THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Training on *Mycobacterium tuberculosis* drug susceptibility testing (first and second line LJ DST)

Module 5; Quality Assurance (QA) for LJ DST

Venue:

Presenter:

Date:

Content Outline

- Introduction
- Learning Objectives
- Body/Content
- Assessment
- Summery
- References
- Acknowledgement

Introduction

- This module details the quality assurance procedures and practices in a TB DST laboratory.
- It also provides information on the key quality indicators to be monitored in a TB DST laboratory

Learning Objective

By the end of the module, participants are expected to:

- Understand the quality control procedures in TB DST
- Attain knowledge on the current TB DST EQA programs
- Understand the Quality Indicators to be monitored in LJ DST

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 15189:2012 standards.

- This will also include the collection of patient samples.

Exercise-5 minutes

1. Identify at least 7 different Quality assurance activities that can be carried out to ensure that LJ DST results released from your laboratory are reliable and accurate.

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.

QA components

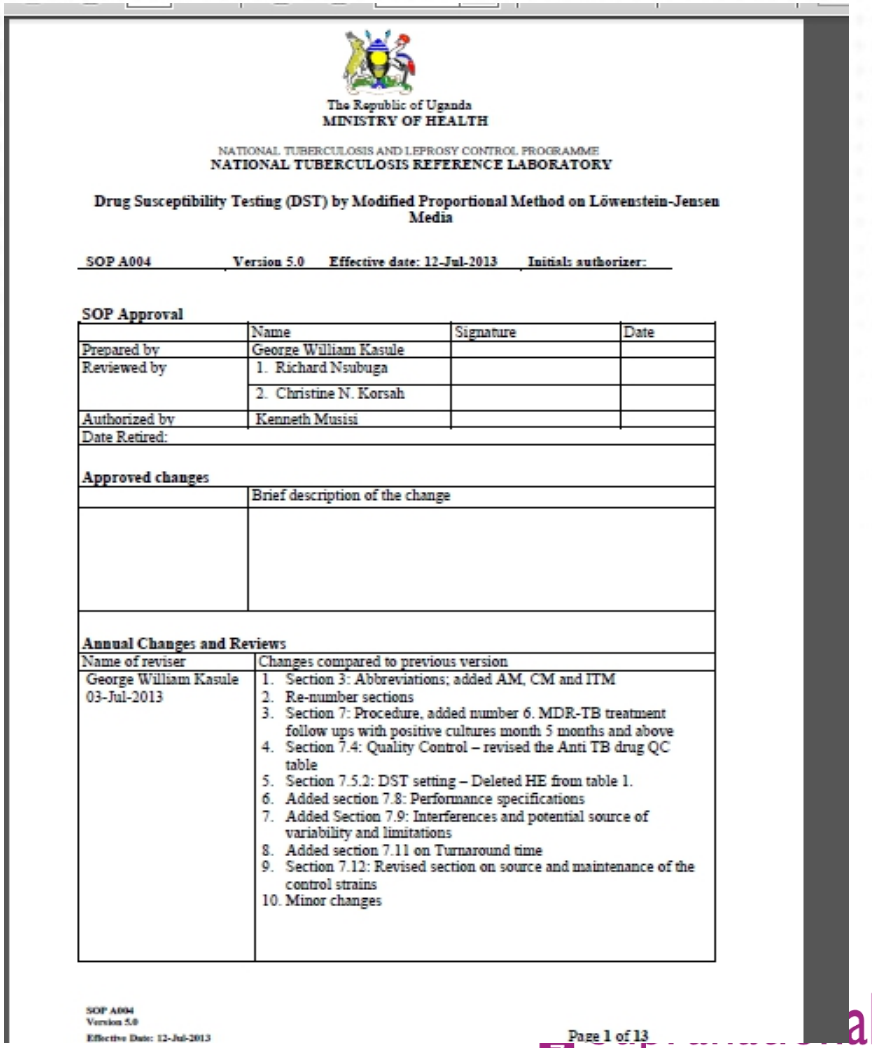
- Management to ensure appropriate infrastructure is available such as well functioning BSL 3 lab is available for culture and DST.
- Panel testing.

Reagent QC

- Lot-to-lot testing of drug powders.
- Quality control for prepared drug solutions
- Sterility check of drug containing media.
- Storage of LJ DST drug powders
- Document batch no. expiry date and date opened

Procedure QC (1)

- SOPs
- Controls
  - Use of certified *MTB* control strains
- Contamination control
  - Tools
  - Reagents
  - Infrastructure
  - Procedure



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NATIONAL TUBERCULOSIS AND LEPROSY CONTROL PROGRAMME
NATIONAL TUBERCULOSIS REFERENCE LABORATORY

Drug Susceptibility Testing (DST) by Modified Proportional Method on Löwenstein-Jensen Media

SOP A004 Version 5.0 Effective date: 12-Jul-2013 Initials authorizer:

SOP Approval

	Name	Signature	Date
Prepared by	George William Kasule		
Reviewed by	1. Richard Nsubuga		
	2. Christine N. Korsah		
Authorized by	Kenneth Musisi		
Date Retired:			

Approved changes

	Brief description of the change

Annual Changes and Reviews

Name of reviser	Changes compared to previous version
George William Kasule 03-Jul-2013	1. Section 3: Abbreviations; added AM, CM and ITM 2. Re-number sections 3. Section 7: Procedure, added number 6. MDR-TB treatment follow ups with positive cultures month 5 months and above 4. Section 7.4: Quality Control – revised the Anti TB drug QC table 5. Section 7.5.2: DST setting – Deleted HE from table 1. 6. Added section 7.8: Performance specifications 7. Added Section 7.9: Interferences and potential source of variability and limitations 8. Added section 7.11 on Turnaround time 9. Section 7.12: Revised section on source and maintenance of the control strains 10. Minor changes

SOP A004
Version 5.0
Effective Date: 12-Jul-2013

Page 1 of 13

Template SOP for LJ DST

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Procedure QC (2)

- Interpretation of results
  - Growth of NTMs on PNB control
  - Correct identification of *Mtb* colony morphology

DST testing EQA schemes

Inter-Laboratory Comparative Analysis (ILCA)

- In ILCA, Positive culture isolates or sputum sediments are referred to another laboratory(SRL) for DST with the aim of comparing results between the two laboratories.

Proficiency Testing (PT)

- In a PT secheme, a laboratory receives a DST panel from an external provider(SRL),runs the panel and sends back results for analysis.

Panel testing for TB DST

Key performance areas for participating laboratories

- Accuracy per drug
- Test TAT per test method used
- Frequency (Participation at least once annually)

Quality Indicators of LJ DST

Indicators:-

- DST Turn around Time (8 weeks from date of positive culture)
- Monitor any critical results, e.g. XDR TB cases.
- Contamination rate of set LJ DST media.

WHO guidelines on QA in an LJ DST lab

- WHO recommends that NTRLs/CTRLs establish formal links with one of the laboratories in the Supranational Reference Laboratory Network (SRLN) to help ensure the quality of laboratory services and validation of DST results.

WHO GUIDELINES ON QA IN A DST LAB

As a minimum, external quality assurance with an SRL should consist of the following:

•A baseline assessment visit from an SRL.

• proficiency testing with an adequate number of coded isolates;

• periodic rechecking of isolates obtained within the MDR-TB programme at the NTRL.

Assessment

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

2. What is the importance of running Quality controls on LJ DST drug powders?

3. What are some of the minimum WHO quality assurance guidelines for Laboratories implementing DST techniques?

Summary

- Adequate QA/QC for LJ DST is vital for minimizing false results.
- High contamination rates can greatly be reduced with adequate QA/AC.
- Use of certified controls if very key in producing quality DST results
- Routine EQA is an important component of QA/QC for LJ DST technique.
- Make appropriate corrective action whenever the internal process controls of LJ DST fail.

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References

- GLI TB training package http://www.stoptb.org/wg/gli/trainingpackages.asp
- WHO Policy guidance on drug susceptibility technique(DST) of second line drugs anti-tuberculosis drugs 2018.
- ISO 15189:2012 standard

Acknowledgments

KOFIH
Korea Foundation for International Healthcare
한국국제보건의료재단

KNCV
TUBERCULOSISFOUNDATION

gli
global laboratory initiative
advancing TB diagnosis

DEPARTMENT OF HEALTH AND HUMAN SERVICES - USA

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