REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

REPORT ON INSPECTION/RE-INSPECTION OF MEDICAL LABORATORIES.

Pursuant to the Medical Laboratory Technicians and Technologists Act CAP 253 A Laws of Kenya –

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	REPORT ON INSPECTION/RE-INSPECTION OF MEDICAL LABORATORIES.		DOCUMENT CONTROL Serial: KMLTTB/LABS/05 Version 001
	OWNER OF THE FORM	REGISTRAR	Date: 2ND JANUARY, 2025

ABBREVIATIONS

FGD	- FOCUSED GROUP DISCUSSION
GoK	- GOVERNMENT OF KENYA
HOD	- HEAD OF DEPARTMENT
KMLTTB	-KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
MLS	- MEDICAL LABORATORY SCIENCES
MoA	- MEMORANDUM OF AGREEMENT
MoH	- MINISTRY OF HEALTH
MoU	- MEMORANDUM OF UNDERSTANDING
MLD	- MEDICAL LABORATORY DIRECTOR
MSDS	- MATERIAL SAFETY DATASHEET
SoP	- STANDARD OPERATING PROCEDURE

INTRODUCTION

This report for the Inspection/re-inspection of ……Medical **LABORATORY** pursuant to section 40 (g) of Medical Laboratory Technicians and Technologist Act Cap 253A Laws of Kenya. The report was as a result of assessment of the suitability of the Medical **LABORATORY** in terms of physical facilities, Human resource capacity, Environmental suitability, Biosafety and Biosecurity, Reagents and Equipment (invitro diagnostics) as well as focus on External Quality Assurance (EQA) and Internal Quality Assessment (IQA).

KMLTTB AUDIT TEAM

1.

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THE MEDICAL LABORATORY TEAM.

1.
2.

Section I: General Medical Laboratory Information	
Name of the Medical laboratory	
KMLTTB Registration number	
County	
Sub-County	
Geolocation	
Affiliation	
Location	
Head of institution affiliated to (where Applicable)	

Name,	**ID No**	Mobile Number	**Email**	**Postal Address**	**KMLTTB registration**

Head of Medical Laboratory /Medical Laboratory Director/ Superintend /In charge (persons whose documents have been used to register the laboratory)					
Name	ID No	Mobile number	Email	Postal Address	KMLTTB Registration No & Status
Date of application of the medical Laboratory business premises inspection					
Date of Inspection					

The National Tuberculosis Reference Laboratory

The Medical laboratory was found ……

FINDINGS

Section II: Supplies, Medical laboratory infrastructure & equipment: ***Score 2 Yes =2, Partial =1, No= 0.***	**RESPONSE**	**SCORE**
1. Availability of contingency plan in case of stock outs of reagents		
2. Availability of a contingency plan in case of equipment down time		
3. Availability of a contingency plan in case of challenges in staffing?		
4. Availability of plans (1, 2,3-) above documented		
5. Is there an efficient inventory management system for Consumables? *Describe the system*		
6. There was Availability of medical laboratory reagents, equipment's and other supplies for analysis and investigations validated by KMLTTB.		

7. All medical laboratory reagents, equipment's and other supplies for analysis and investigations were inspected upon receiving before storage.		
8. There was Availability of a functional inventory management.		
9. There was Availability in the medical laboratory space for testing.		
10. There was Availability of adequate space designated as a medical laboratory store for reagents with environmental conditions monitored.		
11. There was Availability of adequate space designated for phlebotomy and collection other specimens.		
General cleanliness of the laboratory;		
12. There was Availability of work areas that can easily be cleaned, are clean and well maintained.		
13. There was Availability of a Bench tops that were impervious to water. organic solvents, acids, alkalis and other chemicals.		
14. The members of staff were trained on the use of spill kits		
15. There was Space available in the Medical Laboratory was adequate to perform the work without compromising quality and safety of personnel?		
16. There was Availability in the medical laboratory of separate fridges and freezers for storage and archiving specimen.		
17. There was Availability in the medical laboratory of a designated area for specimen collection.		
18. There was Availability in the medical laboratory of adequate space for the following functions: -		
a) Specimen reception		
b) Testing		
c) Data analysis		
d) There was a Medical laboratory Directors/Superintendent/ Manager's office.		
e) Staff Clean area.		
19. The designated areas or sections clearly labelled.		
20. The Medical laboratory is well ventilated.		
21. There was Monitoring and recording of freezers and refrigerators temperatures is done twice daily.		
	FINDINGS	SCORE

Section III: Specimen Collection, Packaging, Transportation and Storage: ***Score 2 Yes =2, Partial =1, No= 0.***		
22. There was Medical laboratory specimen collection, packaging, transportation and storage guidelines/procedures documented and available to relevant personnel.		
23. The Medical laboratory has a guideline (SOP) for specimen acceptance and rejection.		
24. The Medical laboratory have specimen collection guideline.		
25. There was a standard specimen request form available for those requesting tests for medical investigations and analysis? ***See copy attached***		
26. There was Availability in the laboratory of appropriate packaging materials for referring specimens (triple package or any package in conformity with KMLTTB recommendations)		
27. There was a procedure for specimen archiving? (Attach a copy of the procedure).		
Section IV: Biosafety and Biosecurity: ***Score 2 Yes =2, Partial =1, No= 0.***	**FINDINGS**	**SCORE**
28. There was a Bio-risk assessment for medical laboratory analysis and investigations been conducted and findings acted upon.		
29. The Medical laboratory had a medical surveillance program		
30. There was Availability in the medical laboratory an exposure control plan and written emergency procedures readily available to employees with at least the safety manual; Bio-risk assessment & management-universal precautions, work practices such as hand washing, personal hygiene, sharps handling; use of PPE, spills management, PEP, exposure incident reporting & recordkeeping, initial & refresher trainings, waste management.		
31. The medical laboratory was located away from the general public where there is low human traffic.		
34. The access to the medical laboratory was always limited or restricted.		
32. There was availability of access control measures in place (Door locks, secured windows, biometric device, CCTV, "unauthorized entry prohibited" with List of measures in place in the comment section.		

33. There was availability of their appropriate security measures (24hrs) in place to minimize potential inappropriate removal or release of biological agents? (e.g. security guards, CCTV).		
34. There was ***NO*** medical laboratory security concern in the past 12 months e.g. theft, break-ins, vandalism		
35. There was availability in the medical laboratory of an occurrences book that allow good documentation and regular review.		
36. There was availability in the laboratory of the following biosafety & biosecurity measures in place.		
i. Signage (Biohazard, no gloves on door, fire exit)		
ii. Hand wash station		
iii. Hangers for PPE		
iv. Eye wash station		
v. Waste bins (three colour coded bins with the respective liners)		
vi. Adequate appropriate PPE (Gloves, N95 masks, Full body suit or lab coats, Face shields/eye googles)		
vii. Autoclave		
viii. Disinfectants (Ethanol, Bleach *etc.*)		
ix. Lockable freezers and refrigerators		
x. Lockable doors.		
xi. Functional fire extinguisher (& training on how to use)		
xii. Emergency exit		
xiii. The Laboratory have a fire assembly point.		
37. There was in the medical laboratory a job aid available on proper donning and doffing of all recommended medical laboratory analysis and investigations PPEs? (we observed proper use of PPE by laboratory staffs)		
38. Apart from availability of bins, there was waste segregation and decontamination of waste before disposal.		
39. There was functional incinerator available for use by the Medical Laboratory.		
Section V: Human Resource: ***Score 2 Yes =2, Partial =1, No= 0.***	**FINDINGS**	**SCORE**
40. (a)There were the following numbers of staff in the medical laboratory according to their professional qualifications.		
(i). Medical Laboratory specialists (PhD in MLS)		
(ii). Medical Laboratory Scientists (MSc in MLS)		
(iii). Medical Laboratory Technologists (Higher Diploma & BSc in MLS)		

(iv). Medical Laboratory Technologists (Diploma in MLS)		
(v). Medical Laboratory Technicians (Certificate in MLS)		
(vi). Other- Specify (e.g. Data clerks)		
(b). There were the following numbers of staff in the medical laboratory with illegal professional qualifications.		
41. There was adequate number of Medical Laboratory staff with requisite competence to undertake the required for analysis and investigations required of this level of facility.		
42. If no in question 42 above, how many members of staff would be adequate to run medical laboratory analysis and investigations in this facility? **(based on workload and operational hour)**		
43. The personnel working in the medical laboratory were supervised by a qualified medical laboratory staff. (Superintendent/Manager/Director.)		
Section VI: Quality Assurance: ***Score 2 Yes =2, Partial =1, No= 0.***	FINDINGS	SCORE
44. The Medical laboratory was IS ISO 15189:2022 or any other relevant ISO standard accredited and/or was implementing it. NB:(ISO standards implementation is recommended but accreditation is not mandatory for licensure)		
45. The Medical laboratory had a quality manual?		
46. The quality manual had been reviewed.		
47. Does the laboratory have and implement procedures for validation and verification of new tests, new consumables lots for testing kits? (Provide evidence and comment)		
48. Does the medical laboratory adhere to correct labelling procedures for all specimens and testing devices? (Give comment)		
49. Are specimens handling and testing SOPs, and job aids for analysis and investigations available in the appropriate sections of the medical laboratory and to the personnel? (Review the SOP)		
50. Are all specimens processed in line with the SOP, documented and corrective actions taken in case of failure? (Give comments.		
51. Are medical laboratory analysis and investigations results reviewed and authorized by a qualified Medical laboratory		

professional before release? (Provide evidence if testing has commenced and comment)		
52. The Medical Laboratory implements Internal Quality Control (IQC) Measures.		
53. The Medical Laboratory IQCs are reviewed regularly.		
54. Is the medical laboratory enrolled to any EQA scheme (PT panels or inter-laboratory comparison)? (Provide evidence and comment)		
55. The medical laboratory able to take preventive and corrective action in-case of failed results.		
Section VII: Data Management & Communication: ***Score 2 Yes =2, Partial =1, No= 0.***	**FINDINGS**	**SCORE**
56. There was a data management plan for medical laboratory analysis and investigations.		
57. There was a functional communication equipment available in the medical laboratory. E.g. *telephone*, *Email*,		
58. The medical laboratory had an efficient data back up in place to prevent loss of patient results in case of theft, computer breakdown *etc.*?		
59. The Medical laboratory had capacity to perform basic data analysis to inform outbreak response within the locality.		
60. The medical laboratory had the mechanism to communicate all notifiable disease to Director General of health through the relevant channels.		

MAKE GENERAL COMENTS ON THE FOLLOWING PARTINENT ISSUES.

SECTION Viii	
ISSUES	COMMENTS
1. The inventory of suppliers for medical laboratory reagents, equipment's and other supplies used for analysis and investigations including KMLTTB validation status.	
2. Types of specimens the medical laboratory collect for analysis and investigations.	
3. What specimens does the medical laboratory receive / intends to receive from other medical laboratories	
4. What challenges the medical laboratory has experienced with the test kits used in their analysis and investigations including during Method validation	
5. The medical laboratory current and projected workload on daily basis.	
6. The target population for the medical laboratory	
7. The results of analysis and investigations for proficiency test on the past EQA participation or inter Medical Laboratory comparison if applicable	
8. The average turnaround time for the medical laboratory analysis and investigations from collection to return of results and its acceptability.	
9. Whether the medical laboratory a quality /safety officer with delegated responsibility to oversee compliance with QMS	
10. The Medical Laboratory test menu, inventory of equipment and space measurements used to determine its classification	

SECTION IIX		
FINDINGS		
AREAS CHECKED:	MINIMUM SCORE (%)	SCORE ACHIEVED (%)
a) Supplies, Medical laboratory infrastructure & Equipment		
b) Specimen Collection, Packaging, Transportation and Storage		
c) Biosafety& Biosecurity		
d) Human resource		
e) Quality Assurance		
f) Data management and communication		
A. RECOMMENDATIONS:		
B. Register Laboratory as Medical Laboratory CLASS:		
C. Declined Registration:	D. Reasons for the declined registration:	
E. Any other conditions prescribed by the board to ensure compliance		

……THE END……