THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

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

Training on New and rapid Tuberculosis diagnostics (first and second line Probe Assay)

Module 13: Quality Assurance for LPA

Uganda Supranational Reference Laboratory

Content outline

- Definition
- QA components
- Reagent QC
- Procedure QC
- Current EQA programs
- Quality Indicators of LPA

Quality Assurance

Quality Control

External Quality Assessment

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QA Definition

- Quality Assurance (QA) programs consist of activities within all sections of the laboratory that are needed in order to ensure that testing is being performed according to ISO 15189 standards.

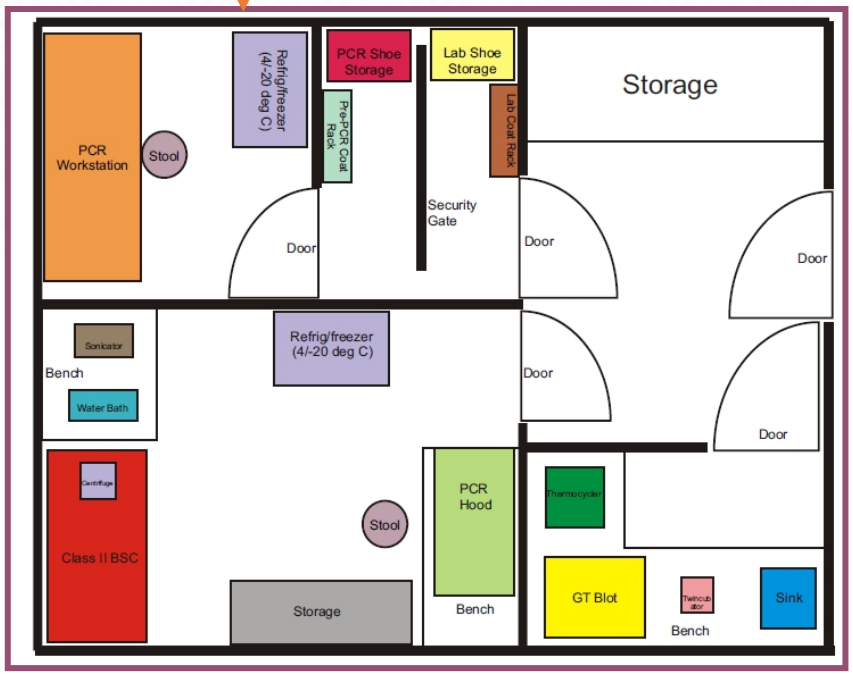
- This will also include the collection of patient samples

Group exercise-5 minutes

1. Identify at least 7 different Quality assurance activities carried out for LPA testing at your laboratory.

Infrastructure QC

Reagent preparation



Specimen preparation

Adding DNA

Hybridization

Sentinel testing:

- 1ml molecular-grade water in 1.5 ml at different areas for 24h

Appropriate lab lay out is a key QC component

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QA components

- All staff should be appropriately trained and deemed competent prior to running the assay.
- All competent staff should participate in testing the PT samples and not left only to a few individuals.
- All equipment should have a regular service and maintenance schedule.
- Appropriate equipment SOPs should be in place.
- Daily/ scheduled usage logs should be on all equipment.

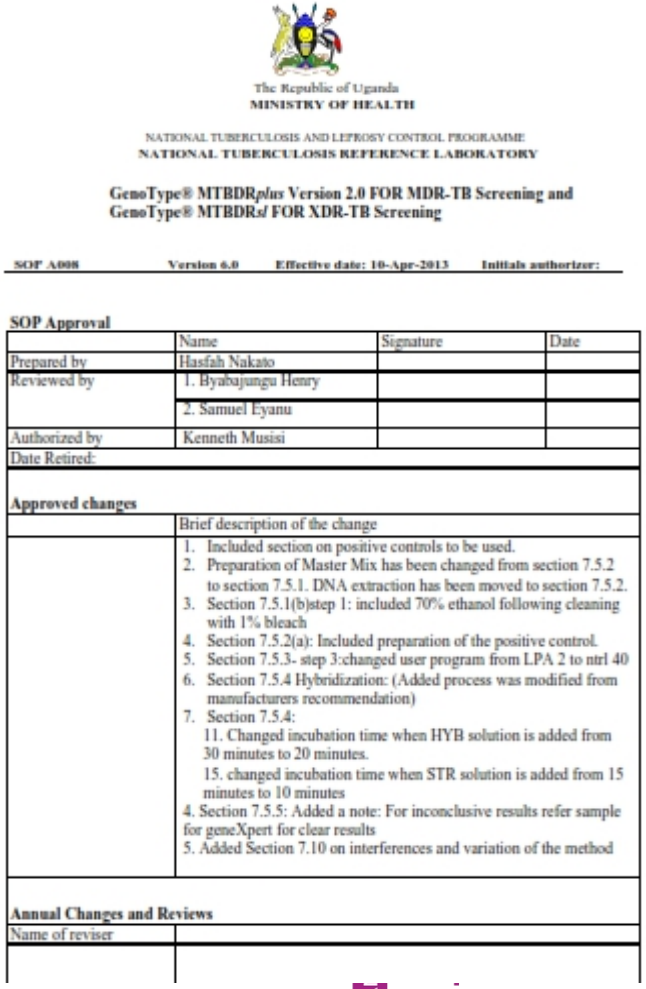
Reagent QC

- Lot-to-lot testing
- Integrity testing upon receipt
- Storage in customs
- Proper supply chain (cold chain) including in-country distribution
- Document batch no. expiry date and date opened

A kit of LPA supplies

Procedure QC (1)

- SOPs
- Controls
  - Positive MTB control for entire procedure (specimen preparation)
  - Negative control for MM preparation
  - Negative control for specimen preparation
- Contamination control
  - Tools
  - Reagents
  - Infrastructure
  - Procedure



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NATIONAL TUBERCULOSIS AND LEPROSY CONTROL PROGRAMME
NATIONAL TUBERCULOSIS REFERENCE LABORATORY

GenoType® MTBDR*plus* Version 2.0 FOR MDR-TB Screening and GenoType® MTBDR*sl* FOR XDR-TB Screening

SOP A008 **Version 6.0** **Effective date: 10-Apr-2013** **Initials authorizer:**

SOP Approval

	Name	Signature	Date
Prepared by	Hasfah Nakato		
Reviewed by	1. Byabajungu Henry		
	2. Samuel Eyanu		
Authorized by	Kenneth Musisi		
Date Retired:			

Approved changes

	Brief description of the change
	1. Included section on positive controls to be used. 2. Preparation of Master Mix has been changed from section 7.5.2 to section 7.5.1. DNA extraction has been moved to section 7.5.2. 3. Section 7.5.1(b)step 1: included 70% ethanol following cleaning with 1% bleach 4. Section 7.5.2(a): Included preparation of the positive control. 5. Section 7.5.3- step 3:changed user program from LPA 2 to ntrl 40 6. Section 7.5.4 Hybridization: (Added process was modified from manufacturers recommendation) 7. Section 7.5.4: 11. Changed incubation time when HYB solution is added from 30 minutes to 20 minutes. 15. changed incubation time when STR solution is added from 15 minutes to 10 minutes 4. Section 7.5.5: Added a note: For inconclusive results refer sample for geneXpert for clear results 5. Added Section 7.10 on interferences and variation of the method

Annual Changes and Reviews

Name of reviser	

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Template SOP for LPA

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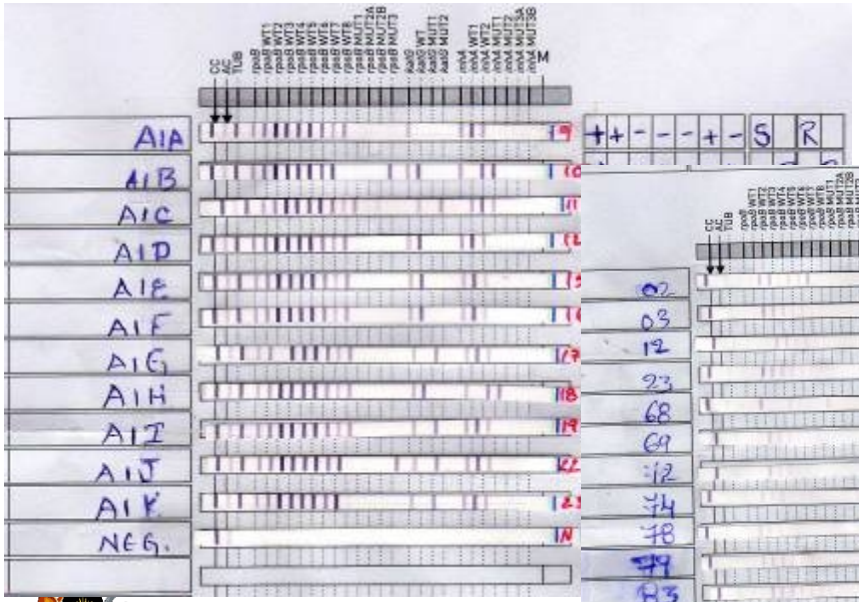
Procedure QC (2)
Result interpretation

- Interpretation of results
  - adequate runs
  - inadequate runs
  - Faint bands
  - Genoscan vs manual



Various LPA results strips
With varing intensity of the bands

Genoscan used for strip interpretation

External quality assurance (EQA)

- Panel testing
  - Entire procedure including specimen preparation and NaOH/NALC processing
  - Susceptible strain
  - Resistant INH mono, RMP mono, FlQ mono, INJ/AG mono
  - MDR (common and uncommon mutations)
  - NTM strains
  - XDR TB strains are not recommended to be included in EQA panels

LPA testing EQA schemes

- **Inter-Laboratory Comparative Analysis (ILCA)**

(Where National Tuberculosis Reference Laboratory (NTRL) sends a panel of 10 specimens consisting of either non-infectious DNA or culture isolates for LPA proficiency testing)

- **Proficiency Testing (PT)** (may consist a number of live M. tuberculosis specimens that must be subjected to NaOH-NALC decontamination in order to make a smear and culture inoculation. Afterwards, the LPA is performed on these cultures)

Quality Indicators of LPA

3 Indicators:-

- Time taken from specimen collection to receipt in lab (1-3 days)
- Time taken in the lab from specimen receipt, decontamination and reporting of LPA results (1-4 days)
- Monitor any critical results, e.g. XDR TB cases.

NB: If batch testing is to be carried out then LPA TAT should not exceed 5 days for the results to have clinical significance.

Assessment

1. What is the difference between Quality assurance and quality control?

2. What is the importance of lot-to-lot testing of LPA kits?

3. How would you trouble shoot a failed negative process control sample for LPA?

4. How would you trouble shoot a failed positive process control sample for LPA?

Summary

- Adequate QA/QC for LPA is vital for minimizing false results.
- Cross contamination can greatly be reduced with adequate QA/AC.
- A regular service and maintenance schedule is an important component of QA/QC in LPA.
- Routine EQA is an important component of QA/QC for LPA.
- Make appropriate corrective action whenever the internal process controls for LPA fail.

References

- GLI TB training package http://www.stoptb.org/wg/gli/trainingpackages.asp
- www.hain-lifesciences.com

Acknowledgments

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gli
global laboratory initiative
advancing TB diagnosis

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CDC

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