THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Training on Proficiency Testing Scheme GeneXpert DTS

Module 4: Workflow on preparation of DTS panels

Venue

Presenter

Date

Introduction

- To prepare a quality panels internal developed SOPs should be followed and adhere to in the preparation process.

Objectives

By the end of this module participants should be able to:

- Describe the technical work flow process in preparation of genexpert PT panels
- Describe the management work process in the preparation of genexpert PT panels

Module outline

- Workflow on preparation of DTS panels(Technical)
- Workflow on preparation of DTS panels(management)

Work flow Processes (Technical)

- Culture Selection and Freezer Storage
- Inactivation and Stock Preparation
- Pre-testing and Stock Selection
- Panel Aliquoting
- Panel Validation
- Labeling and Packing
- Shipping

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1. Culture selection and freezer storage

Isolates selected should have all the parameters tested by Xpert

- susceptible
- resistant
- Negative

And from the subculture isolates a freezer stock should be prepared for future use

Prepare culture isolates

- Inoculate the selected freezer stocks on MGIT, Incubate until MGIT positive
- Remove positive MGIT, write the date of positivity on the side of tube and place in axillary incubator at 35-37°C for 4-6 days.
- Store at 2-8°C until inactivation

Prepare culture isolates

Inoculate seed culture into MGIT tube

Incubate in MGIT until positive

Incubate 4-6 days longer

Store at 2-8° until inactivation

2. Inactivation

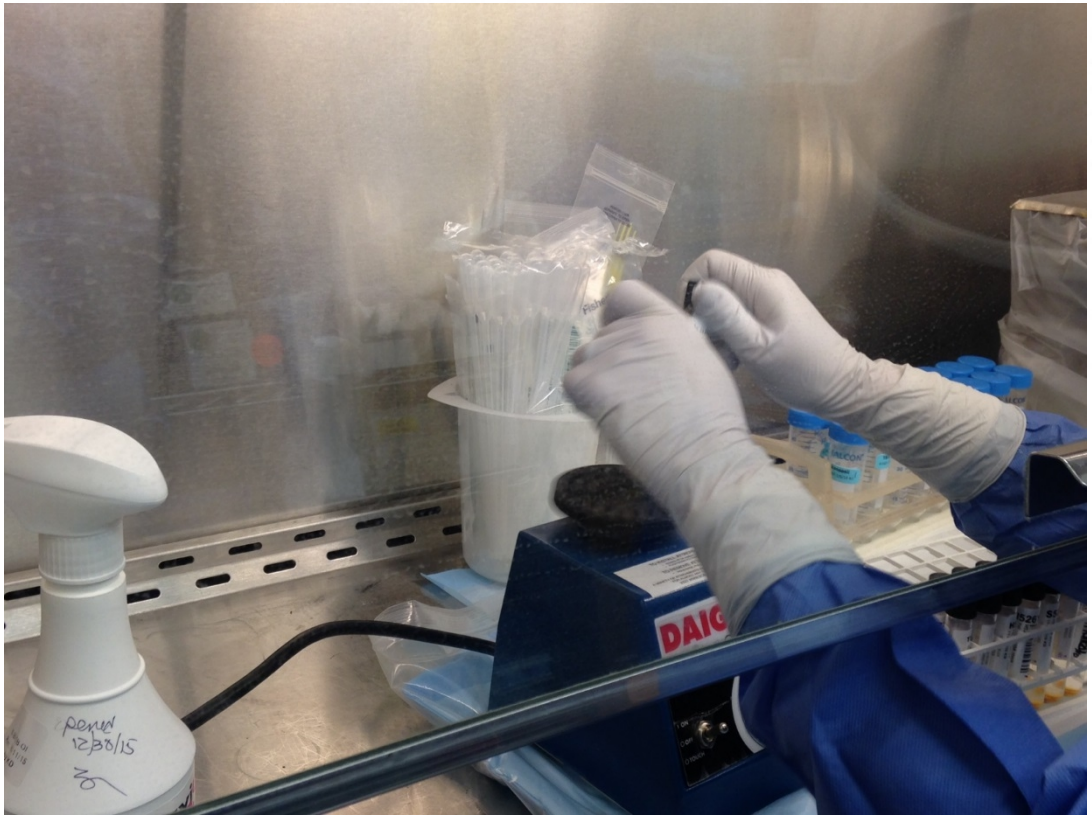
This process is undertaken to ensure non viable organisms rea used for the preparation of the panel

Different equipment can be used for this process ie

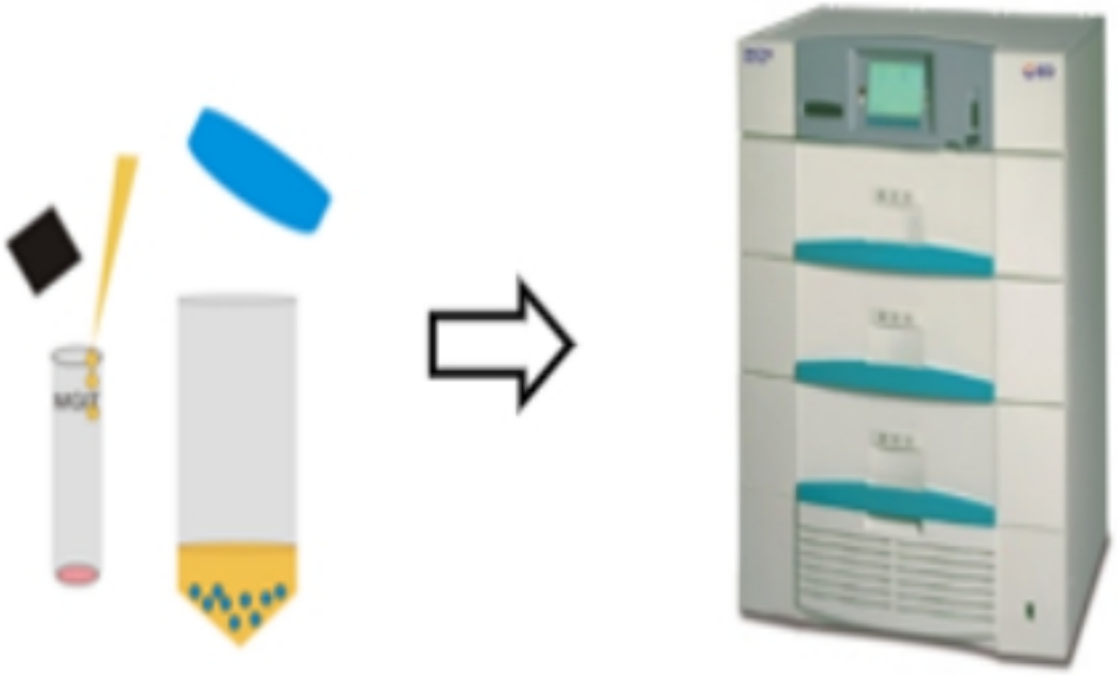
- Hot air oven 85°C(Preferred since the temperatures are closely controlled and monitored)
- Water bath 85°C
- Autoclave 121 Pa

The identified isolates on MGIT are used and after inactivation they can be pooled together

Briefly vortex MGIT cultures to be inactivated



Inactivation verification



Incubate stock solution in MGIT for 84 days

3. Pretesting and stock selection

The inactivated organisms are pretested to see if

- The dilution factor gives the expected results
- Choose the best stocks based on the factor above.

Dilute and aliquot

4. Panel aliquoting

Aliquoting the final panel depends on

- The pretest results
- Inactivation verification results(any growth on this process leads to automatic disqualification of the stock)

5. Panel validation

5% of the aliquoted stock is used for the validation process

Essential to ensure that the aliquoted stocks give a

- To obtain consensus results
- Taken as a test of homogeneity
- Stability of the panel

6. Labelling and packaging

Good quality labels should be considered

- To avoid falling of or fading and facilitate testing the actual panels and obtaining correct results

Quality packaging materials should be considered

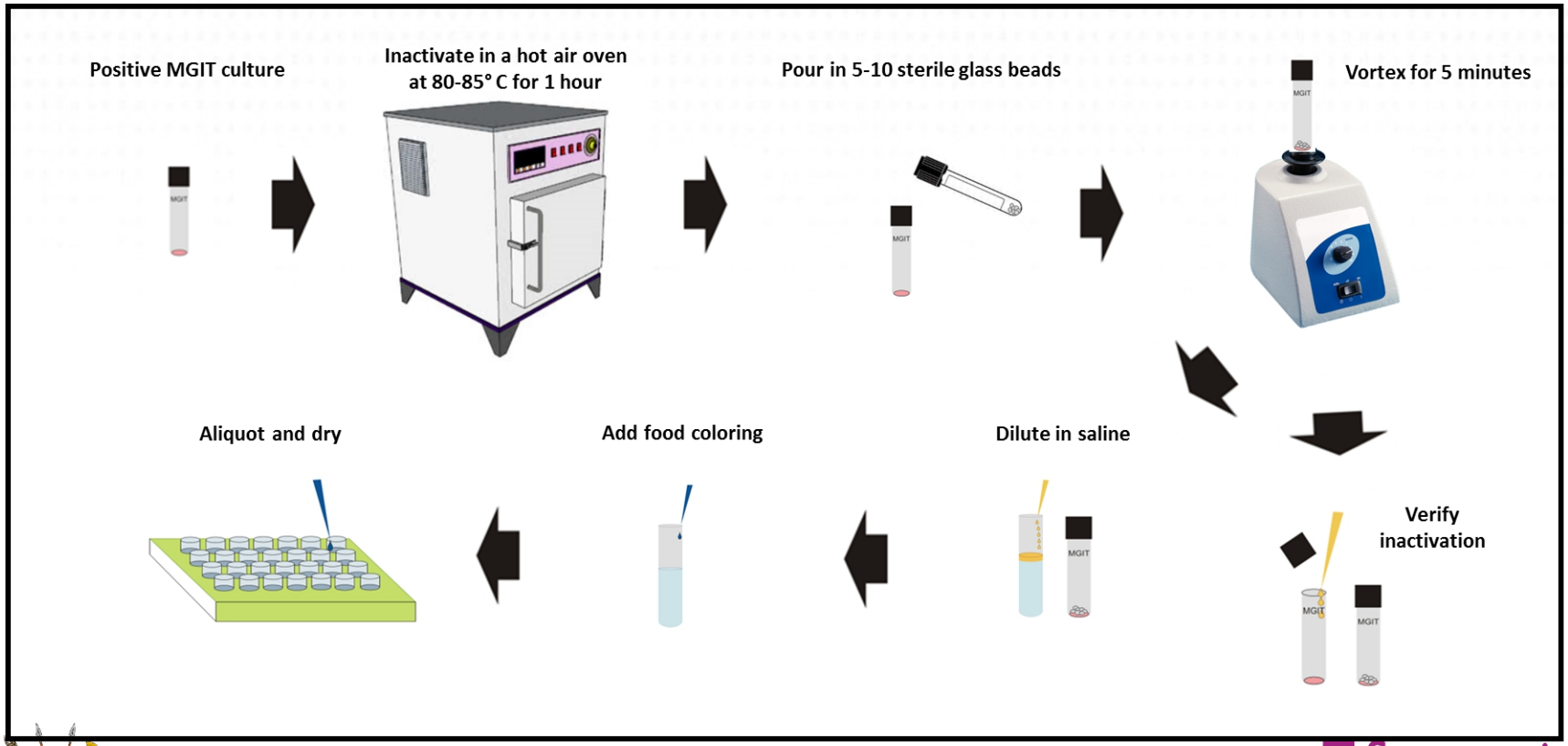
- To maintain the integrity of the panels during transportation

7. Shipping culture PT panels

Local and international regulations should be followed to ensure PT panels are delivered to the testing facilities

- In time
- safely

Dried Tube Specimens using Heat Inactivation



Workflow processes(program management)

- **Program Scheduling and Enrollment**
- **Data Collection and Analysis**
  - Online and Manual (MS Excel and Word)
- **Following Up Non-Conformities with Sites**
  - Contacting sites and documenting root cause analysis
  - Corrective actions
- **Record keeping for genexpert PT scheme**
- **Indicators genexpert PT scheme**
- **Check ISO 17043:10 indicators where applicable**

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Assessment

1. List the 6 work flow technical processes in preparation of genexpert PT panels

2. What is the method employed to verify inactivation of the inoculum?

3. List atlest 4 programme/ scheme management workflow process in the genexpert PT scheme?

Summary

- The technical work flow process include, Culture Selection Freezer Storage, Inactivation, and Stock Preparation, Pre-testing, Stock Selection, Panel Aliquoting, Panel Validation, Labeling and Packing

- MGIT culture is the method employed to verify inactivation of the inoculum

- MGIT culture is preferred to LJ for growth of the inoculum because of the growth-time factor

REFERENCES

- ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*
- ISO Guide 34, *General requirements for the competence of reference material producers*
- ISO Guide 35, *Reference materials — General and statistical principles for certification*
- 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