REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
Make Testing a Safe Reality

REPUBLIC OF KENYA
KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

MEDICAL LABORATORY INSPECTION CHECKLIST

Pursuant to the Medical Laboratory Technicians and Technologists Board Act CAP 253A Laws of Kenya
KMLTTB QUALITY ASSURANCE SERVICES

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD *Make Testing a Safe Reality*	MEDICAL LABORATORY INSPECTION CHECKLIST		DOCUMENT CONTROL **Serial: KMLTTB/LAB/02.** **Version:** 002 **Date:** 25TH March 2025
	Owner	**Registrar**	

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INTRODUCTION TO MEDICAL LABORATORY INSPECTION CHECKLIST.

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a statutory body mandated to oversee the training, practice, business, and employment of medical laboratory technicians and technologists and advises government on related matters as stipulated under Cap 253A of the Laws of Kenya.

The Board also undertakes validation of in vitro diagnostics through Legal Notice No. 113 of 2011.

The Act gives the Board the responsibility of ensuring that all medical laboratories undertaking analysis and investigations meets the desired standards necessary for the delivery of quality medical laboratory services. These standards shall ensure the development of a robust medical laboratory services necessary to meet national and international health obligations that include sustainable development goals and universal health coverage. The implementation of this checklist will no doubt contribute to achievement of the right to the highest attainable standard of health as outlined in the constitution of Kenya 2010 as well as achievement of Vision 2030.

It is anticipated that compliance with the standards will enable medical laboratory run and sustain their analysis and investigations are ensuring the safety of the professionals, the patient and the environment.

This checklist is for inspection of Medical Laboratories in Kenya pursuant to section 40 (g) of Medical Laboratory Technicians and Technologist Act Cap 253A Laws of Kenya. The objective of this checklist is to assess suitability of Medical Laboratories to offer Medical Laboratory Services.

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REGULATION OF APPLICATION FOR INSPECTION OF MEDICAL LABORATORIES

1. A person or entity seeking to establish a medical laboratory shall apply to the Board for registration in the Form KMLTTB/ LAB/ 02.
2. An application under procedure (1) shall be accompanied by the following—

(a). registration certificate in respect of a company or business name.

(b). KMLTTB Registration certificate.

(c). a copy of the KRA pin.

(d). the comprehensive list of test menu (medical Laboratory Investigations and analysis) envisaged to be conducted in the facility.

(e). prescribed fee;

(f). evidence of physical facilities, Validated medical laboratory equipment, reagents other chemicals and any other required resources;

(g). memorandum of understanding with a referral Medical laboratory recognized as such by KMLTTB.

(h). waste management certificate or contract for waste disposal.

(i). any other requirement as may be determined by the Board.

(ii) Requirements for the superintendent include

(KMLTTB valid superintendent License issued in accordance with the provisions of medical Laboratory regulations.

NB: SUPERINTENDENT LICENSE IS ISSUED FOR ONLY ONE MEDICAL LABORATORY PER PROFESSIONAL.

(a) Certificate of registration as a medical Laboratory sciences professional.

(b). current practice license.

(c). evidence of five years of active practice post registration.

(d). updated curriculum vitae.

(e). List of all medical Laboratory staff complete with copies of current licenses.

(f) Appointment and acceptance letters for those employed to superintend.

(g). copies of National Identity card, KRA Tax compliance certificate.

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(h). certificate of good conduct from the Directorate of criminal investigations.

3. The Board shall review the application within seven days of receipt and notify the applicant of the status of the application.

4. Where the application under procedure (1) meets the meets the minimum requirements, the Board shall notify the applicant of the date for inspection of the proposed medical laboratory upon payment of the prescribed fee.

5. The Board shall cause the inspection of the medical laboratories for applicants who have paid the inspection fee.

6. Where the information submitted under procedure (2) is incomplete, the Board shall notify the applicant to avail additional information within fourteen days.

7. Where an applicant, without good cause, fails to provide the additional information required by the Board under procedure (6), within the fourteen days, the Board shall reject the application.

8. An applicant whose application has been rejected in accordance with procedure (6), may reapply in accordance with procedure (1).

9. There shall be Inspectors appointed by the Board after competitive recruitment process.

10. The Inspectors shall hold office on such terms and conditions as the Board shall determine from time to time.

11. The Inspectors shall conduct inspection of medical laboratories as the Board shall determine from time to time.

12. Medical laboratories shall be classified in accordance with the Checklist set out in the Schedule.

13. The Inspectors shall conduct the inspection and share with the medical laboratory a preliminary report with recommendations within thirty days.

14. The Inspectors shall submit a final report with recommendations to the Board, within seven days.

15. The recommendations referred to in procedure (3) may either be for—

(a). the issuance of a medical laboratory registration certificate; or

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(b). the rejection of the application.

16. Where the Board approves the recommendation of the Inspectors report, it shall issue the registration certificate within seven days of receipt of the Inspectors' final report.

17. Where the Board rejects the application in accordance with procedure15 (b), it shall notify the medical laboratory of the rejection within seven days of receipt of the Inspectors' final report.

18. An applicant whose application has been rejected in accordance with procedure (16b), may appeal to the Board within ninety days for review or re-inspection, as the case maybe, upon payment of the specified fees.

19. The Board may issue an immediate closure notice to a medical laboratory that has not complied with the provisions of the Act, any Regulations or standard set by the board.

The medical laboratory superintendent/in-charge director/manager is responsible for the application, registration, and renewal of practicing certificate for any class of a medical laboratory in public and private sector. All medical laboratory services shall be supervised by persons holding a practicing certificate and an annual license.

CROSS-BORDER TRANSFER OF MEDICAL LABORATORY SPECIMENS

The cross-border transfer of Medical Laboratory specimens involves a complex interplay of ethical principles centered on participant rights, professional accountability, and international justice. These issues primarily arise from the potential for exploitation, loss of local control, and the long-term management of human biological materials.

CORE ETHICAL ISSUES

- **Informed Consent & Autonomy**: Kenyan Participants must be explicitly informed that their samples will be sent abroad. A major ethical gap often exists when consent covers only the initial test but fails to address future storage, international transport, or secondary use. "Broad consent"—where donors agree to general future research—is controversial because participants cannot know the specific risks of future, as-yet-unplanned studies.

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- **Ownership & Control**: Once specimens cross Kenyan borders, local researchers and participants often lose the ability to monitor their use. Ethical concerns arise over who "owns" the sample and whether host countries have continued access to the data or benefits derived from it.
- **Justice & Fairness (Benefit Sharing)**: A significant concern is "helicopter research," where specimens are taken from resource-limited regions of Kenya but the resulting therapies or scientific credit (authorship) primarily benefit developed regions or nations. Justice requires that the benefits of research are shared with the contributing community.
- **Cultural Sensitivities**: Different Kenyan cultures have varying beliefs regarding human tissue, particularly Blood. Transporting Blood samples abroad without respecting local Kenyan cultural norms can lead to community mistrust, rumors of exploitation, or spiritual concerns.
- **Data Protection & Privacy**: Human/Biological samples are inherently linked to sensitive personal data. Cross-border sharing increases the risk of privacy breaches, especially in genetic research where de-identified samples might still be re-identified using public databases.

REGULATORY & SAFETY RESPONSIBILITIES

To mitigate these ethical risks, KMLTTB has instituted several requirements that are mandatory:

- **Material Transfer Agreements (MTAs)**: These legally binding contracts between the sending and receiving institutions must define the purpose of the transfer, duration of storage, and rights to intellectual property or publications.
- **Ethics Review Committees (ERCs)**: Both the providing and receiving countries should have their ethics boards review the transfer to ensure it meets local legal and ethical standards.
- **Capacity Building**: KMLTTB Ethical guidelines **DICTATE** that international partners should help build local Medical laboratory capacity so that testing can eventually be done within the country, reducing the need for export.

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- **Safety Standards**: Ethical conduct includes a duty of care during transit. Shippers must follow KMLTTB and international regulations (e.g., IATA and WHO guidelines) for "Dangerous Goods" to prevent environmental exposure or sample degradation.

Feature	Ethical Implication	Requirement/Mitigation
Storage Duration	Prolonged storage may exceed original consent scope.	Clearly define storage limits in MTAs.
Secondary Use	Unapproved tests violate participant autonomy.	Require new consent or ERC waiver for new research.
Incidental Findings	Unexpected results may cause distress.	Have a plan for communicating clinically relevant findings.
Vulnerable Groups	Risk of exploiting those with limited resources.	Avoid using vulnerable populations unless the research directly benefits them

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THE ROLE OF A MEDICAL LABORATORY DIRECTOR/MANAGER/ SUPERINTENDENT/IN-CHARGE

1. A registered and licensed medical laboratory professional shall only be legible to superintendent over a registered premise if she/he holds a valid practicing license.

2. A medical laboratory professional shall be eligible to superintendent over premises registered by the Board if she/he has worked as a medical laboratory technician, technologist or officer under supervision for a period of not less than 5 years in medical laboratory sciences practice.

3. Any person(s) who wants to apply for registration of premises shall complete the application forms in his own hand writing and provide all the necessary documents as prescribed by the Board.

4. One person shall only be eligible to superintendent over one registered premise.

5. A health institution may apply to operate more than one business premise (medical laboratory branches). However, each medical laboratory branch must apply, be inspected, registered, licensed, and must have a different medical superintendent laboratory.

6. The board shall be notified in writing at least 30 days prior to any changes affecting the following:

   i. Change of ownership-including share distribution, change of directors etc.
   ii. Change of medical laboratory director/manager/ superintendent/in-charge
   iii. Change in registered premises i.e. Location Plot number, building etc.
   iv. Change in nature of business i.e. change of laboratories class.
   v. Any other significant changes

7. All Medical laboratory superintendents shall file returns for their respective medical laboratories that they superintend in the approved form.

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The inspection covers the following areas:

SECTION I: FACILITY PROFILE		
Name of the Facility		
Type (standalone, or integrated)		
KMLTTB Registration number		
County		
Sub-County		
Constituency		
Ward		
Geo-location – latitude and longitude.		
Affiliation (Private, Public, FBO, NGO, others)		
Email address		
Postal Address		
Contact		
KMLTTB Classification (if any)		
Head of Facility		
Name	ID No	Mobile Number
Medical Laboratory Superintendent (persons whose documents was used/is to be used to register the laboratory)		

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Name	ID No	Contact	Email	Reg. No	Renewal status
Date of application					
Date of Inspection					
Purpose of the Visit (Drop Down) Initial Inspection, Re-inspection					
SECTION II: SCORING GUIDE			Score		
If YES			2		
If PARTIAL			1		
If NO or NOT APPLICABLE			0		

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SECTION III: INFRASTRUCTURE, EQUIPMENT, & SUPPLIES	Y	P	N	N/A	Comments
1. Does the medical laboratory have adequate infrastructure? *Separate scoring to be done based on phlebotomy, testing areas, waiting bay, doffing and donning area, refreshment area.* *(Refer to KMLTTB infrastructure guide.)*					
2. Is there a documented contingency plan for stock outs of reagents?					
3. Is there a documented contingency plan for equipment down time?					
4. Is there a documented contingency plan for challenges in staffing?					
5. Is there an inventory management system?					
6. Are the medical laboratory reagents, equipment's and supplies validated by KMLTTB? (*Attach a copy of validation report and certificate)*					
7. Are all medical laboratory reagents and supplies inspected upon receiving before storage?					
8. Does the medical laboratory have designated medical laboratory store for reagents with environmental conditions monitored?					
9. Does the medical laboratory have fridges for separate storage of reagent, blood component and archiving of specimen?					
10. Does Monitoring and recording of freezers and refrigerators temperatures is done twice daily?					

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SECTION IV: SPECIMEN COLLECTION, PACKAGING, TRANSPORTATION AND STORAGE	Y	P	N	N/A	Comments
11. Are medical laboratory specimen collection, packaging, transportation and storage guidelines documented?					
12. Are procedures available to relevant personnel?					
13. Does the medical laboratory have a guideline (SOP) for specimen acceptance and rejection?					
14. Is there a standard specimen request form available for those requesting tests for medical investigations and analysis? (*If yes attach a copy)*					
15. Does the laboratory have appropriate packaging for referring specimens (triple package or any package in conformity with KMLTTB recommendations)? *(check the packaging material)*					
16. Is there a procedure for specimen archiving? *(Attach a copy of the procedure)*					
17. Is the archival procedure available to relevant personnel?					
SECTION V: BIO-SAFETY AND BIO-SECURITY	**Y**	**P**	**N**	**N/A**	**Comments**
18. Has a bio-risk assessment for medical laboratory been conducted? *(Check the report)*					
19. If yes in above; has the of bio-risk assessment findings acted upon?					
20. Does the laboratory have a medical surveillance program?					
21. Has Medical laboratory staff been vaccinated against Hepatitis B?					

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22. Has the Medical Laboratory staff undergone surveillance for TB? *(TB Testing lab)*					
23. Is the Laboratory participating in Disease Surveillance Program?					
24. Does the medical laboratory have an exposure control plan?					
25. Does the medical laboratory have a safety officer with delegated responsibility to oversee compliance with Biosafety requirements?					
26. Does the Medical Laboratory have a written Emergency procedure available to employees?					
27. Is the medical laboratory located away from the general public where there is low human traffic in and around the laboratory?					
28. Is access to the medical laboratory always limited or restricted?					
29. Are Access Control measures in place?					
30. Is there appropriate security measures (24hrs) in place to minimize potential inappropriate removal or release of biological agents? *(e.g. security guards, CCTV etc.)*					
31. Has the medical laboratory experienced any security concern in the past 12 months? *(e.g. theft, break-ins, vandalism etc.)*					
32. Does the medical laboratory have an occurrences book that will allow good documentation and regular review?					
33. Does the Medical Laboratory have Signages? *(e.g. Biohazard, "No gloves on door)*					

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34. Does the Medical laboratory have Hand wash station?					
35. Does the Medical laboratory have Hangers for PPE?					
36. Does the Medical laboratory have Eye wash station?					
37. Does the Medical laboratory have an Emergency shower?					
38. Does the Medical laboratory have Spill Kit?					
39. Are members of staff trained on the use of spill kits mentioned above?					
40. Does the Medical laboratory have Waste bins? *(three colour coded bins with the respective liner)*					
41. Does the Medical laboratory have adequate appropriate PPE? *(e.g. Gloves, N95 masks, Full body suit or lab coats, Face shields/eye googles)*					
42. Does the Medical laboratory have an autoclave?					
43. Does the Medical laboratory have Disinfectants? *(E.g. Ethanol, Bleach etc.)*					
44. Does the Medical laboratory have Lockable freezers and refrigerators?					
45. Does the Medical laboratory have Functional fire extinguisher training on how to use?					
46. Are members of staff trained on the use of the fire extinguishers mentioned above?					
47. Does the Medical laboratory have an Emergency exit?					
48. Does the Medical Laboratory have a fire assembly point?					

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49. Does the medical laboratory have Job Aids available on proper donning and doffing?					
50. Are all medical laboratory wastes decontaminated before disposal? *(E.g. chemical treatment, autoclave etc.)*					
51. Does the medical laboratory have access to a functional incinerator?					
SECTION VI: HUMAN RESOURCE	**Y**	**P**	**N**	**N/A**	**Comments**
52. What is the total number of laboratory staff?					
53. Number of staffs in the medical laboratory dis-aggregated by cadre and with their KMLTTB registration numbers where applicable **(provide a comprehensive list)**					
i. Medical Laboratory Technologists, PhD					
ii. Medical Laboratory Technologists, MSc.					
iii. Medical Laboratory Technologists, BSc.					
iv. Medical Laboratory Technologists, Higher National Diploma					
v. Medical Laboratory Technologists, Diploma					
vi. Medical Laboratory Technicians, Certificate					
vii. Laboratory support staff					
viii. Other- Specify *(e.g. Data clerks)*					
54. Is the Medical Laboratory staff number adequate for the average workload?					

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55. Are the Medical Laboratory staff competent to undertake the required medical laboratory analysis and investigations?					
56. Are the personnel supervised by a qualified medical laboratory staff? *(Give qualification and KMLTTB registration number of the supervisor)*					
SECTION VII: QUALITY ASSURANCE	**Y**	**P**	**N**	**N/A**	**Comments**
57. Is the Medical laboratory ISO 15189:2022 accredited? *(Provide evidence and comment)* *(ISO 15189-2022 implementation is recommended but accreditation is not mandatory for licensing)*					
58. Does the laboratory have a Quality Management System?					
59. Has your Quality Management System (QMS) been reviewed?					
60. Does the medical laboratory have a quality officer with delegated responsibility to oversee compliance with QMS?					
61. Does the Medical laboratory have a validation/verification procedure for new tests?					
62. Does the laboratory implement the above verification procedure?					
63. Does Medical Laboratory conduct lot to lot verification for new testing kits?					
64. Does the medical laboratory adhere to correct labeling procedures for all specimens and testing devices? *(Give comment)*					
65. Are Standard Operating Procedures (SOPs) for the Medical Laboratory analysis and investigations available?					
66. Are all specimens processed in line with the respective SOP?					

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67. 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)*					
68. Does the Medical Laboratory implement Internal Quality Control (IQC)?					
69. Are the IQCs reviewed regularly?					
70. Is there corrective action taken when IQC violations are noted?					
71. Is the medical laboratory enrolled to any EQA scheme? *(PT panels or inter-laboratory comparison)* *(Provide evidence)*					
72. Does the medical laboratory take preventive and corrective action in-case of failed EQA results?					
73. Is there documented procedure for handling and resolving disputed medical laboratory results? ***(does not require scoring but comment)***					
SECTION VIII: DATA MANAGEMENT & COMMUNICATION	**Y**	**P**	**N**	**N/A**	**Comments**
74. Is the data protection policy applied in the Medical Laboratory?					
75. Is there a data management plan for medical laboratory analysis and investigations?					
76. Is there a functional communication system available in the medical laboratory? (e.g. *telephone*, *Email)*					
77. Does the medical laboratory have an efficient data back up in place? *(To prevent loss of patient results in case of theft*, *computer breakdown etc.)*					
78. Does the medical laboratory have capacity to perform basic data analysis to inform outbreak response within the locality?					

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(e.g. monthly reports)					
79. Does the medical laboratory have the mechanism to communicate all notifiable disease to Director General of health through the relevant channels?					
80. Is access to and modification of patient data protected (for paper-based and/or electronic system? ***(does not require scoring but comment)***					

ITEM	AVAILED	NOT AVAILED
Inventory of all medical laboratory Equipment that are in working order. Please attach the list		
Inventory of all medical laboratory reagents that are in working order. Please attach the list		
Inventory of all medical laboratory Equipment that are NOT in working order. Please attach the list		
Inventory of all medical laboratory reagents that are NOT in working order (e.g. expired). Please attach the list		

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<table>
<tr><td colspan="9">SECTION IX: FINDING AND RECOMMENDATIONS</td></tr>
<tr><td colspan="9">FINDINGS</td></tr>
<tr><td colspan="5">AREAS CHECKED</td><td>MINIMUM SCORE (%)</td><td colspan="3">SCORE ACHIEVED</td></tr>
<tr><td colspan="5">1. Infrastructure, Equipment, & Supplies</td><td>75</td><td colspan="3"></td></tr>
<tr><td colspan="5">2. Specimen Collection, Packaging, Transportation and Storage</td><td>75</td><td colspan="3"></td></tr>
<tr><td colspan="5">3. Bio-safety& Bio-security</td><td>75</td><td colspan="3"></td></tr>
<tr><td colspan="5">4. Human Resource</td><td>75</td><td colspan="3"></td></tr>
<tr><td colspan="5">5. Quality Assurance</td><td>75</td><td colspan="3"></td></tr>
<tr><td colspan="5">6. Data Management and Communication</td><td>75</td><td colspan="3"></td></tr>
<tr><td colspan="9">RECOMMENDATIONS</td></tr>
<tr><td rowspan="2">Register Laboratory as Class (Tick where appropriate)</td><td>B</td><td>C</td><td>D</td><td>E</td><td>F</td><td>G</td><td colspan="2" rowspan="2">To comply and register within 60 days</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="9">If the laboratory has an average score of 74% and below, Issue a Compliance Notice. The Medical Laboratory is hereby given 30 working days to fully comply with the standard. If the Medical Laboratory Fails to comply within this given period, issue a Closure Notice. If the Medical Laboratory does not have a Superintendent DO NOT register the Medical Laboratory.</td></tr>
<tr><td rowspan="2">Closed</td><td>Yes</td><td>No</td><td colspan="6" rowspan="2">If yes, attach an Immediate Closure Form</td></tr>
<tr><td></td><td></td></tr>
</table>

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After immediate closure, the Medical Laboratory to comply within an agreed period of time. (To comply within _____ Days)

INSTITUIONS TEAM				
	AUDITOR'S NAME:	KMLTTB REG NO:	SIGNATURE	DATE:
1.				
2.				
3				
4				

INSTITUIONS TEAM				
	NAME:	KMLTTB REG NO:	SIGNATURE	DATE:
1.				
2.				
3				
4				

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