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 PT)

Module 1: Overview

Dd-dd-Month-Year

Facilitator's name

Venue

Course outline

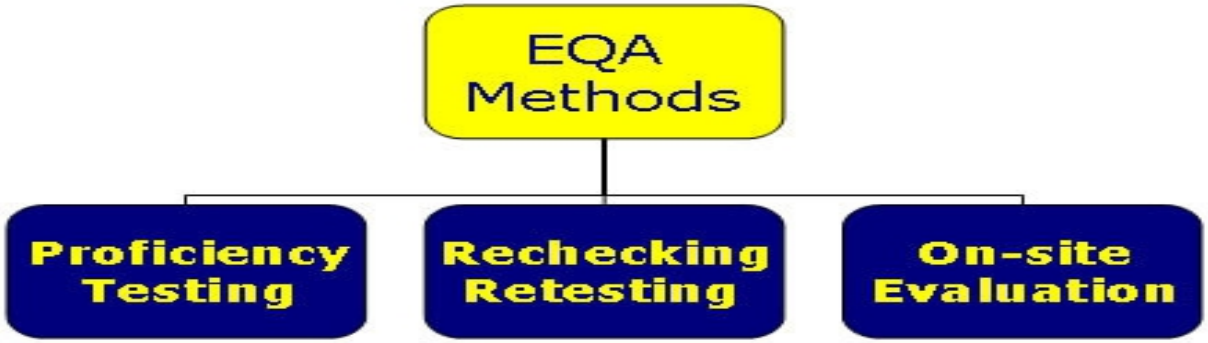
- Introduction
- Objectives
- Getting started: Issues to Consider for a PT scheme
- Uganda SRL scenarios
  - Microscopy PT scheme
  - GeneXpert PT scheme
  - DST PT Scheme
  - GeneXpert PT
  - LPA PT
- ISO 17043:2010 requirements

Overview of Quality Assessment

- **Introduction:** Assessment is a critical aspect of laboratory quality management, and it can be conducted in several ways with the commonest being EQA;
- **Define EQA??**

Method that allows for comparison of a laboratory's testing to a source outside the laboratory

Types of EQA



What is Proficiency Testing?

- Is an evaluation of participant performance against pre-established criteria by means of inter-laboratory comparison.
- A PT program is a quality assessment tool that provides a retrospective measure of technical quality and verifies the reliability of lab results
- However such programs are expensive to establish hence meagre in developing countries.

Types of PT schemes

- **Quantitative scheme** — Quantifies one or more measurands of the proficiency test item;

- **Qualitative scheme** — Identifies or describes one or more characteristics of the proficiency test item. The results of qualitative tests are descriptive and reported on a categorical or ordinal scale, e.g. identification of micro-organisms, or by identifying the presence of a specific measurand (such as a drug or a grading of a characteristic).

- **Simultaneous scheme** — where proficiency test items are distributed for concurrent testing or measurement within a defined time period;
- **Continuous scheme** — where proficiency test items are provided at regular intervals

Objectives of PT schemes for laboratories

- Provides objective evidence of laboratory competence through continual monitoring
- Provides laboratories the opportunity to identify issues related to systemic error, imprecision, or human error;
- Evaluation of reliability of a test procedure
- Aides in acquiring accreditation for participating labs when being assessed for the various standards.

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)
- Production of relevant information to participating labs when necessary
- Collecting information for the purpose of licensing or accreditation of laboratories

The Uganda National Tuberculosis Reference Laboratory (NTRL) case

- **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.

Group Exercise

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

Uganda SRL PT schedule

EQA panels category	Microscopy	LPA	GeneXpert	DST*	Culture and MTB/NTM identification
Frequency/ year	Biannual	Annual	Biannual	Annual	Annual
Sending out Month	February and August	August	February and August	August	August
Quantity	10 slides/round	10 isolates/round	05 isolates/round	20 isolates/round	5 Isolates/round
Expected TAT (from date of dispatch)	44 days	44 days	44 days	76 days genotypic DST 116 days for solid phenotypic DST	7 Weeks for liquid Culture and 9 weeks for solid Culture

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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
- Performance criteria
- Feedback and corrective action if needed
- Mechanism to resolve discrepant results

Getting Started: Issues to Consider

- **Dispatch of PT panels**

- Delivery system based on services, regulations, resources available:
  - mail/post
  - courier
  - supervisory visit
- Turnaround time; consideration of
  - total no. of days from dispatch of panels to closing dates,
  - preparation of individual and summary reports,
  - presentations to PT team,
  - dispatch of the individual and summary reports

Getting Started: Issues to Consider

- Safe package to prevent breakage/damage of PT materials:
  - strong plastic slide holders
- 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

Getting Started: Issues to Consider

Analysis of PT Results

- 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

Getting Started: Issues to Consider

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

Roles of Participating labs

- . To be successful, PT instructions must be followed carefully, all paper work completed accurately, and results submission deadlines met.
- All PT results, as well as corrective actions, should be recorded and the records maintained for an appropriate period of time.
- There must be no difference in the treatment of PT samples and the patient's sample
- Avoid discussion of results with other laboratories.

Limitations Of PT Schemes

- PT results are affected by variables not related to patient samples Such as preparation of the sample, clerical functions, selection of statistical methods of evaluation.
- PT will not detect all problems in the laboratory, particularly those that address the pre- and post-examination procedures.
- A single unacceptable result does not necessarily indicate that a problem exists in the laboratory.

Uganda SRL: GeneXpert PT Scheme

- Materials; Standard control strains of *Mycobacterium tuberculosis (MTB)* H37R*v* , PBS, Escherichia coli, stock, MacConkey Agar Plates, Cryovials etc,

- Composition; 5 PT panels

- Must be **viable**

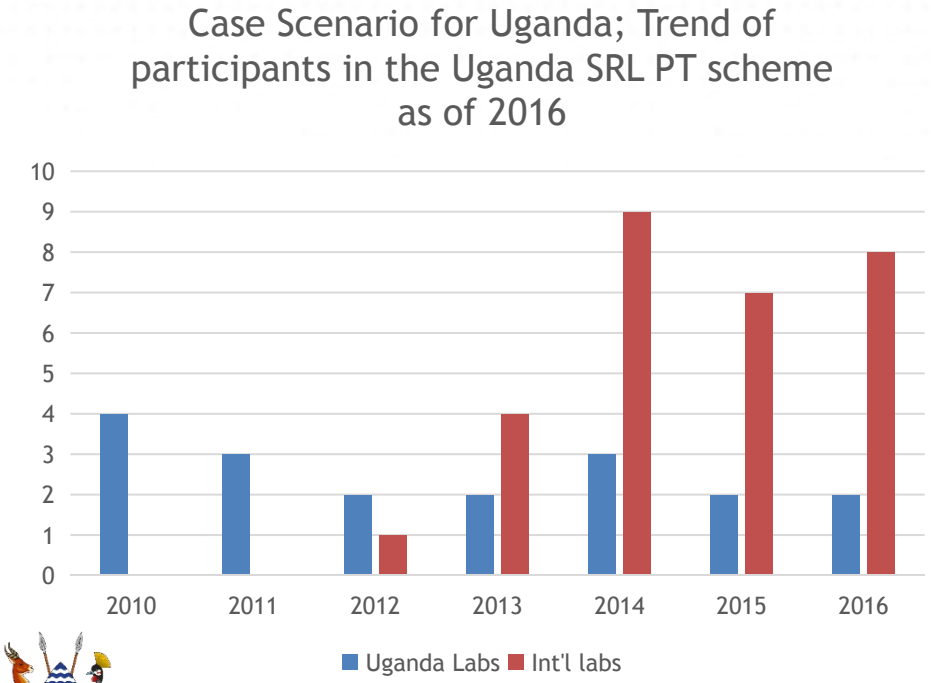
- Frequency;
  - Availability of funds and purpose
  - At least once a year

Uganda SRL: Microscopy PT Scheme

- 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

Uganda SRL: DST PT Scheme

- 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

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

Assessment

- Define the term EQA and discuss its importance
- What factors might drive the choice of an EQA program to implement
- List the 3 EQA programmes that a TB network can implement

Summary

- EQA plays a crucial role in evaluating the performance of a laboratory network
- Proper planning and considerations are vital to drive the choice of an EQA program to implement
- List the 3 EQA programmes that a TB network can implement

References

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- Guide 34, ISO Guide 35 and ISO 13528 (homogeneity and stability)
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Acknowledgments

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