REPUBLIC OF KENYA
MINISTRY OF HEALTH

REPUBLIC OF KENYA
KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
VALIDATION AND VERIFICATION OF INVITRO DIAGNOSTICS MEDICAL LABORATORY INSPECTION CHECKLIST

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

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD *Make Testing a Safe Reality*	VALIDATION AND VERIFICATION OF INVITRO DIAGNOSTICS MEDICAL LABORATORY INSPECTION CHECKLIST	DOCUMENT CONTROL Serial: KMLTTB/VALIDATION/LAB/01 Version 001 Effective Date: 2NDJANUARY,2026

VALIDATION AND VERIFICATION OF INVITRO DIAGNOSTICS MEDICAL LABORATORY INSPECTION CHECKLIST

This checklist has been developed for inspection of medical laboratories for approval to participate in validation and verification of invitro diagnostics in Kenya pursuant to section 40 (g) of Medical Laboratory Technicians and Technologist Act Cap 253A Laws of Kenya. The check list will assess 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).

DEFINITION OF TERMS

For purposes of this document the following terms and definitions shall apply.

Accreditation: procedure by which an authoritative body e.g. KMLTTB gives formal recognition that an organization e.g. medical laboratory is competent to carry out specific tasks against defined standards**.**

Clinical Evaluation: the assessment and analysis of clinical data pertaining to an Medical laboratory Reagents and equipment in order to verify the clinical safety and performance of the Medical laboratory Reagents and Equipment.

Conformity assessment: The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the KMLTTB, to determine that a medical laboratory reagents and equipment device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

Dossier: the documented evidence, normally an output of the quality management system, which demonstrates conformity of medical laboratory reagents and equipment to the Essential Principles of Safety and Performance of Medical laboratory reagents and equipment

Medical laboratory Reagents and Equipment: a reagent, an instrument, apparatus, or system, whether used alone or in combination, intended by the manufacturer (including laboratory developed tests) for *in-vitro* examination of a specimen derived from the human body solely or principally to provide information for diagnosis, screening, monitoring, predisposition, prognosis, prediction, or determination of physiological status.

Local Dealer (LOCAL DISTRIBUTORS): any corporate body registered in Kenya that has received an authorization from the manufacturer with regard to matters pertaining to the sale and registration of the Medical laboratory Reagents and Equipment in Kenya, (the local distributors can be a distributor, importers, or suppliers).

Manufacturer: any person or company with responsibility to design and/or manufacture an Medical laboratory Reagents and equipment with the intention of making the Medical laboratory Reagents and equipment available for use, under his name; whether or not such an Medical laboratory Reagents and equipment is designed and/or manufactured by that person himself or on his behalf by another person(s).

Nnonconformity: nonfulfillment of a requirement.

Quality: Consistent and reliable performance of services or products conforming with specified standards.

Quality Management System (QMS): management system to direct and control an **organization** with regard to quality.

Post Market Surveillance (PMS): the process of monitoring the safety of a device after it has been released to the market; it can further refine, confirm or deny, the safety of a device when it is used in the general population by large numbers of people.

Reciprocal Recognition (RR): the process whereby an *Medical laboratory Reagents and equipment* diagnostic) already in use in the country, bearing the approval of an external Regulatory Authority, is recognized by KMLTTB upon meeting a given criteria

Validation: confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled

Verification: comparison of performance characteristics with package insert or documented specifications.

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The inspection will major on the following areas:

Section I: General Medical Laboratory Information					
Name of the Medical laboratory					
KMLTTB Registration number					
KMLTB CLASSIFICATION					
County					
Sub-County					
Include Geolocation					
Affiliation					
Location (include land mark)					
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 were used to register the medical laboratory)					
Name	ID No	Mobile number	Email	Postal Address	Registration Status
Date of application of the medical Laboratory business premises inspection					
Date of Inspection					

Section II: Supplies, Medical laboratory infrastructure & equipment *Mark boxes with tick (□). Score 4 = Yes, 2=Partial, 0=No and Not Applicable*	Y	P	N	N/A	Comments
1. Availability of a contingency plan in case of stock outs of reagents.					
2. Availability a contingency plan in case of equipment down time.					
3. Availability a contingency plan in case of challenges in staffing.					
4. Availability of plans (1, 2, 3) above documented.					
5. Efficient inventory management system for Consumables. *Describe the system*					
6. Availability of suppliers for medical laboratory reagents, equipment's and other supplies for medical laboratory analysis and investigations.					
7. Availability of medical laboratory reagents, equipment's and other supplies for analysis and investigations validated by KMLTTB. Attach a copy of validation report and certificate.					
8. Availability of medical laboratory reagents, equipment's and other supplies for analysis and investigations inspected upon receiving before storage.					
9. Medical laboratory have a functional inventory management. *If no, give in comments*					
10. Medical laboratory hav prescribed space for testing. Refer to KMLTTB standards					
11. Availability of adequate space designated as a medical laboratory store for reagents with environmental conditions monitored.					

12. Availability of adequate space designated for phlebotomy and other specimen collection					
General cleanliness of the laboratory;					
13. Work areas can easily be cleaned, are clean and well maintained.					
14. Bench tops are impervious to water.					
15. Bench tops are resistant to moderate heat.					
16. Bench tops are impervious to water.					
17. Bench tops are resistant to the organic solvents.					
18. Bench tops are impervious acids.					
19. Bench tops are impervious alkalis.					
20. Bench tops are impervious chemicals.					
21. Members of staff trained on the use of spill kits					
22. Space allocated is adequate to perform the work without compromising quality and safety of personnel.					
23. Medical laboratory have separate fridges and freezers for storage and archiving specimen.					
24. Medical laboratory have a designated area for specimen collection.					
25. Medical laboratory have adequate space for the following functions.					
a) Specimen reception					
b) Testing					
c) Data analysis					
d) Medical laboratory Directors/Superintendent/ Manager's office.					
e) Staff Clean area.					
26. Designated areas or sections clearly labelled.					
27. Medical laboratory is well ventilated.					

28. Monitoring and recording of freezers and refrigerators temperatures is done twice daily.					
Section III: Specimen Collection, Packaging, Transportation and Storage ***Mark boxes with tick (✓). Score 4 = Yes, 2=Partial, 0=No and Not Applicable***	**Y**	**P**	**N**	**N/A**	**Comments**
29. Medical laboratory specimen collection, packaging, transportation and storage guidelines/procedures documented and available to relevant personnel.					
30. Medical laboratory have a guideline (SOP) for specimen acceptance and rejection.					
31. Medical laboratory have specimen collection guideline.					
32. Standard specimen request form available for those requesting tests for medical investigations and analysis. *If yes attach a copy*					
33. Medical laboratory have appropriate packaging for referring specimens (triple package or any package in conformity with KMLTTB recommendations). (check the packaging material)					
34. Availability of a procedure for specimen archiving. (Attach a copy of the procedure).					
35. Procedure for how medical laboratory specimens are transported from the medical laboratory to reference medical laboratory for purposes of confirmatory testing					
Section IV: Biosafety and Biosecurity ***Mark boxes with tick (✓). Score 4 = Yes, 2=Partial, 0=No and Not Applicable***	**Y**	**P**	**N**	**N/A**	**Comments**
36. Has a bio-risk assessment for medical laboratory analysis and investigations been conducted and findings acted upon. (Check the report)					

37. Medical laboratory handle other potentially highly infectious agents. (In the comment section give examples) **(does not require scoring but comments is a MUST)**					
38. Medical laboratory have a medical surveillance program. (Describe the program)					
39. Medical laboratory have an exposure control plan and written emergency procedures readily available to employees. (Check for the following minimums in 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) Give in summary the finding at the comment section.					
40. Medical laboratory located is away from the general public where there is low human traffic in and around the laboratory.					
41. Access to the medical laboratory always limited or restricted.					
42. Access control measures in place (Door locks, secured windows, biometric device, CCTV, "unauthorized entry prohibited" note) List the measures in place in the comment section.					
43. Appropriate security measures (24hrs) are in place to minimize potential inappropriate removal or release of biological agents. (e.g. security guards, CCTV)					
44. Medical laboratory experience on any security concern in the past 12 months. e.g. theft, break-ins, vandalism					
45. Does the medical laboratory have an occurrences book that will allow good documentation and regular review.					

46. Medical laboratory have the following biosafety & biosecurity measures in place.					
i. Signage (Biohazard, no gloves on door)					
ii. Hand wash station					
iii. Hangers for PPE					
iv. Eye wash station					
v. Waste bins (three colour coded bins with the respective liner)					
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. Fire assembly point.					
47. Medical laboratory have job aids available on proper donning and doffing of all PPEs recommended for medical laboratory analysis and investigations. (Observe proper use of PPE by laboratory staffs)					
48. Medical laboratory waste from the properly segregated and decontaminated before disposal. (Indicate how; chemical treatment, autoclaving etc.)					
49. Medical laboratory dispose of sharps. (Describe the process e.g. incineration, burn pit, burying etc.)					

50. Medical laboratory disposal of solid biohazardous waste. (Describe the process e.g. incineration, burn pit, burying etc.)					
51. Medical laboratory disposal of liquid biohazardous waste. (Describe the process e.g. incineration, burying, chemical treatment, drain disposal etc.)					
52. Medical laboratory disposal of non-biohazardous waste. (Describe the process incineration, burn pit, burying etc.)					
53. Medical laboratory access to a functional incinerator. (Give comments)					
Section V: Human Resource ***Mark boxes with tick (☐). Score 4 = Yes, 2=Partial, 0=No and Not Applicable***				**No.**	**Comments**
54. Medical laboratory staff disaggregated by cadre and with their KMLTTB registration numbers. **(provide a comprehensive list)**					
i. Medical Laboratory Technologists (Diploma, Higher Diploma, *BSc*)					
ii. Medical Laboratory Technicians (Certificate)					
iii. Laboratory support staff					
iv. Other- Specify (e.g. Data clerks)					
55. Adequacy and competency of staff to undertake the required medical laboratory analysis and investigations work.					
56. Number of staff deemed adequate to run medical laboratory analysis and investigations in this facility. **(based on workload and operational hour, give comments)**					
57. Personnel supervised by a qualified medical laboratory staff. (Give qualification and KMLTTB registration number of the supervisor)					
Section VI: Quality Assurance ***Mark boxes with tick (☐). Score 4 = Yes, 2=Partial, 0=No and Not Applicable***	**Y**	**P**	**N**	**N/A**	**Comments**

58. ISO 15189:2022 accreditation. (evidential)					
59. Challenges experienced with the test kits used in medical laboratory analysis and investigations. (During Method validation)					
60. Type of specimens the medical laboratory collect for analysis and investigations.					
61. Type of specimens the medical laboratory receive / intend to receive from other medical laboratories.					
62. Medical laboratory current or projected workload.					
63. Medical laboratory quality manual.					
64. Target population for the medical laboratory.					
65. Quality manual reviewed regularly. How often.					
66. Medical laboratory have or intend to have a quality officer/safety officer with delegated responsibility to oversee compliance with QMS.					
67. Medical laboratory have implemented procedures for validation and verification of new tests, new consumables lots for testing kits. (Provide evidence and comment)					
68. Medical laboratory adheres to correct labelling procedures for all specimens and testing devices.					
69. 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)					
70. Specimens processed in line with the SOP, documented and corrective actions taken in case of failure.					
71. 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)					
72. Medical laboratory implement Internal Quality Control (IQC) Measures.					
73. IQCs reviewed regularly.					
74. Medical laboratory enrolled to EQA scheme (PT panels or inter-laboratory comparison).					
75. Results of analysis and investigations for proficiency test for the past EQA participation or interlab comparison.					
76. Medical laboratory take preventive and corrective action in-case of failed results.					
77. Medical laboratory resolve analysis and investigations disputed results.					
Section VII: Data Management & Communication ***Mark boxes with tick (✓). Score 4 = Yes, 2=Partial, 0=No and Not Applicable***	**Y**	**P**	**N**	**N/A**	**Comments**
78. Availability of data management plan for medical laboratory analysis and investigations.					
79. Medical laboratory analysis and investigation results being sent to clinicians within the health facility via a LIMS.					
80. Functional communication equipment available in the medical laboratory. e.g. *telephone*, *Email*,					
81. Medical laboratory have an efficient data back up in place to prevent loss of patient results in case of theft, computer breakdown *etc*.					
82. Medical laboratory have capacity to perform basic data analysis to inform outbreak response within the locality.					
83. Medical laboratory have the mechanism to communicate all notifiable disease to Director General of health through the relevant channels.					

84. What is the average turnaround time for medical laboratory analysis and investigations results from collection to return of results **(does not require scoring but comment)**					
85. Access to and modification of patient data protected (for paper-based and/or electronic system.					

Criteria for selection of medical laboratory to perform validation and verification of reagents and equipment.

KMLTTB shall conduct an evaluation of each prospective validation laboratory prior to any engagement between the laboratory and KMLTTB.

The criteria for selection of validating laboratories can include but is not limited to:

- The laboratory must be registered and licensed and certified for the test under evaluation
- Availability of suitably trained, registered and licensed adequate and competent personnel
- The test under evaluation should be routinely performed at the evaluating laboratory.
- Adequate ,relevant and functional laboratory facilities for conducting the evaluation

- Ability to obtain, prepare and characterize specimens.
- Capacity to store specimens in appropriate conditions.
- Capacity and ability to ensure safety and security of specimens and Medical laboratory Reagents and equipment.
- The laboratory must have an established, and demonstrate compliance to, an accepted Quality Management System.
- Availability of appropriate Standard Operating Procedures (SOPs). Ability and willingness to comply with the given SOPs
- Sufficient data-handling capacity (for example, staff and computers) and Able to perform data analysis (on site, if possible).
- No medical laboratory in Kenya shall conduct any validation or verification excise for any medical laboratory of use in the country unless such a laboratory for a registered under this act and specifically authorized by the Board to conduct the specific validation or verification.
- A medical laboratory that contravene this requirement shall be guilty of an offence of contradiction of medical laboratory code of ethics and shall be barred from operating as a medical laboratory
- A medical laboratory professionals involved in an authorized validation or verification of medical laboratory reagents, equipment's or shall be referred to the disciplinary committee of the Board to answer to charges of contradiction of medical laboratory code of ethics and the applicable oath for medical laboratory professionals pursuant to section 26 of MLTT Act and technologies act, CAP 253 A laws of Kenya.
- Medical laboratory professionals referred to the disciplinary committee for conducting illegal validation and verification of medical laboratory reagents, equipment or chemicals shall be disciplined in accordance with the provisions of section 26 and 39 of the medical laboratory technicians and Technologies Act.

- Medical laboratory facilities used for unethical validation and verification of medical laboratory reagents equipment's and reagents also known as Invitro diagnostics (IVDs) shall be removed from the register of deceased medical laboratories until such a time a committee of the board specifically constituted to investigate the laboratory and give it a clean bill of health and payment of any charged applicable as if the laboratory was the vender of the reagent equipment of chemical under investigation.

Confidentiality Requirements;

The laboratory management and personnel involved in verification/ validation activities shall be independent of both the manufacturers and Local Dealers for Medical laboratory Reagents and equipment under study.

Following appointment, the validating laboratories will be monitored at intervals determined by KMLTTB. Reserves the right to withdraw services of a validation agency if the agency fails to maintain and comply with set standards.

The Validation agencies shall have made adequate arrangements to ensure confidentiality of the information obtained in the course of carrying out a Verification/ validation study. This shall ensure no details, records, results or any other information is disclosed to any party except KMLTTB and the manufacturer.

The validation agency must demonstrate impartiality in the assigned validation activities.

SECTION Viii		
FINDINGS		
AREAS CHECKED	**SCORE ACHIEVED**	**MINIMUM SCORE (%)**
1. Supplies, Medical laboratory infrastructure & Equipment	___	**100**
2. Specimen Collection, Packaging, Transportation and Storage	___	**100**
3. Biosafety& Biosecurity	___	**100**
4. Human Resource	___	**75**
5. Quality Assurance	___	**100**
6. Data Management and Communication	___	**75**
RECOMMENDATIONS		
Register Laboratory as class _____		
Closed _____		
To comply in _____ days		
Register with mentorship and follow-up		

LABORATORY AUDITORS' DETAILS	
AUDITOR'S NAME:	KMLTTB REG NO:
SIGNATURE OF AUDITOR:	DATE:
CO-AUDITOR'S NAME:	KMLTTB REG NO:
SIGNATURE OF CO-AUDITOR:	DATE:
CO-AUDITOR'S NAME:	KMLTTB REG NO:
SIGNATURE OF CO-AUDITOR:	DATE:
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CO-AUDITOR'S NAME:	KMLTTB REG NO:
SIGNATURE OF CO-AUDITOR:	DATE:

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