

Training on LJ Culture technique

Module 12: Quality Assurance, Indicators and Trouble shooting for LJ Culture Method

DATE:

VENUE: SRL, Uganda

FACILITATOR:

Content outline

- Definition
- QA components
- Reagent QC
- Procedure QC
- Current EQA programs
- Quality Indicators of LJ culture method

Quality Assurance



Quality Control

External Quality Assessment



QA and QC Definition

- Quality Assurance (QA) programs consist of activities within all sections of the laboratory that are needed to ensure that testing is being performed according to ISO 15189 standards to obtain reliable and consistent results.
- Quality Control: Procedures undertaken during performance of a given process/ test to obtain quality results. Primarily concerns the control of errors in the performance of tests and verification of test results.



Group exercise-5 minutes

1. Identify at least 7 different Quality assurance practices
2. List three quality indicators employed in LJ culture method at your laboratory.
3. What are the different cut off points for LJ culture method indicators

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
- All equipment should have a regular service and maintenance schedule.
- Appropriate equipment and assay SOPs should be in place.
- Results review system should be in place
- Process controls should be incorporated in all laboratory procedures
- Samples should be inspected for suitability during reception



Reagent and Test KITs QC

- Ensure appropriate storage in customs
- Ensure Proper supply chain (cold chain)
- Integrity testing upon receipt at the lab
- Perform Lot-to-lot testing using known standard strains.
- Document batch no. expiry date and date opened.
- Sterility checks for media



Procedure QC (1)

- SOPs

Periodically reviewed to ensure continued suitability

- Process Controls

- Positive and Negative MTB control for entire procedure



NATIONAL TUBERCULOSIS AND LEPROSY CONTROL PROGRAMME
NATIONAL TUBERCULOSIS REFERENCE LABORATORY

Storage of Mycobacterium Isolates

SOP P040 Version 5.0 Effective date: 21-Jun-2016 Initials authorizer: _____

SOP Approval			
	Name	Signature	Date
Prepared by	Osduky Shuka		
Reviewed by	1. Fred Kanywa		
	2. Christine Keraah		
Authorised by	Kenneth Mubisi		
Date Retired:			
Approved changes			
Brief description of the change			
Annual Changes and Reviews			
Name of reviewer	Changes compared to previous version		
Osduky Shuka	1- Section 0.4 (a) 4: changed from 0.2 to 0.3 2- Minor changes		
Patrick J. Adamson 02-Jun-2017	Annual review: No changes		

Template SOP for
Storage



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Procedure QC (2)

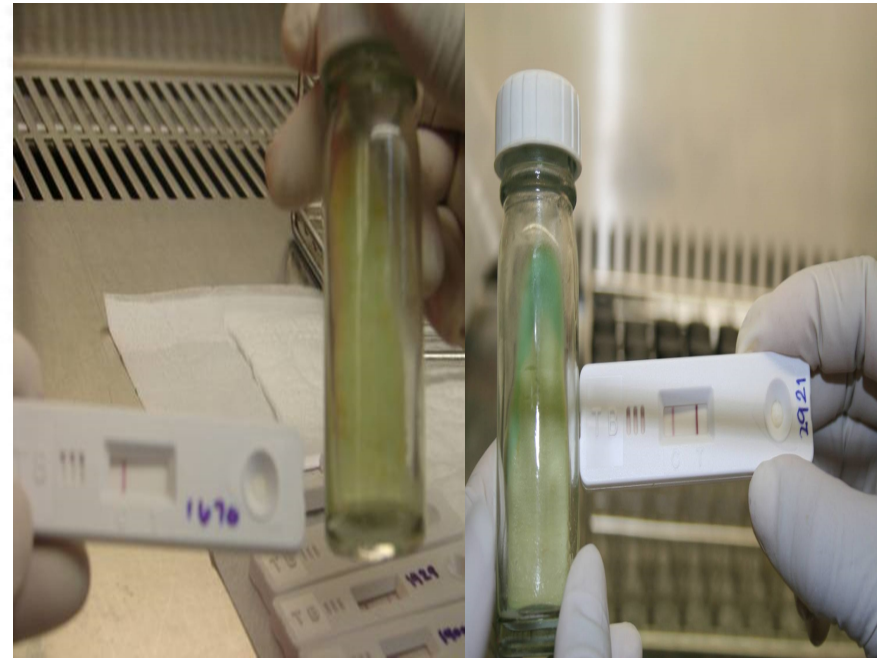
Result interpretation

- Interpretation of results

- adequate incubation
- Proper processing
- Job aids to aide in identification
- colony morphology



Fig: Cultural Characteristics of *Mycobacterium tuberculosis*



External quality assurance (EQA)

- Proficiency Testing (PT)

Entire procedure including specimen preparation and NaOH/NALC processing
Should cover all expected outcomes/strains

🚌 MTBC

🚌 NTM

🚌 Contaminant

NOTE: XDR TB strains are not recommended to be included in EQA panels

LJ CULTURE testing EQA schemes

Inter-Laboratory Comparative Analysis (ILCA)

- Involves two or more labs exchanging the same sample amongst themselves to be tested .
- Results obtained by either labs are compared to determine proficiency of each of the laboratories.

Performance Indicators of LJ Culture method

Importance of performance indicators

- Establishes “normal” laboratory values/baseline
- Identifies potential problems with pre-analytical, analytical and post-analytical phase of testing
- Gives credibility to laboratory results
- Ensures optimization of laboratory methods
- Identifies potential training needs

Performance indicators

- ✦ Contamination rate (specimen, solid, liquid)
- ✦ Correlation between positive smears and positive cultures
- ✦ Percentage of negative smears resulting in positive cultures
- ✦ Turn-around time of culture
- ✦ Proficiency testing performance in culture
- ✦ Positivity rate
 - ✦ Percentage of MTB / total number of specimens



Contamination rate

Importance of monitoring contamination rates

- May reflect problems with pre-analytical phase of testing
- May reflect the technical proficiency of the laboratory
- May identify training needs (field and laboratory)

- **Expectation: 3-5%**
- **Increases (>5%) may be due to:**
 - Incomplete decontamination
 - Suboptimal reagents
 - Improper collection, storage or transport
 - Equipment default (BSC, incubators, centrifuge)
 - Incompetent personnel
- **Decreases (<3%) may be due to:**
 - Harsh decontamination procedures
 - Stringent reagents



Correlation between smear microscopy and culture

- **Proportion of diagnostic AFB smear positive specimen that test positive culture**
- Expectation: 85-90%
- Less than 85% may be due to:
 - Specimens submitted from patients on treatment
 - Reporting of false-positive smears
 - Hash decontamination procedures
 - Stringent reagents
 - Problems with media
 - Problems with equipment
 - Excessive contamination

Correlation between smear microscopy and culture

- **Proportion of diagnostic AFB smear negative specimen that test culture positive for MTB**
- Expectation: **20-30%**
- **Less than 20% may be due to:**
 - Examination of few field by staff
 - Reporting of false-positive cultures

Turn- around time

Expected target (80-90%within test specific TAT)

Importance of monitoring TAT

1. Critical to patient management
2. Ensures laboratory procedures are optimized
3. Assists in identifying challenges with laboratory workflow algorithms, information systems and reporting systems

Assessment

1. What are the major LJ culture performance indicators?
2. What are the different cut off points for LJ culture method indicators

Summary

- Adequate QA/QC is vital for minimizing false results.
- Cross contamination can greatly be reduced with adequate QA/QC.
- A regular service and maintenance schedule of equipment is an important component of QA/QC in LJ culture method.
- Training and competency is critical for consistent and accurate LJ culture results
- Monitoring Indicators is key to understand performance and progress of a LJ culture TB lab



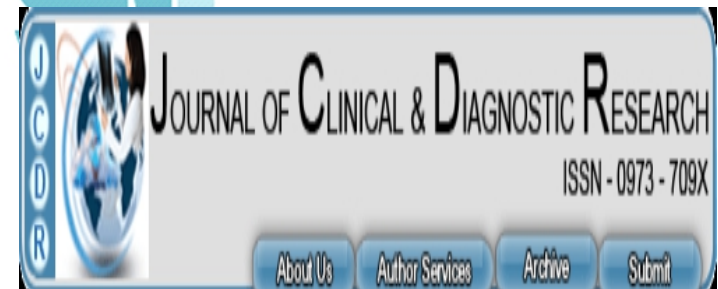
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Acknowledgement⁺



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