Vuka! Let's unite towards a TB-free world!

9th SA TB Conference
8 – 11 June 2026

New and Repurposed TB Drugs – keeping up with changes, a Quality Assurance perspective

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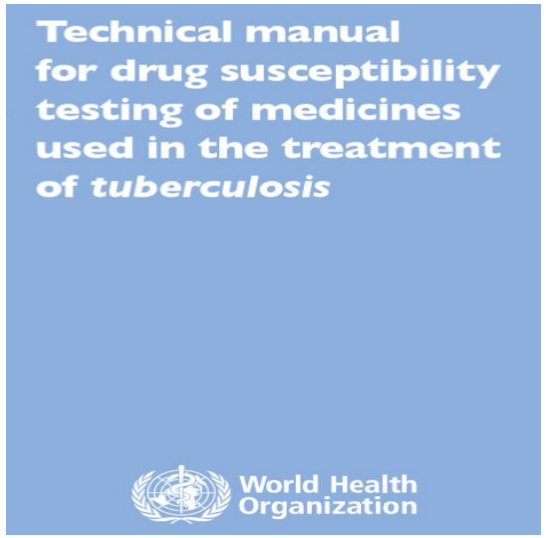
Background



WHO 2018[1]

- Quality Management System (QMS) & Proficiency Testing (PT/EQA) – essential components of organizational quality requirements and diagnostic testing services[1,2]
- PT performance, ongoing quality improvements, Root-Cause-Analysis (RCA) and corrective actions (CA) are vital for sustainable QA processes & accurate, reliable results → Clinicians depend on diagnostic results to efficiently manage patient treatment outcomes

2017 - 2018
WHO TB Program and External Review Group Meeting

2018
WHO Revised & established new CC & CB for New & Repurposed TB Drugs **FLQ, BDQ, LZD, CFZ**

2018
No pDST commercial assays available for New & Repurposed drugs

Aug 2018
NHLS/NICD TB Expert Group standardize pDST for NHLS TB Referral Labs

Sept 2018
Implement WHO new CC + CB & SA NDoH TB diagnostic & treatment algorithms

2019
CTB, NICD NHLS TB Inter-lab PT/EQA started **LVX, BDQ, LZD**

Aims and Objectives

- Verification and implementation of standardised pDST for 2nd-line, new & repurposed TB drugs with revised Critical Concentrations (CC) as per WHO recommendations and South African TB diagnostic and treatment algorithms

In order to

- To establish an inter-lab PT for NHLS TB Referral Laboratories of pDST for LVX, BDQ & LNZ with revised CC

in the absence of any commercial assays for pDST

Methods

Participant Labs

- CTB NTBRL, NICD
- 6 NHLS TB Referral Labs

PT Panels

- Characterised MTBC strains
- BD MGIT^3 960 pDST
- LVX, BDQ LZD

BD MGIT TUBE

BD PACT LJ

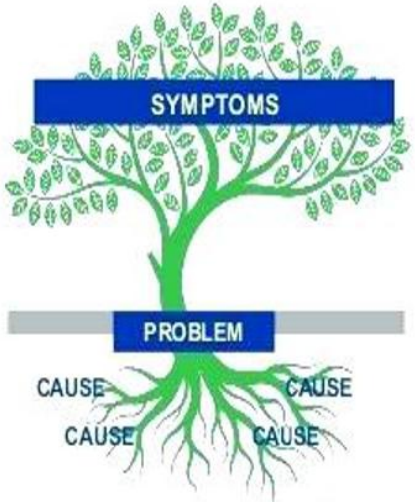
BD MGIT 960®

Analysis done by CTB, NICD

MGIT pDST consensus evaluation of majority findings

- Target score of **≥80%** acceptable
- Reproducibility assessment **≥95%** acceptable
- Error classification
  - Major Error (ME) = False Resistant
  - Very Major Error (**VME**) = **False Susceptible**
- Root-Cause-Analysis (**RCA**), corrective actions

RCA



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Results Summary 2020 to 2024

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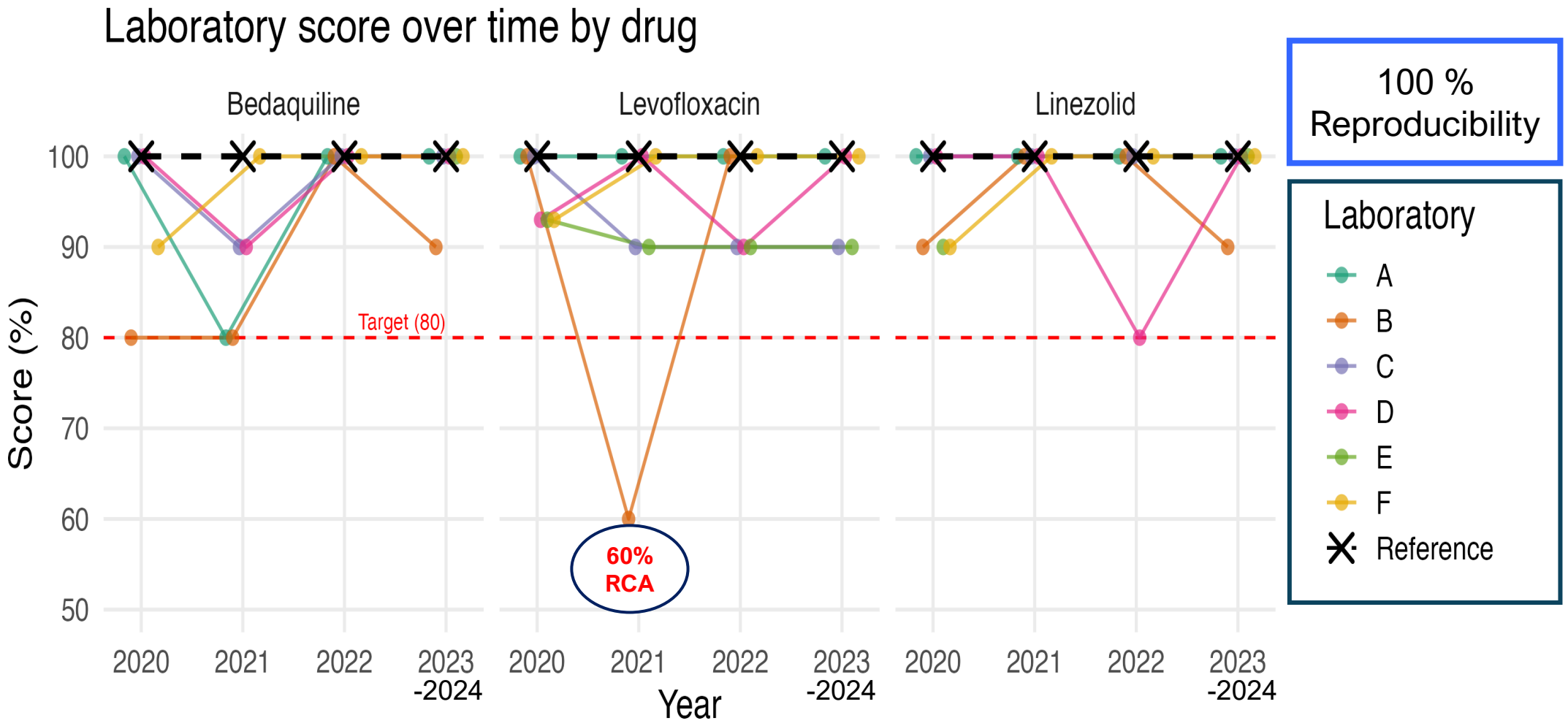

Key findings and Recommendations

- From 2020 to 2024 most participating laboratories scored >80% pDST with 1 participant laboratory scoring 100% for all panels
- In 2021, after RCA with Participant B it was found lab was ***not testing*** pDST as per BD manual → within 0 – 5 days MGIT positivity
- **BD BDQ kit is the only *commercial assay currently available for pDST for New TB drugs***
- Proficiency in pDST quality assurance programs ensures accuracy of results for laboratory diagnosis.
- Quality assurance is therefore crucial as it ensures the reliability and reproducibility of pDST results.
- This Inter-lab program has been integrated into CTB/NTBRL, NICD responsibilities and is provided to NHLS TB Referral laboratories annually.

Acknowledgements

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Academic, Universitas

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Thank you