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Health
REPUBLIC OF SOUTH AFRICA

KnowledgeHub

2030 NDP

TB Case Finding

END TB

THIS WEBINAR WILL DISCUSS THE IMPLEMENTATION AND ROLL-OUT of the new TB diagnostics and testing algorithm

DATE 6 March 2024

13:00 – 15:00 | 2 Hours

- Thank you for your interest in this webinar.
- The session is recorded and will be shared with all the presentations on the Knowledge Hub – www.knowledgehub.health.gov.za/lms.
- The chat has been disabled.
- **Please use the Q&A box to post questions for our panel of experts.**

Programme Director: Prof. Norbert Ndjeka

Time	Duration	Topic	Presented by
13:00 - 13:05	5min	Opening and Welcome	Prof. Norbert Ndjeka
13:05 - 13:15	10min	Aims and objectives of webinar	Prof. Norbert Ndjeka
13:15 - 13:35	20min	Overview of laboratory services supporting new testing algorithms: laboratory tests, laboratory request forms and SMS Notifications	Dr Shaheed Vally Omar
13:35– 13:40	5min	Discussion	ALL
13:40 – 14:00	20min	Testing algorithms and Reflex testing	Dr Lindiwe Mvusi
14:00 – 14:05	5min	Discussion	ALL
14:05 – 14:20	15min	Sample collection, specimen rejection and turn-around-times	Mr Kabelo Lioma
14:20– 14:25	5min	Discussion	ALL
14:25 – 14:40	15min	U-LAM testing	Mr Mokete Phungwayo
14:40 - 14:45	5min	Discussion	ALL
14:45 - 14:50	5min	Vote of thanks	Prof. Norbert Ndjeka
14:50 - 15:00	10min	Closing remarks	Prof. Norbert Ndjeka

At the end of the session, it is expected that participants will:

- Understand how the new testing platforms work, scale up plan and how the specimen referral will be done.
- Understand the revised TB testing algorithms, results interpretation and patient management
- Understand the challenges faced by the laboratories and some of the measures that can be implemented to reduce rejections
- Be able to conduct and interpret the results of the urine LF-LAM TB diagnostic algorithm

Main Objectives:

- To explain how the different testing platforms work, the type of specimens used for each test, how to request the test and interpret the test.
- To discuss TB testing algorithms and reflex testing and considerations to be taken before making the decision to treat.
- Discuss the laboratory report on rejections, the contributing factors and challenges faced by the laboratory.
- Discuss the eligibility criteria for the urine LF LAM test, how the test is performed, interpretation of test results and what to do about discordant results.

Key issues to be covered:

- Diversification of the testing platform and implications on TB testing including reflex testing
- Revised TB diagnostic algorithms and reflex testing
- Laboratory sample rejection rates and root causes
- Role of urine LF-LAM assay

Prof Norbert Ndjeka serves as the Chief Director TB Control and Management, under the National Department of Health in South Africa. He previously served as the Director, Drug-Resistant TB, TB & HIV. Under his leadership, there has been a decline in the number of cases of DR -TB in South Africa and a remarkable improvement in proportion of patients successfully treated for DR- TB.

He is a Specialist Family Physician with interest in TB and HIV. He has authored a numerous paper in peer-reviewed journals.

He is currently the Chairperson of the Afro-GLC (African Green Light Committee), a committee that advises WHO on how to manage drug-resistant tuberculosis. He recently (July 2021) received an Honorary Doctorate from UCT in recognition of his outstanding contribution to the fight against DR-TB locally and globally. He was recently (January 2022) nominated as Honorary Associate Professor of Medicine, University of Cape Town.

Qualifications
MD, DHSM (Wits), MMed (Fam Med) (MED), Dip HIV Man (CMSA), DSc (h.c.)

Dr Shaheed Vally Omar is a Medical Scientist, with a research focus on Mycobacterium tuberculosis with over 15 years' experience. Currently serving as the Head of the Centre for Tuberculosis at the National Institute for Communicable Diseases a division of the National Health Laboratory Service in South Africa. Further he oversees operations encompassing the National & WHO Supranational TB Reference Laboratories. He has been instrumental in advancing diagnostic evaluations and laboratory interpretative criteria for drug resistance determination. His current research focus is directed to improving national surveillance methodologies through the adept application of next-generation sequencing techniques. His contributions transcend laboratory confines, as he actively shapes national and global policy guidance pertaining to tuberculosis management. His direction has facilitated the seamless implementation of cutting-edge TB diagnostics into the routine laboratory, thereby strengthening standard practices and augmenting the efficacy of tuberculosis control measures.

Qualifications
PhD (Medical Microbiology)

Dr Lindiwe Mvusi is a medical practitioner with post graduate training in occupational and public health. She has over 20 years' experience in clinical practise and public health working in both the private and public sectors. She has vast experience in policy and guideline development, training, monitoring and evaluation of policy implementation and overall coordination of the TB programme. She has also served in several WHO Guideline Development Groups, WHO Working Groups, National TB Think Tank, National Essential Medicines List Committee. She has co-authored several publications and coordinated the national surveys on the TB prevalence, TB patient cost and TB Community, Rights, Gender and Stigma.

Qualifications

MBChB

Mr Kabelo Lioma holds a Diploma and a B-Tech degree in Biomedical Technology from the Vaal University of technology and has just completed a Post Graduate Diploma in Public Health with the university of Pretoria. He has over 20 years of Laboratory experience and 7 years in the clinic laboratory interface (CLI). He is also a qualified SANAS Technical Assessor which focuses on compliance to testing requirements as per ISO15189.

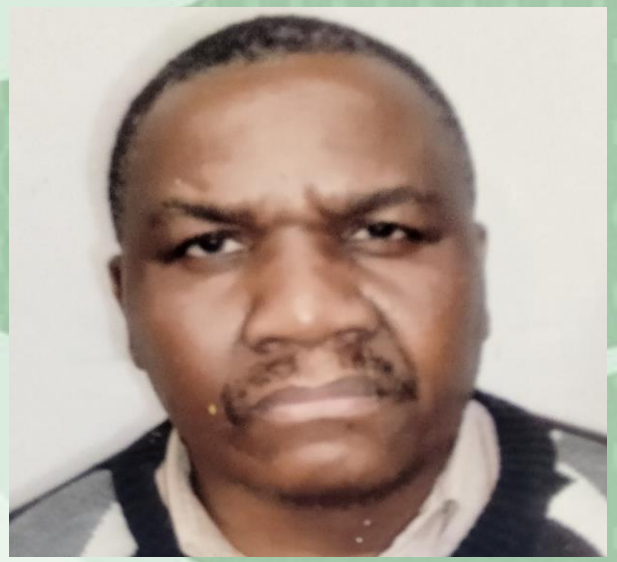
Qualifications

National Diploma: Biomedical Technology

BTech Degree: Biomedical Technology

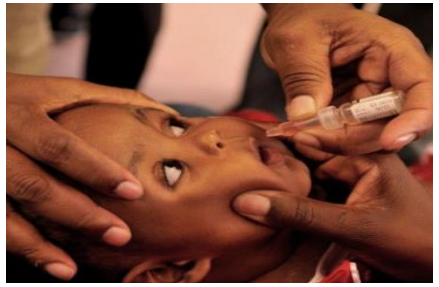
Postgraduate diploma: Public Health

Mr Mokete Phungwayo was previously employed as a Medical Scientist for a period of six years at the National Institute for Communicable Diseases (NICD). His first involvement in the TB programme was in 2004 when he was appointed as a TB Programme Manager at Maluti sub-district in the Alfred Nzo district in the Eastern Cape. He later left the TB Programme to further his studies in public health, pursuing his MPH studies under the sub-track, Field Epidemiology and Laboratory Training Programme, jointly offered by the NICD and the School of health Systems and Public Health at the University of Pretoria. He rejoined the TB Programme at the National Department of Health in 2012. He is currently based in the Drug Susceptible TB directorate within the TB cluster at NDoH



Qualifications

M.Sc. (Med) (Wits); MPH (Pretoria)



Ensuring Quality of Laboratory samples:
TB sample rejections

Kabelo Lioma
National Tuberculosis Programme

Date: 06/03/2024

Presentation Outline

- Purpose of the Presentation
- Overview of the rejection criteria
- Sample rejection statistics
- Key Interventions

Purpose

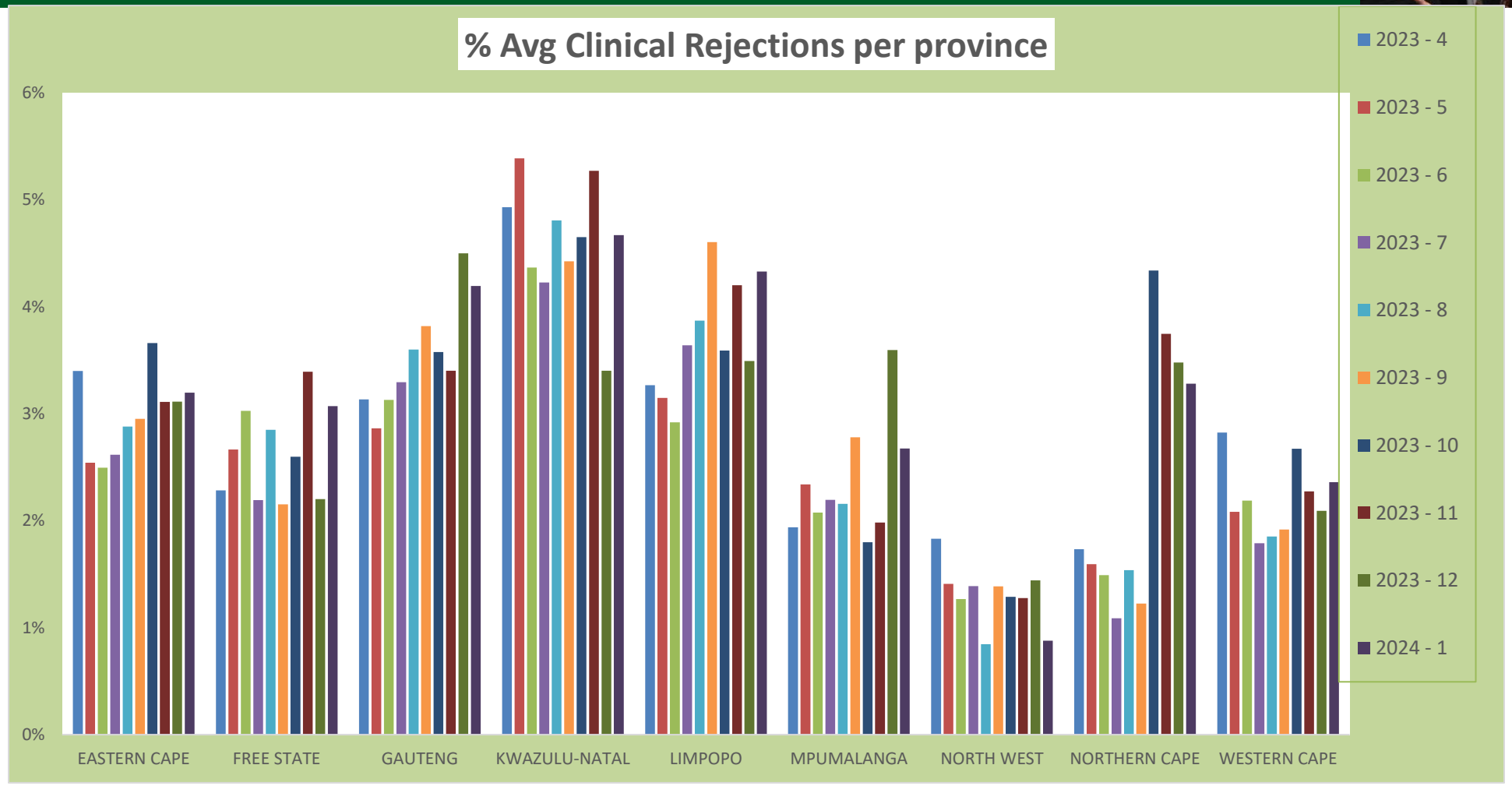
- Quality assurance: Emphasizes the commitment to accuracy and reliability in diagnostic procedures, contributing to overall laboratory quality assurance.
- Education and awareness: Raises awareness about the significance of proper sample collection, handling, and documentation to avoid rejections
- Continuous Improvement: Provides insights into common issues leading to rejections, fostering proactive measures for improvement.
- Collaboration and communication: Encourages collaboration to address challenges and work collectively towards improving sample quality.

Common rejection reasons

CLERICAL ERROR	UNSUITABLE SPECIMEN	INSUFFICIENT SPECIMEN
SPECIMEN NOT LABELED	NOT DONE: POOR QUALITY SPECIMEN (SALIVA OR	UNSUIT: LEAKED
INFO DOES NOT MATCH (ON SAMPLE & FORM)	SAMPLE HAS FOOD PARTICLES)	SPEC CONTAINER EMPTY
NO TEST SET REQUESTED		SPECIMEN INSUFFICIENT
NO REQUEST FORM RECEIVED		SPECIMEN NOT RECEIVED
NOT DONE: NO PATIENT NUMBER		
NOT DONE: NO PATIENT NAME/SURNAME		
NOT DONE: NO AGE/DOB		
NOT DONE: NO FACILITY NAME		
NOT DONE: NO WARD/CLINIC		
NOT DONE: NO GENDER INDICATED		
NOT DONE: NO HCW NAME/NUMBER		
NOT DONE: NO HEALTH CARE WORKER SIGNATURE		


PATIENT INFORMATION
NATIONAL HEALTH LABORATORY SERVICE
CCMT
YES
NO
Practice number 5200296
NHLS LAB NUMBER BARCODE
for NHLS use only
AAAA0001P
MARK IF URGENT
PHC REQUEST FORM N1
FACILITY
Hospital folder number, or Clinic file number
ID or passport number
Patient name: Surname First name Title
Sex Date of birth Age
CLINIC FOLDER NUMBER
PATIENT ID / PASSPORT
SURNAME
FIRST NAME/S
TITLE:
GENDER:
RACE:
DATE OF BIRTH
AGE
PHYSICAL ADDRESS
TELEPHONE:
CELL:
PATIENT
FACILITY NAME
SERVICE POINT
EGK CODE
NHLS FACILITY CODE
COLLECTION DATE
TIME
SPECIMEN TYPE
REQUESTED BY: HEALTH CARE WORKER (HCW)
HEALTH CARE WORKER (HCW) SIGNATURE
HPCSA / SANC NO
CONTACT NO
IF SPECIMEN COLLECTED BY OTHER: NAME:
HPCSA / SANC NO
Facility name
Service point e.g. TB Clinic
eGK approval code
SPECIMEN
Collection date and time
Specimen type
HEALTHCARE WORKER
Healthcare worker: Name
Registration no.
Contact number

Rejections overview



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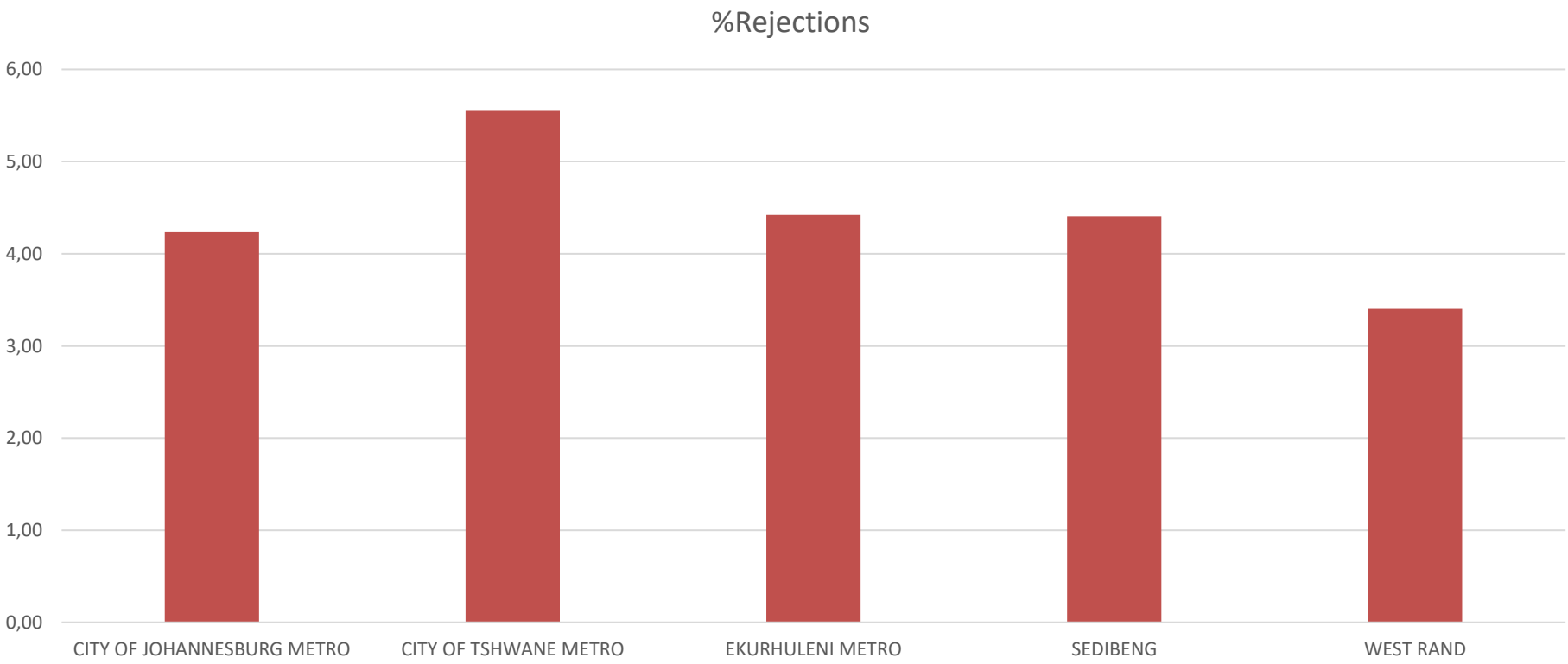
Gauteng Districts



Gauteng Rejections

Row Labels	Sum of CLERICAL ERROR	Sum of UNSUITABLE SPECIMEN	Sum of INSUFFICIENT SPECIMEN
CITY OF JOHANNESBURG METRO	220	1069	5591
CITY OF TSHWANE METRO	663	1023	874
EKURHULENI METRO	565	466	3611
SEDIBENG	92	73	1442
WEST RAND	170	256	648

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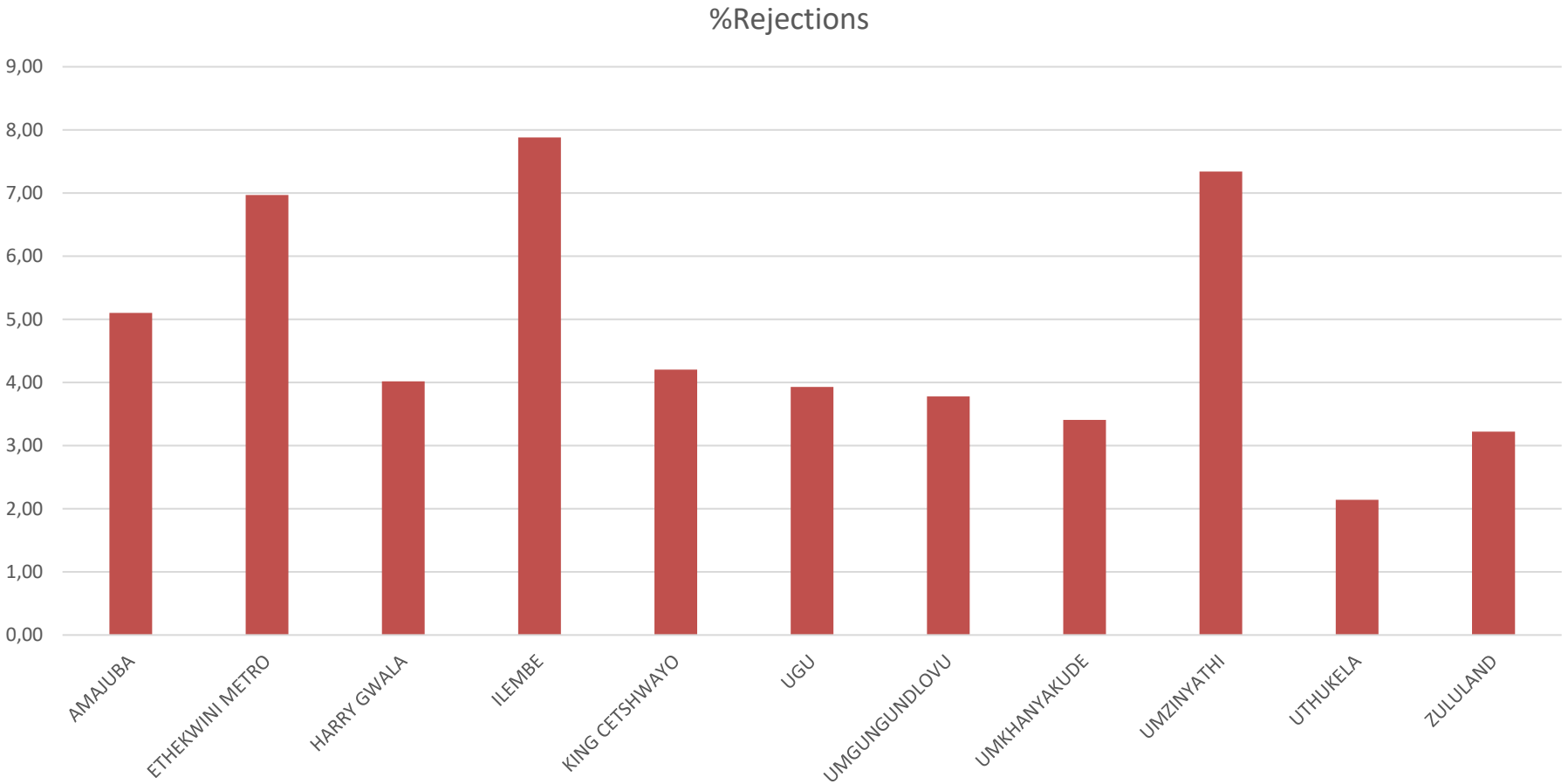
KZN Districts



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Phila
Inspired to live

2030 NDP

KZN Rejections

Row Labels	Sum of CLERICAL ERROR	Sum of UNSUITABLE SPECIMEN	Sum of INSUFFICIENT SPECIMEN
AMAJUBA	205	87	1203
ETHEKWINI METRO	667	1038	12046
HARRY GWALA	134	445	1563
ILEMBE	122	32	3048
KING CETSHWAYO	203	136	2622
UGU	117	90	1655
UMGUNGUNDLOVU	390	152	3145
UMKHANYAKUDE	307	109	3145
UMZINYATHI	182	57	3909
UTHUKELA	26	35	902
ZULULAND	129	49	2284
Grand Total	2482	2230	35522

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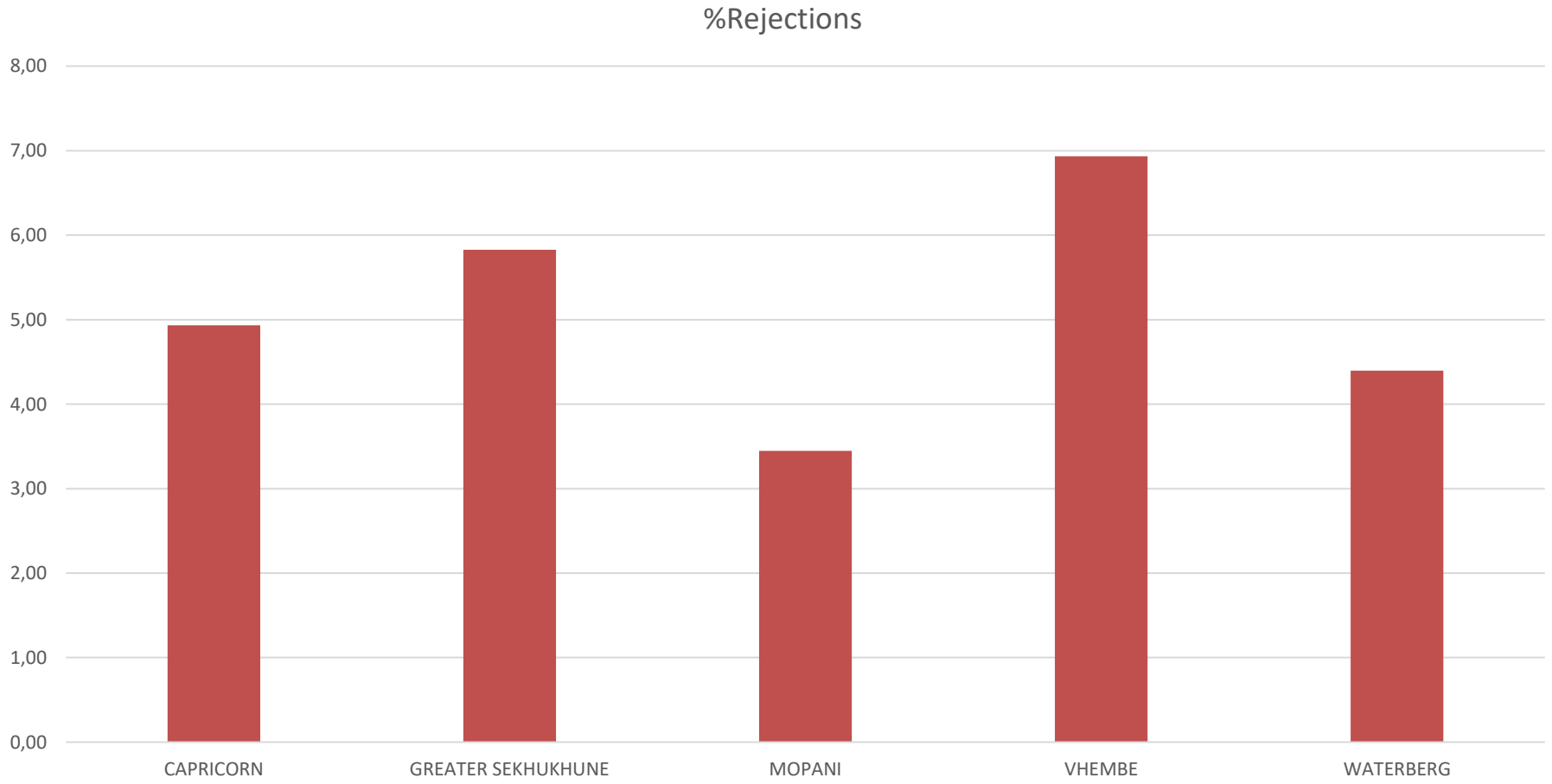
Limpopo Districts



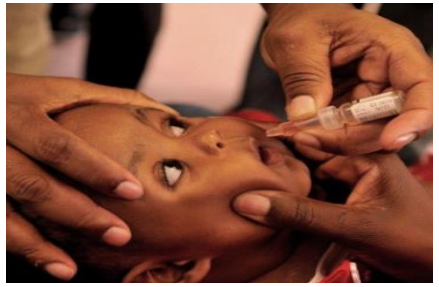
Limpopo Rejections

Row Labels	Sum of CLERICAL ERROR	Sum of UNSUITABLE SPECIMEN	Sum of INSUFFICIENT SPECIMEN
CAPRICORN	24	157	862
GREATER SEKHUKHUNE	57	25	571
MOPANI	13	48	519
VHEMBE	60	85	1272
WATERBERG	14	44	352
Grand Total	168	359	3576

Key Interventions

- Educate patients on proper sample collection method
- Evaluate sample quality and quantity
- Ensure proper sealing
- Correct labeling (Form and sample)
- Check for completeness of the request form
- Package sample and form in appropriate sample bag pockets

Thank you



LF-LAM (Urine LAM)

Mokete Phungwayo
National Tuberculosis Programme

Date: 6 March 2024

Presentation Outline

- Background and rationale
- Criteria for the use of the urine LF-LAM test
- LF-LAM test and the results
- LF-LAM Algorithm
- Advantages and limitations of the test

Background and Rationale

- The End TB Strategy prioritizes the early diagnosis and prompt treatment of all persons with TB.
- Early diagnosis of TB will lead to:
  - Early initiation of treatment;
  - Curb the transmission in the community
  - Reduce TB-related mortality.
- It is difficult to diagnose TB in people with advanced HIV disease (AHD), or who are seriously ill, with sputum-based tests.
- Tests based on the detection of mycobacterial lipoarabinomannan (LAM) antigen in urine have been developed as potential point-of-care tests for TB.
- LAM is a polysaccharide which is a major component of mycobacterial cell wall.

Background and Rationale (2)

- It is released by metabolically active or degenerating mycobacterial cells in people with active TB and is detectable in urine following clearance by the kidneys.
  - Its presence in urine is indicative of active TB disease.
- Detection of the TB LAM antigen allows for the diagnosis of both pulmonary and extrapulmonary TB.
- In 2019, the WHO issued an updated policy on the use of the test, based on new evidence from various studies that were done.
- These recommendations were adapted to the South African situation,
- Criteria for the use of the test in different healthcare settings were developed.

Criteria for the use of the test in S. African

Inpatient Healthcare Setting

The test can be used to assist in the diagnosis of active TB in **PLHIV**:

- irrespective of whether TB is suspected or not (i.e., irrespective of signs and symptoms of TB,
- irrespective of the patient's CD4 cell count, and
- irrespective of whether advanced HIV disease (AHD) is present or not.

Outpatient Healthcare Setting

The test can be used for the diagnosis of active TB in **PLHIV:**

- with signs and symptoms of TB (PTB and/or EPTB), **AND**
- have a CD4 count of < 200 cells/ul, or
- have advanced HIV disease stage 4 or are seriously ill.

LF-LAM test

- The LF-LAM test is manufactured by Abbott Laboratories and distributed locally, by Obsidian Health (Pty) Ltd.

- The test kit contains the following:
  - 25 Determine TB LAM Ag test strips
    - These are packaged as 5 cards each holding 5 strips
  - 1 Determine TB LAM Ag reference scale card
  - 1 Determine TB LAM package insert
  - A desiccant is also included in the foil pouch.

- A separate package containing 60 µL pipette tips (25) are included

LF-LAM test strip

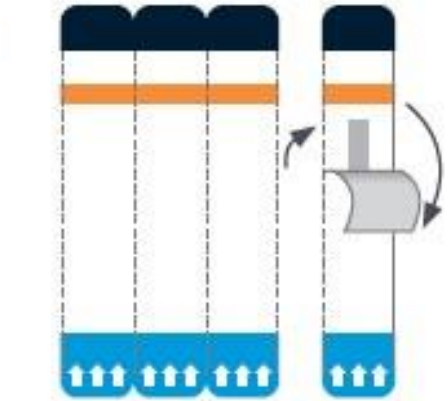
Discontinued Product	New Rebranded Product
	
Alere Determine™ TB LAM Ag	Determine™ TB LAM Ag
100 Test Kit	25 Test Kit

Product Name: Determine ™ TB LAM Ag
Quantities: 25 Test Kit
Code: 7D2741

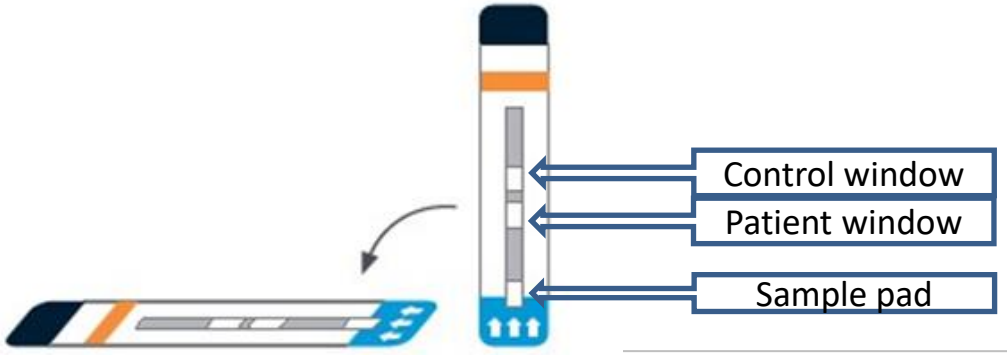
Collection of Urine specimen

- Clear instructions must be provided to the patient on the collection of urine
- Advise patient to:
  - Clean and wipe the urogenital area before collecting urine
  - Allow the first stream of urine to flow and collect mid stream urine into the container provided
  - Wipe the sides of the container and wash hands after collecting urine
  - Early morning urine is preferred where it is feasible to obtain i.e. hospital settings
- **NB**: Collect urine in a universal screw-cap sterile container

Performing the Test



- Remove the test strip starting from the right by bending and tearing at the perforation
- This is to ensure that the Lot Number on the left side of the card is always available
- Remove the protective foil cover by pulling from the top to expose the test strip



- Place the test strip flat on the counter/ table where the test is to be performed facing up

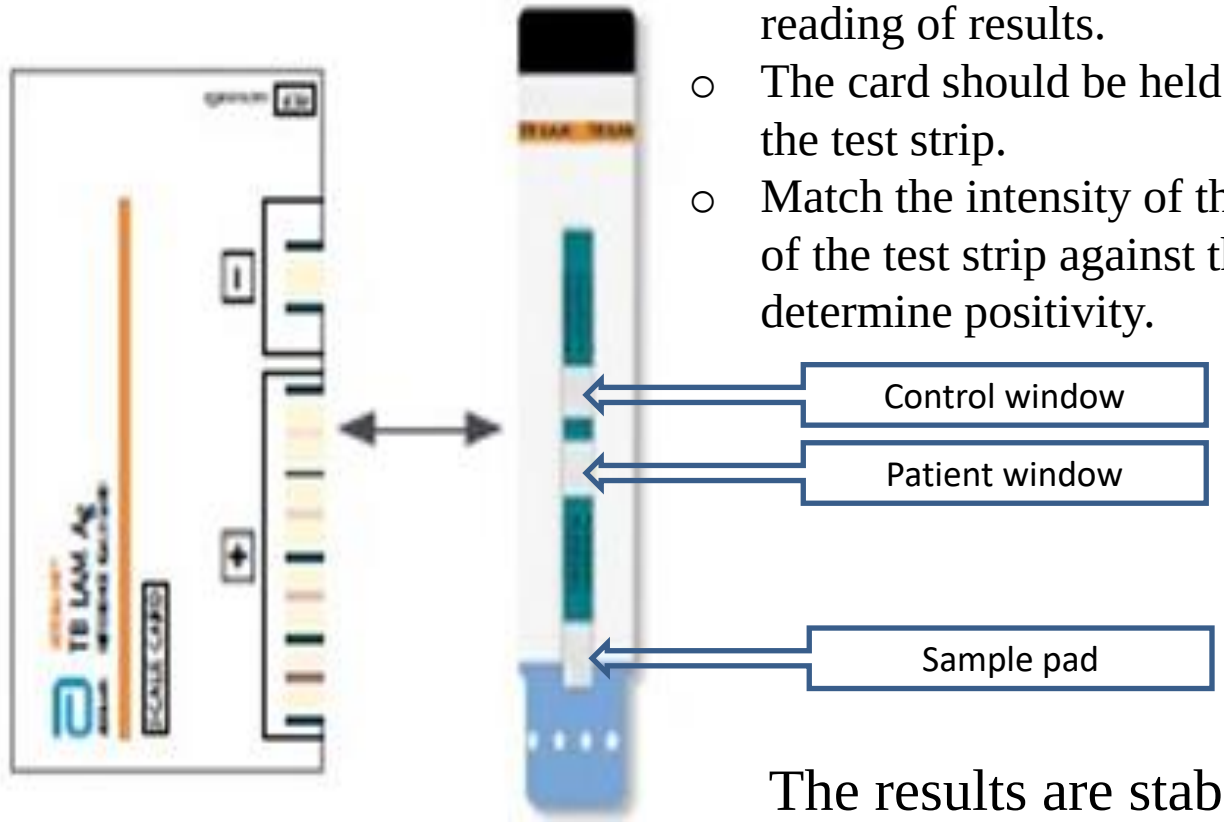
Performing the Test (2)

- Draw urine from the specimen bottle/ jar using the pipette by squeezing and releasing the upper bulb of the pipette

- Place about 60 µL of urine in the white pad marked by arrows (sample pad), by squeezing the upper bulb of the pipette.
- Wait for **25 minutes** and read the results

<u>NB</u>: A specimen should be collected for TB NAAT.

Reading of results



- Reference scale card must be used to assist with reading of results.
- The card should be held next to the result window of the test strip.
- Match the intensity of the band in the patient window of the test strip against the reference scale card to determine positivity.

The results are stable up to 35 minutes. **Do not read after 35 minutes**

LF-LAM Results

LINE	POSITIVE	NEGATIVE	INVALID	EQUIVOCAL/INDEFINITE
CONTROL				
PATIENT				

SETTING	ADMITTED HOSPITALIZED SETTING.	CLINIC OUTPATIENT SETTING, AND PATIENT AMBULATORY, AND WITH SIGNS AND SYMPTOMS OF TB.
Step 1 Assess for TB signs and symptoms.	All hospitalized patients are considered seriously ill.	• If CD4 count ≤ 200 cells/ul, and the results are not older than 6 months, perform LF-LAM. • If no CD4 count is available, this should be requested. • Patients who have advanced disease and/or patients who are seriously ill, should be tested with LF-LAM.
Step 2 • Perform LF-LAM test. • Collect a specimen and perform TB NAAT concurrently.	• Collect urine for LF-LAM. • Collect sputum or any other suitable specimen (e.g., CSF, lymph node aspirate for TB NAAT). • Conduct additional clinical evaluation for TB. • Conduct chest X-ray if available.	
Step 3 Interpret LF-LAM results.	**LF-LAM Positive** • Start patient on 1st line TB treatment. • Review TB NAAT results when they become available.	**LF-LAM Negative** Review TB NAAT results.
Step 4 Interpret LF-LAM results.	**TB NAAT Positive** Modify treatment according to Rif and/or INH status. **TB NAAT Negative** • Collect a specimen for culture & DST. • Continue with treatment and review the culture & DST results when they become available. • Modify treatment according to culture & DST results.	**TB NAAT Negative** • Collect specimen for culture & DST. • Perform CXR if available. • If clinical picture & CXR are suggestive of TB, start patient on 1st line TB treatment. • If clinical picture & CXR are NOT suggestive of TB, defer treatment & review culture & DST results. **TB NAAT Positive** Treat according to RIF and/or INH status.

Limitations of the test

- The Determine™ TB LAM Ag test is a “rule in” test for TB in co-infected patients with low CD4 count or who are very sick.
- It does not distinguish between the different species of mycobacteria therefore should be used in combination with confirmatory tests – TB NAAT assay or culture.
- It does not eliminate the need to determine the resistance pattern therefore TB NAAT, or culture & DST will have to be conducted
- The test may only be used on urine
  - It is not recommended for use on other samples

Thank you

Acknowledgements:

- All Speakers
- The Knowledge Hub Unit (NDoH)
- The TB Control and Management Programme (NDoH)
- TB TSU (NDoH)
- National Health Laboratory Service (NHLS)
- National Institute for Communicable Diseases (NICD)

- Thank you for attending this webinar.
- For any enquiries regarding the webinar, please email: SAEDP@health.go.za
- The session recording and all the presentations will be shared on the Knowledge Hub – www.knowledgehub.health.gov.za

THANK YOU