



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB NATIONAL REGULATORY STANDARD FOR ALL MEDICAL LABORATORY OPERATIONS

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

QUALITY ASSURANCE SERVICES

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INTRODUCTION

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Based on WHO IHR (2005) and CLSI Guidelines

KMLTTB was established in the year 2000 through an Act of Parliament CAP 253A of the Laws of Kenya. In accordance with this Act, the KMLTTB is mandated to provide general supervision and control over the training, business, employment and practice of medical laboratory profession; It advises the government on all matters thereof. This mandate means that the Board provides guidelines and standards to offer services in MLS.

The main goal of the MLS services is to ensure provision of safe, professional, competent and ethical Medical Laboratory Services in accordance to Cap 253A of the Laws of Kenya.

This official regulatory document establishes the definitive operational, quality, and biosafety protocols for all medical laboratories operating within the Republic of Kenya. This standard seamlessly integrates the World Health Organization International Health Regulations (IHR 2005) and the Clinical and Laboratory Standards Institute (CLSI) Quality Management System core requirements to ensure uniform diagnostic accuracy, safe execution, and robust public health protection.

Our Vision

“That the Health of every Kenyan will be fully protected through effective regulation of the practice of laboratory medicine.”

Our Mission

“To Exercise General Control and Supervision over training, business, employment and practice of Laboratory Medicine and Advise the Government on all related matters.”

Our Core Values

Integrity; Selfless service; Innovation and open-mindedness; Sense of belonging; Pride in what we do.

The Medical Laboratory Science Profession

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) has established that Medical Laboratory sciences is a profession: as an autonomous profession; characterized by its own Body of Knowledge and Scope of Practice, which certifies its own



practitioners; and requires of its practitioner's competency in scientific, technical, managerial and scholarly principles, and high standards of performance and professional conduct.

KMLTTB defines the profession of Medical Laboratory Sciences as encompassing the design, performance, evaluation, reporting, interpreting, and clinical correlation of medical Laboratory testing, and the management of all aspects of these services. Medical laboratory tests are utilized for the purpose of diagnosis, treatment, monitoring and prevention of disease.

Section 1: Legal and Regulatory Framework

1.1 Statutory Authority

This regulatory document is issued under the explicit statutory mandate of the **Kenya Medical Laboratory Technicians and Technologists Act (Cap 253)** of the Laws of Kenya. All medical laboratory facilities operating within the territories of the Republic of Kenya—including public, private, faith-based/NGO, and research institutions—must comply fully with every provision set forth in this standard.

1.2 International Alignment

- **CLSI Quality Management System (QMS) Framework:** Adopts the 12 Quality System Essentials (QSE) as the mandatory national benchmark for structuring, running, and assessing clinical laboratory quality workflows.
- **WHO International Health Regulations (IHR 2005):** Standardizes the core laboratory capacities required at every tier of the health system for early detection, rapid verification, and timely notification of biological threats and international public health risks.

Section 2: The 12 CLSI Quality System Essentials (QSE)

2.1 Organization and Leadership

Every medical laboratory must maintain a legally defined organizational chart displaying clear lines of authority. A designated Laboratory Director, Manager, or Head holds ultimate institutional accountability for quality assurance, safety compliance, and regulatory adherence.



2.2 Facilities and Safety

- **Spatial Separation:** Laboratories must feature absolute physical and spatial separation between administrative areas, pre-examination (sampling/reception), examination (testing benches), and post-examination spaces.
- **Environmental Monitoring:** Controlled environmental parameters, including ambient temperature, humidity, and airflow directions, must be monitored daily and documented in log sheets to preserve reagent integrity and prevent cross-contamination.
- **Access Control:** Facilities must enforce restricted access protocols via physical locks, biometric tokens, or guarded barriers to safeguard testing zones from unauthorized personnel.

2.3 Personnel

- **KMLTTB Licensing:** All practicing laboratory technologists and technicians must possess a valid, active annual practicing license issued directly by KMLTTB. Practicing with an expired license or employing unlicensed staff is strictly illegal.
- **Personnel Files:** Laboratories must maintain updated personnel files containing verified copies of academic certificates, KMLTTB registration details, specialized training logs, and comprehensive job descriptions.
- **Competency Assessments:** Personnel must undergo documented bi-annual competency assessments for every diagnostic assay or analytical platform they are authorized to operate.

2.4 Equipment

- **Validation and Verification:** All analytical platforms, instrumentation, and backup equipment must undergo formal validation and verification protocols prior to clinical sample processing.
- **Preventative Maintenance:** Facilities must establish a rigorous preventative maintenance schedule for every instrument, managed either internally by certified biomedical engineers or externally via service-level agreements.
- **Calibration Traceability:** Equipment calibration must be strictly traceable to international metrology standards, with all physical calibration certificates and data charts retained securely for the lifetime of the instrument.



2.5 Purchasing and Inventory

- **Vendor Qualification:** Reagents, consumables, and test kits must be sourced exclusively from KMLTTB-approved, qualified vendors who provide complete certificates of analysis.
- **Inventory Log:** An active inventory control log must track batch lot numbers, dates of receipt, current shelf-life/expiration dates, and storage conditions for every item.
- **Parallel Testing:** Parallel testing of newly arrived reagent lots against current valid lots must be executed and explicitly documented prior to running clinical diagnostic samples.

2.6 Process Management

- Pre-Examination:** Standard Operating Procedures (SOPs) must meticulously govern patient identification, specimen collection, tube labeling, preservation, and cold-chain transport. Sample rejection criteria for hemolyzed, cross-contaminated, or mislabeled samples must be strictly enforced without exception.
- Examination:** Validated analytical procedures must be followed precisely as documented in approved SOPs. Laboratories must execute and document Internal Quality Control (IQC) at specified, regular intervals during every single operational shift.
- Post-Examination:** Analytical data and test reports must go through a documented multi-tier verification process (technologist review followed by a laboratory supervisor sign-off) prior to official authorization and clinical release.

2.7 Documents and Records

A centralized master document control index must govern all active policies, operational guidelines, and standard testing procedures. Archived clinical patient records, raw instrument data logs, and historic quality control charts must be securely preserved for a minimum of **20 years** to enable long-term public health tracking, retrospective research, and legal audits.

2.8 Information Management

Whether using automated Laboratory Information Systems (LIS) or manual paper registries, data systems must incorporate role-based access privileges to strictly safeguard patient data confidentiality. Electronic database backups must be executed daily and stored in secure, off-site secondary locations.



2.9 NONCONFORMING EVENT MANAGEMENT

Medical Laboratories must maintain a centralized, unalterable log to record all diagnostic errors, accidents, bio-safety breaches, and procedural deviations. Every single nonconforming event requires an immediate, documented root-cause analysis followed by the application of Corrective and Preventive Actions (CAPA).

A. 2.10 ASSESSMENTS (INTERNAL AND EXTERNAL)

- B. **Internal Audits:** Comprehensive internal audits covering all 12 QSE domains must be conducted at least annually by trained internal audit teams.
- C. **External Quality Assessment (EQA):** Medical Laboratories must enroll in KMLTTB-certified External Quality Assessment / Proficiency Testing (PT) schemes for all diagnostic parameters. Any EQA failure triggers a mandatory, documented corrective action workflow within 7 days of receiving results.

2.11 CONTINUAL IMPROVEMENT

Medical Laboratories must consistently monitor specific Quality Indicators (QIs), including turnaround time (TAT) compliance rates, sample rejection trends, and clinician feedback scores. These indicators must be thoroughly evaluated during quarterly management review meetings to drive operational refinements.

2.12 CUSTOMER SERVICE

Functional administrative processes must be in place to formally capture, track, investigate, and resolve feedback and service complaints received from clinicians, public health organizations, and patients.

SECTION 3: DISEASE-SPECIFIC DIAGNOSTIC AND MONITORING MATRICES

3.1 HIV/AIDS CLINICAL PATHWAY

- A. **Diagnosis:** Execution of the national HIV testing algorithm utilizing rapid diagnostic test (RDT) kits officially validated and batch-approved by KMLTTB. Reactive initial screens must be confirmed using the mandated secondary independent assay.
- B. **Monitoring:** Plasma Viral Load (VL) testing using quantitative real-time RT-PCR must be conducted exactly 6 months post-ART initiation and annually thereafter for stable patients.
- C. **Therapeutic Threshold:** Viral load counts exceeding 1,000 copies/mL indicate potential treatment failure, triggering immediate intensive adherence counseling (IAC) and reflex resistance testing evaluation.



3.2 TUBERCULOSIS (TB) OPERATIONAL PROTOCOL

- A. **Molecular Testing:** Automated real-time PCR (e.g., GeneXpert) stands as the mandatory primary diagnostic modality for all suspected pulmonary tuberculosis cases across all diagnostic tiers.
- B. **Supportive Diagnostics:** Digital chest radiography and LED fluorescence sputum smear microscopy serve as secondary supportive pillars for diagnosis and tracking.
- C. **Resistance Reflex:** The Medical laboratory identification of Rifampicin-resistant TB strains must automatically trigger immediate reflex testing for second-line drug resistance via Line Probe Assays (LPA) or Next-Generation Sequencing (NGS).

3.3 MALARIA AND HEMOPARASITES

- A. **Gold Standard:** High-quality Giemsa-stained thick and thin blood film microscopy remains the mandatory diagnostic benchmark for definitive malaria parasite speciation and accurate density quantification.
- B. **Point-of-Care:** Rapid Diagnostic Test (RDT) cassettes targeting HRP2 and pLDH antigens are approved exclusively for peripheral level-2 facilities lacking functional microscopy infrastructures.

3.4 ANTIMICROBIAL RESISTANCE (AMR) SURVEILLANCE

- A. **Testing Standards:** Antimicrobial Susceptibility Testing (AST) must be strictly performed using standardized Kirby-Bauer disk diffusion or automated Minimum Inhibitory Concentration (MIC) methods fully aligned with current, annual CLSI M100 performance documents.
- B. **Critical Alerts:** Confirmed isolates of high-consequence multi-drug resistant organisms, such as Carbapenem-Resistant Enterobacteriaceae (CRE), Vancomycin-Resistant Enterococci (VRE), and Methicillin-Resistant Staphylococcus aureus (MRSA), must be tracked and immediately communicated to the local infection control committee.

3.5 NON-COMMUNICABLE DISEASES (NCDs)

- A. **Diabetes Mellitus:** Glycated Hemoglobin (HbA1c) testing must be performed using platforms certified by the National Glycohemoglobin Standardization Program (NGSP) and traceable to the DCCT reference method.
- B. **Cardiovascular and Renal Markers:** Standardized enzymatic and colorimetric assays must be utilized to process Lipid Profiles and Serum Creatinine. Estimated Glomerular Filtration Rate (eGFR) values must be automatically calculated using the CKD-EPI formula and appended to all renal Clinical chemistry reports.



SECTION 4: IHR (2005) DISEASE SURVEILLANCE AND PUBLIC HEALTH EMERGENCIES

4.1 NOTIFIABLE PATHOGENS

Medical Laboratories must maintain active detection and safe-handling capabilities for Public Health Emergencies of International Concern (PHEIC) and high-consequence pathogens, explicitly including:

- A. **Viral Haemorrhagic Fevers:** Ebola, Marburg, Lassa, Crimean-Congo, and Rift Valley Fever viruses.
- B. **Arboviruses:** Yellow Fever, Dengue, and Chikungunya.
- C. **Respiratory Pathogens:** Pandemic Influenza strains and Novel Coronaviruses (including SARS-CoV-2 variations).
- D. **Enteric Pathogens:** *Vibrio cholerae* and causative agents of Acute Hemorrhagic Diarrhea Syndrome.
- E. **Zoonotics:** Lyssaviruses (Human Rabies) and *Bacillus anthracis*.

4.2 EARLY-WARNING NOTIFICATION TIMELINES

The identification of any suspected or confirmed case of a highly infectious or regulated high-consequence pathogen triggers an immediate alert phase. A formal verbal and secure electronic notification must be completed within **30 minutes** of initial Medical laboratory detection.

Alert files must be routed simultaneously through the following official pathways:

- A. **Ministry of Health:** Division of Disease Surveillance and Response (DDSR).
- B. **County Government:** Office of the County Director of Health and County Epidemiologist.
- C. **Regulatory Authority:** KMLTTB Executive Secretariat (Registrar).

SECTION 5: BIOSAFETY, BIOSECURITY, AND WASTE MANAGEMENT

5.1 SAMPLE LOGISTICS AND TRANSPORT

- A. **Triple Packaging System:** Specimens suspected of containing Category A infectious substances must be packaged using the certified Triple Packaging System (complying strictly with UN 2814 specifications).
- B. **Documentation:** Fully completed Medical laboratory requisition profiles and clinical epidemiological summaries must be sealed inside a separate, waterproof external compartment away from the sample tubes.



- C. **Cold-Chain Integrity:** Logistics networks must incorporate continuous temperature tracking devices to maintain strict cold-chain parameters specified for target pathogens.

5.2 MEDICAL LABORATORY CONTAINMENT TIERS

- A. **Level 2 and 3 Facilities: Class B, C and D Medical Laboratories** are restricted to processing low-risk, routine diagnostics. Class II Biosafety Cabinets (BSC) must be used for any manual aerosol-generating procedures.
- B. **Level 5 and 6 Facilities: Class E and F;** Mandatory for viral cultures, high-consequence molecular processing, and pathogen isolation. These national reference zones require continuous negative air pressure gradients, dual-stage HEPA air filtration systems, and airlock access doors.

5.3 BIO-WASTE ELIMINATION PROTOCOLS

- A. **Liquid Decontamination:** All liquid bio-hazardous effluents and serum specimens must undergo complete chemical decontamination using a freshly prepared 0.5% Sodium Hypochlorite solution with an absolute minimum contact duration of 30 minutes before drainage disposal.
- B. **Solid Segregation:** Solid infectious clinical waste must be strictly segregated at the point of origin into heavy-duty, puncture-resistant, color-coded biohazard bags.
- C. **Autoclaving and Incineration:** All solid Medical laboratory bio-waste must undergo a validated dual-stage autoclaving cycle (121°C at 15 psi for a minimum of 30 minutes) to achieve biological sterilization prior to final, high-temperature thermal destruction in an approved incinerator.

SECTION 6: STATUTORY ENFORCEMENT, INSPECTIONS, AND PENALTIES

6.1 REGULATORY INSPECTIONS

Duly commissioned KMLTTB inspectors possess full statutory authority under Cap 253A to enter any medical laboratory facility across the country at any time, without prior notification, to execute comprehensive operational audits. Establishments are legally required to grant inspectors unrestricted access to quality records, licensure databases, reagent stores, and equipment files.



6.2 PENALTIES FOR NON-COMPLIANCE

- A. **Unlicensed Operations:** Operating a medical laboratory facility without a current, validated KMLTTB facility registration certificate and active annual operating license is a criminal offense.
- B. **Failure to Remediate:** Failure to correct major operational non-conformances flagged by inspectors within the designated grace window will result in immediate physical closure and suspension of operations.
- C. **Illegal Personnel Employment:** Employing unregistered or unlicensed individuals to perform clinical testing will result in the immediate revocation of the institutional license and criminal prosecution of the facility's management board.
- D. **Data Falsification:** Any deliberate manipulation, alteration, or falsification of diagnostic data, patient reports, quality control statistics, or EQA samples will lead to the permanent decommissioning of the facility, permanent blacklisting of the participating practitioners, and direct criminal prosecution under the penal code.

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

