
256 - 41 - 340872
256 - 41 - 231584



Ministry of Health,
P. O. Box 7272,
Kampala,
Uganda.

IN ANY CORRESPONDENCE ON
THIS SUBJECT PLEASE QUOTE No

CUSTOMS INVOICE

Date:

Shipper address:

National TB Reference Laboratory Uganda
P.o.Box 16041, Kampala Uganda
Plot 106-1062, Butabika Road, Luzira.
Opposite Butabika Hospital – Kampala, Uganda.
Toll free: 0800111133
XXXXXX XXXXX
PT Scheme Manager
Tel: +256 702 857 513
Email: pt@ntrl.or.ug

Consignee address:

.....
.....
.....

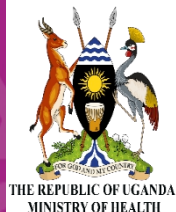
Contact Person:
Mobile:

Contents: Biological Substance cat A, UN2814 PI620 Infectious TB Isolate culture samples
Quantity: 20 mL
Packed Ambient

For laboratory testing only.

Terms of delivery: DDP
No commercial Value _ For customs Purposes Only \$10 USD

Name/ title/ signature



Confirmation of receipt

- Design means for confirming receipt of PT panels.

For example

- I. confirmation of receipt date may be through (a) email from participating lab
- II. confirmation of receipt date maybe through (a) phone calls to the participating labs
- III. *Acknowledgement receipt Form*

Assessment

1. List the key materials needed for packaging of PT materials
2. What are some of the details that are denoted on the transport box?
3. Highlight the storage conditions for PT materials

Summary

- It is ideal to design means for confirming receipt of PT panels.
- Ideal storage conditions must be adhered to for storage of the DTS panel reservoirs
- One ought to familiarize oneself with the IATA numberings

References

- ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*
- ISO 15189:2012, *Medical laboratories – Particular requirements for quality and competence*
- ISO Guide 34, *General requirements for the competence of reference material producers*
- ISO Guide 35, *Reference materials – General and statistical principles for certification*
- ISO/IEC 17043 First edition 2010-02-01
- Guide 34, ISO Guide 35 and ISO 13528 (homogeneity and stability)
- ISO/IEC Guide 98-3, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)
- ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*



Acknowledgments

