

# Training on Proficiency Testing Scheme (GeneXpert DTS)

## Module 3: Introduction to GeneXpert PT

**Venue:**

**Presenter:**

**Date:**

# Introduction

- PT independent & unbiased assessment of the testing performance at of the testing site.
- We need it To assure the quality of the results generated
- Test results reported by each testing site are compared to the reference test results.
- The testing site is then provided with a report indicating the accuracy of their results

# Objectives

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

- describe why PT provision is important for a TB laboratory network
- Need for implementation of genexpert PT scheme

# Module outline

- Introduction to GeneXpert PT
- Methods of GeneXpert PT prep

# Implementation of the GeneXpert technique

Following the endorsement of Xpert MTB/RIF by WHO in 2010, it acknowledged:

- An increased case detection, especially in areas with high rates of TB and HIV (compared to microscopy)
- Improved surveillance of drug resistant TB (using Rifampicin resistance as a proxy to MDR TB)

# Genesis of the GeneXpert PT

Following the endorsement of the genexpert testing technique there has not been QA programs in the network.

It was therefore recommended for TB programme to support NTRL and oversee and implement a proficiency testing scheme



# Purpose of the Genexpert PT

To check the competence of participating laboratories regarding use of GeneXpert technique as a TB diagnostic method.

By performing statistical evaluation of the data obtained the following are identified

- Proficiency of staff
- Identify training needs
- Testing technique
- Result reporting errors
- Machine functionality and maintenance

# Purpose of the Genexpert PT

Genexpert PT panels can also be used for Verification/ validation :

- Once off or upon instrument maintenance/ module swap-out
  - Prove the instrument is fit-for-purpose
  - Every module tested with a sample known outcome
- Note: Keep validation certificate/report



# Type of scheme

## Semi-Qualitative scheme

Identifies presence of *Mycobacterium tuberculosis* DNA and describes resistance to Rifampicin.

# Determining the frequency of a genexpert PT scheme

## Network factors

- How often is the test run
- Implications of unsatisfactory results (false positive or false negative)

## Provider factors

- PT preparation process
- Funds

# Group Exercise

- describe the different methods available for making Genexpert PT items. (5 minutes)



# Requirements to prepare Genexpert PT panels

- MTB strains with known genotypic resistant patterns for both RIF and INH (through molecular typing)
- Preparation materials( Depending on the preparation method of Choice)
- Packaging materials
- Necessary documentation e.g. SOPs, results capture forms

# Methos used to prepare Xpert PT panels

☁ Liquid

☁ FTA

☁ DTS(Dry Tube Specimen)

# 1. Liquid panels

- Entails having sufficient amount of detectable DNA; There is no need to have viable organisms.
- Source; Known MTB strains\NTM
- Safety precautions

TB causative ensure that the material to be packed is non-viable unless otherwise



# Advantages and Disadvantages of liquid PT panels

- **Advantages**

- Shorter preparation procedure
- Cheap

- **Disadvantage**

- leakages during transportation
- Cross contaminations
- Unstable due DNA deterioration in case of delayed transit TAT
- Introduction of contaminants to testing laboratories

## 2. FTA (Flinders technology associates) Cards

- FTA Cards a.k.a Whatman paper are impregnated with a patented chemical formula that lyses cell membranes and denatures proteins on contact.
- Nucleic acids are physically entrapped, immobilized and stabilized for storage at room temperature.

Infectious pathogens in samples applied to FTA Cards are rendered inactive on contact.



# Advantages and Disadvantages of FTA cards

- **Advantages**

- Remove contaminants
- FTA cards protect nucleic acids from nucleases, oxidation, UV damage and microbial and fungal attack.
- Cheap

- **Disadvantages**

- Affected by humidity
- Need a desiccant and humidity indicator cards during transportation



### 3. Dried Tube Specimen( DTS)

- Methodology originally developed by the Serology Unit ILB/DGHA for HIV rapid test proficiency testing. Also used for viral load, syphilis, and malaria

#### DTS advantages:

- Less bio-hazardous than liquid
- Specimens are stable at room temperature and higher
- Does not require cold chain

**“Overall, the DTS approach has great potential to facilitate expansion of PT Programs...”**

# Dried Tube Specimen( DTS)



GXPT/PP/003, Version 2.0, Effective date: 01-Apr-2022

# Assessment

1. What type of PT scheme does GeneXpert scheme belong to?
2. Compare and contrast DTS, FTA and liquid panels



# Summary

- The GeneXpert scheme belongs to the Semi-Qualitative scheme category
- DTS, FTA and liquid panels have a number of differences worth considering for choice of implementation

# 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

