REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS & TECHNOLOGIST BOARD
Make Testing a Safe Reality

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

MEDICAL LABORATORY FACILITY QUARTERLY RETURNS/SUMMARY REPORTS REQUIREMENTS POLICY

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

KMLTTB QUALITY ASSURANCE SERVICES.

	MEDICAL LABORATORY FACILITY QUARTERLY RETURNS/SUMMARY REPORTS REQUIREMENTS POLICY	DOCUMENT CONTROL Serial: KMLTTB/MLRETURNS/01 Version 001 Date: 6TH MAY, 2026
	OWNERSHIP	REGISTRAR

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KMLTT/MLRETURNS//01

INTRODUCTION

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a statutory corporate body mandated to exercise general supervision and control over the training, practice, business and employment of medical Laboratory technicians and technologists under Cap 253A Laws of Kenya. The Board also advises the Government in relations to all aspects thereof including validation of in-vitro diagnostics through Legal Notice NO.113 of 2011.

The implementation of this policy will contribute to achievement of the right to the highest attainable standard of healthcare as outlined in the Constitution of Kenya 2010 as well as achievement of Vision 2030.

Registered and licensed Medical laboratories through their respective Superintendents/Managers/ In-charges/ Directors are required to submit quarterly returns (also known as quarterly summary reports) to KMLTTB to ensure compliance with quality standards, patient safety protocols, and operational efficiency based on International Standards (ISO 15189) and National Regulatory Body, KMLTTB.

KMLTTB requires this to be submitted via a centralized email platform or form; KMLTTB/MLRETURNS/01B

Verifiable indicators required include;

1. Quality Control and Proficiency Testing Data.
    a) Internal Quality Control (IQC) Performance: Summary of daily IQC runs, indicating percentage within Westgard limits, (Target: 95% in-control)
    b) External Quality Assessment (EQA/PT): Reports on participation in proficiency testing, including scores and corrective actions taken on tests results.

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c) Method Validation/Verification: Documentation of any new tests or equipment validated during the period.

d) Calibration Records: Evidence of equipment calibration/re-calibration.

2. Key Performance Indicators (KPIs) and Technical Data.

a) Turnaround Time (TAT) Tracking: Average TAT for key tests.

b) Sample Rejection Rates: Total percentage of samples rejected.

c) Critical Value Reporting Time: Time taken to notify physicians of critical results.

d) Test Volume/Workload: Total number of tests performed in each department.

3. Personnel and Operational Compliance

a) Staff Competency Records: Documentation of continuous training particularly on new procedures or equipment.

b) Staffing levels: Data of registered medical laboratory personnel currently working.

4. Equipment and Inventory Management

a) Equipment Down Time: Total downtime for major analyzers to monitor maintenance and performance.

b) Contingency Plans: Documentation of contingency plans for stock-outs, equipment failure, or staffing shortages.

c) Inventory Control: Records of reagent inspection upon receipt, storage conditions, and expiry monitoring.

5. Documentation and Quality Management System (QMS)

a) Internal Audits: Evidence of regular internal audits conducted, identifying nonconformities.

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b) Corrective and Preventive Actions (CAPA): Records of all incidents and actions taken to prevent recurrence.

c) Notifiable Diseases Reporting: Timely reporting rate of confirmed notifiable diseases to health authorities.

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