



REPUBLIC OF KENYA  
MINISTRY OF HEALTH




**KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD**

**MEDICAL LABORATORY QUARTERLY RETURNS / QUARTERLY SUMMARY REPORTS**

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

**KMLTTB QUALITY ASSURANCE SERVICES.**

|   |   |   |
|---|---|---|
|  | <b>MEDICAL LABORATORY QUARTERLY RETURNS / QUARTERLY SUMMARY REPORTS</b> | <b>DOCUMENT CONTROL</b><br>Serial: KMLTT/MLRETURNS/01B<br>Version 001<br>Date: 15 <sup>TH</sup> , MAY, 2026 |
|   | <b>OWNER</b>  | <b>REGISTRAR</b>  |



## INTRODUCTION

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a statutory corporate body mandated by Law 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 invitro diagnostics through Legal Notice NO.113 of 2011.

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

Registered and licensed Medical laboratories 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 are complied with. KMLTTB requires these to be submitted to the centralized email platform or by use of this form covering:-

|  |                  |                               |
|--|------------------|-------------------------------|
| <b>Name of medical laboratory facility</b>                 |                  |                               |
| <b>Date</b>  |                  |                               |
| <b>Director (s)</b>  |                  |                               |
| <b>NAME</b>  | <b>ID/PP No.</b> | <b>Occupation /Profession</b> |
|  |                  |                               |
|  |                  |                               |
|  |                  |                               |
| <b>Physical address of the medical laboratory facility</b> |                  |                               |
| <b>P.O. Box</b>  |                  |                               |
| <b>Postal Code</b>   |                  |                               |
| <b>LR No</b>   |                  |                               |
| <b>Cell Phone No</b>                                       |                  |                               |
| <b>County</b>  |                  |                               |
| <b>Sub-county</b>  |                  |                               |
| <b>Constituency</b>  |                  |                               |
| <b>Administrative Ward</b>                                 |                  |                               |
| <b>Longitude and Latitude (GPS)</b>                        |                  |                               |
| <b>Integrated or stand-alone?*</b>                         |                  |                               |
| <b>Working Hours (12 or 24 Hours).</b>                     |                  |                               |



|   |  |
|---|--|
| Year of establishment   |  |
| <b>Medical Laboratory Superintendent</b>                              |  |
| Full Name:  |  |
| National ID/ Passport:  |  |
| KMLTTB Registration No.   |  |
| Year of registration  |  |
| CPD Point Score   |  |
| Has valid Practicing License?   |  |
| Highest Professional qualification:                                   |  |
| Practices Medical Laboratory Sciences in the same facility, (Yes/No)? |  |

**NB\***

Integrated Medical laboratory is one located within a health institution that offers other medical health services. Stand-alone means an independent medical laboratory facility.

| <b>Table 1: Quality control and proficiency testing data</b>   |                 |
|--|-----------------|
| <b>Internal Quality Control (IQC) Performance</b>  | <b>Comments</b> |
| Summary of daily IQC runs, indicating percentage within Westgard limits (Target: 95 % in-control)        |                 |
| <b>External Quality Assessment (EQA/PT):</b>   |                 |
| Reports on participation in proficiency testing<br>Scores and corrective actions taken for tests failed. |                 |
| <b>Method Validation/Verification:</b>   |                 |
| Documentation of any new tests or equipment validated during the quarter                                 |                 |
| <b>Calibration Records:</b>  |                 |
| Evidence of equipment re-calibration, particularly for critical analytical instruments.                  |                 |



**Table 2: Monthly workload summary**

| S/No. | Discipline             | Number of patients | Number of tests |
|-------|------------------------|--------------------|-----------------|
| 1.    | Bacteriology           |                    |                 |
| 2.    | Virology               |                    |                 |
| 3.    | Immunology             |                    |                 |
| 4.    | Clinical Chemistry     |                    |                 |
| 5.    | Haematology            |                    |                 |
| 6.    | Blood Transfusion Unit |                    |                 |
| 7.    | Histopathology         |                    |                 |
| 8.    | Cytology               |                    |                 |
| 9.    | Parasitology           |                    |                 |
| 10.   | Molecular Tests        |                    |                 |
| 11.   | Point-of-Care Tests    |                    |                 |

| <b>1.0 Key performance indicators (KPIs) and technical data</b> |  |              |
|---|--|--------------|
| 1.1   | <b>Turnaround Time (TAT) Tracking:</b>                                   | <b>Score</b> |
|   | Average TAT for key tests  |              |
|   | Average percentage of samples rejected                                   |              |
|   | Three most common causes of rejections                                   |              |
| 1.2   | <b>Critical Value Reporting Time</b>                                     |              |
|   | Time taken to notify physicians of critical results (Target: (15) mins). |              |

| <b>2.0 Personnel and operational compliance</b> |   |                |
|---|---|----------------|
| 2.1   | <b>Staff Competency Records</b>   | <b>Yes/No.</b> |
|   | Documentation of continuous training, particularly for new procedures or equipment.               |                |
| 2.2   | <b>Staffing Levels</b>  |                |
|   | Data on the number of registered medical laboratory personnel currently working.                  |                |
| 2.3   | <b>Laboratory Safety Incidents:</b>   |                |
|   | Records of laboratory-acquired infections, needle-stick injuries and/or safety breaches recorded. |                |



| <b>3.0 Equipment and inventory management</b> |   |                              |
|---|---|------------------------------|
| 3.1   | <b>Equipment Down Time</b>                      | <b>Score/Comments/Yes/No</b> |
|   | Total downtime (in months) for major analyzers. |                              |
| 3.2   | <b>Contingency Plans</b>                        |                              |
|   | Contingency plans for stock-outs documented.    |                              |
|   | Equipment failure<br>Staffing shortages         |                              |
| 3.3   | <b>Inventory Control</b>                        |                              |
|   | Records of reagent inspection upon receipt      |                              |
|   | Storage conditions<br>Expiry monitoring         |                              |

#### **4.0 Documentation and quality management system (QMS)**

|     |   |  |
|-----|---|--|
| 4.1 | <b>Internal Audits</b>  |  |
|     | Evidence of regular internal audits conducted.                              |  |
| 4.2 | <b>Corrective and Preventive Actions (CAPA)</b>                             |  |
|     | Records of all incidents and actions taken to prevent recurrence available. |  |
| 4.3 | <b>Notifiable Diseases Reporting</b>  |  |
|     | Timely reporting of notifiable diseases to health authorities               |  |

#### **5.0 Challenges and Improvements**

|     |  |                 |
|-----|--|-----------------|
| 5.1 | <b>Possible Challenges</b>             | <b>Comments</b> |
|     | Regulatory and Quality Compliance      |                 |
|     | Human Resource Shortages               |                 |
|     | Supply Chain and Inventory Constraints |                 |
|     | Equipment Maintenance and Obsolescence |                 |
|     | Data Management and Integration        |                 |
|     | Pre-Analytical Errors                  |                 |

#### **6.0 Detailed improvements for laboratory operations**

|     |   |  |
|-----|---|--|
| 6.1 | Deploy LIMS and Automation              |  |
|     | Adopt Quality Management Systems (QMS). |  |
|     | Continue Workforce Development          |  |
|     | Implement Lean Management methodologies |  |
|     | Proactive inventory management          |  |
|     | Biomedical Engineering partnerships     |  |

.....THE END.....

