UGANDA Supranational® Reference Laboratory
Timely Accurate Diagnostics for a TB-Free Africa

Training on Proficiency Testing Scheme (Microscopy PT)

Module 1: Over view

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Course outline

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- Introduction
- Objectives
- Getting started
  - PT schedule
  - Enrolment
  - Sending
  - Performing
- Results analysis
- ISO 17043 standard

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PT schemes for laboratories

- PT is an EQA programme involving sending a panel of sample to a group of participating labs.
- Means of verifying the reliability of lab results
- The main objective is to assess proficiency of the las in the diagnosing TB
- However such programs are not available in developing countries.

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Group Exercise

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In a group of 3 list the EQA programmes available in your country and explain the limitation of each. (5 minutes)

Objectives of EQA schemes for laboratories

- Evaluation of Lab testing competence
- Assessment of individual testing performance of the lab staff
- Evaluation of reliability of a test procedure
- Production of relevant information to participating labs when necessary

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Objectives of EQA schemes for laboratories

- Providing the basis for the comparability of results during epidemiological surveillance and disease control
- Collecting information on laboratory measurements (intra- and inter-laboratory)
- Collecting information for the purpose of licensing or accreditation of laboratories

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Introduction

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- The Uganda National Tuberculosis Reference Laboratory (NTRL) Proficiency testing scheme
  - microscopy,
  - culture,
  - line probe Assays,
  - GeneXpert MTB/RIF,
  - and drug susceptibility testing techniques.
- design of the NTRL PT scheme;

  randomly selected sub-samples from a bulk homogeneous supply of material distributed simultaneously to participating laboratories.

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Uganda SRL PT schedule

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EQA panels category	Microscopy	LPA	GeneXpert	Phenotypic DST
Frequency/ year	Biannual	Biannual	Biannual	Annual
Sending out Month	February and August	February and August	February and August	August
Quantity	10 slides/round	10 isolates/round	04 isolates/round	20 isolates/round
Expected TAT	10 days	10 days	10 days	3 months

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Getting Started: Issues to Consider

- Capacity of NRL
  - HR
  - Training and expertise
- Type and Composition of PT panels
- Internal QC procedures to ensure
  - Homogeneity
  - Stability
- System for sending PT panels

- Frequency of testing
- Forms to record and report results
- Time allowed for technicians to complete PT
- Availability of microscopes
- Performance criteria
- Feedback and corrective action if needed
- Mechanism to resolve discrepant results

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Sending PT panels

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- 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

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Performing a Panel Test Round

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- Frequency
- A standardized PT reporting form / an accompanying letter to provide instructions
- No incentives or punitive actions as a result of the PT exercise
- Time allowed to complete the PT exercise

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Analysis of PT Results

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- A scoring system is to be developed prior to test
- Distinguish major and minor errors
- Determine successful score
- Determine plan of action for poor performances
- Database for analysis

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Feedback to Laboratories on PT results

- Timely and confidential
- Individual and aggregate test results
- Criteria for acceptable performance
- Reports to TB program coordinator should provide appropriate background information and recommendations and not simply scores
- Poor performance often requires a visit to laboratory

EQA GeneXpert network – PT panels and support supervision

- Materials; Standard control strains of *Mycobacterium tuberculosis (MTB)* H37Rv , Negative stock Cryovials, FTA cards

- Composition; 4 PT panels for each four module machine
  - Must be **non-viable**

- Frequency;
  - Availability of funds and purpose
  - At least once a year

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Microscopy PT

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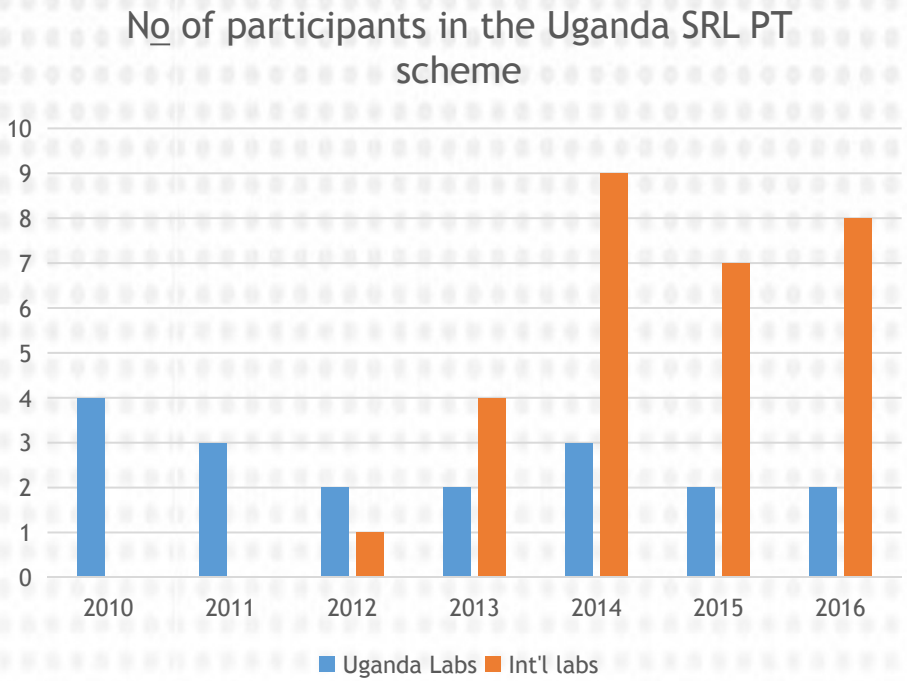
- Panels' Composition
- The composition of a panel set is determined by NRL

- Number and types of slides to reassure that correct or incorrect results are not accidental
  - At least 10 slides provides a valid and fair test
  - Batch of stained and unstained smears

- Unstained smears:
  - Evaluate staining technique; provide information about stain preparation and quality

Culture and DST labs – PT panels and support supervision

- Started in 2010 with 4 labs within Uganda
- Has expanded to include other countries



Composition of PT materials

C & DST – 20 pure characterized isolates

LPA – 10 isolates

Support for PT provision

ISO 17043 accreditation requirements

- **Technical requirements**
  - Personnel, accommodation and environment
  - Design of PT schemes
  - Choice of method or procedure
  - Operation of PT schemes
  - Data analysis and evaluation
  - Reports
  - Communication with participants
  - confidentiality

ISO 17043 accreditation requirements

- **Management requirements**
  - Organization
  - Management system
  - Document control
  - Review of requests, tenders and contracts
  - Sub contracting services
  - Purchasing services and supplies
  - Complaints and appeals
  - Corrective actions
  - Preventive actions
  - Control of records
  - Internal audits
  - Management reviews

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Assessment

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- Define the term EQA and discus its importance
- What factors might drive the choose of EQA programme to implement
- List the PT Scheme that a TB lab can implement

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References

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- ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*
- ISO 15189, *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*

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