REPUBLIC OF KENYA
MINISTRY OF HEALTH
KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

SCOPE OF PRACTICE

Pursuant to the Medical Laboratory Technicians and Technologists Act (CAP253 A Laws of Kenya)

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD *Make Testing a Safe Reality*	SCOPE OF PRACTICE		DOCUMENT CONTROL Serial: KMLTTB/DC/10 Version 001 Date: 29TH FEB 2024
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The Medical Laboratory Science Profession

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) has established that medical laboratory science 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. The profession includes basic trained individual in all medical laboratory sciences namely parasitology, entomology, microbiology, virology, hematology, immunology, blood transfusion medicine, clinical chemistry, toxicology, cytogenetics, histopathology, cytopathology and molecular diagnostics. The medical Laboratory sciences professional also include specialties in all the above basic medical laboratory sciences. Integral features of each of the specialties include diagnostic testing, research, consultation, education, information management, marketing and administration. KMLTTB has a professional code of ethics that sets forth the principles and standards by which medical laboratory professionals' practice.

Description of the Scope of Practice

Medical laboratory Sciences professionals, as members of the healthcare team, contribute to the prevention of disease, and the diagnosis, treatment, and prognosis of pathophysiological conditions in humans. Medical laboratory personnel are responsible for assuring reliable and accurate medical laboratory test results. Quality medical laboratory testing is evidenced by: performing the correct test, on the right person, at the right time, producing accurate test results, with the best outcome, in the most cost-effective manner. This is accomplished by:

[1] Ensuring that appropriate Medical laboratory tests are ordered;
[2] Procuring Medical laboratory test samples in an efficient, timely manner;
[3] Producing accurate medical laboratory test results;
[4] Correlating and interpreting Medical laboratory test data;
[5] Disseminating medical laboratory test information to clinicians and patients in a timely manner;
[6] Evaluating the outcome of medical laboratory testing for each individual patient and the entire health care system;
[7] Utilizing qualified medical laboratory personnel.

[8] The practice of medical laboratory science requires:
[9] Assessing, designing, evaluating and implementing new medical laboratory test methods;
[10] Evaluating the appropriateness of existing and new medical laboratory methods for clinical utility, cost-effectiveness and cost-benefit analysis;

[11] Developing, implementing, and reporting results of medical laboratory research;
[12] Designing and implementing cost-effective delivery models for medical laboratories, including their services and personnel;
[13] Developing and implementing a comprehensive Quality Management System to include:
    a. Quality control and assurance of medical laboratory testing services;
    b. Competency assessment of personnel;
    c. Integration with other aspects of the healthcare delivery system for ensuring appropriate utilization of medical laboratory testing services;
    d. Continuous process improvement activities to effectively utilize human resources.
[14] Designing, implementing and evaluating academic curricula for the education of new medical laboratory professionals;
[15] Designing, implementing and evaluating academic curricula for advanced education of medical laboratory professionals;
[16] Designing, implementing and evaluating continued education activities and career growth opportunities for medical laboratory professionals;
[17] Promoting awareness and understanding of the use of the medical laboratory.

Description of Current Practice

The following scenarios describe specific examples of the scope of practice of medical laboratory sciences.

Providers of Medical Laboratory Services

Medical laboratory officers qualified by education and experience, perform laboratory tests and provide test results to clinicians and to consumers upon request or upon clinician referral. These services can be used to assess wellness and identify disease risk factors, as well as assisting in the diagnosis, monitoring and treatment of disease. Medical laboratory officers exercise prudence and judgment to ensure that such services are consistent with good practice and sound professional ethics. In addition, medical laboratory officers may own or operate laboratories.

Directors of Full-Service medical Laboratories

Medical laboratory officers, with appropriate diploma and degree education, can direct full-service medical laboratories. This function is firmly grounded in Medical Laboratory Technicians and Technologists Act Cap 253A laws of Kenya.

Consultants for medical Laboratory Services

Medical laboratory officers may appropriately provide assistance and advice to clinicians, manufacturers, and consumers of medical laboratory testing services about the:

[1] Design and service scope of medical laboratories;
[2] Appropriate utilization, selection and sequencing of medical laboratory tests;
[3] Clinical correlations and interpretations of the quality and utility of specific laboratory results in collaboration with clinicians;
[4] Design and development of medical laboratory instruments, test kits and other components;
[5] Appropriate use, maintenance, quality assurance and other procedural and informational requirements.

Levels of Practice

There are hierarchical levels of practice, based upon education and experience, for each of the three areas of medical laboratory science practice: scientific, managerial and educational. Specific knowledge and experience are required for each level of practice within the three areas. An individual is eligible to practice at various levels after acquiring additional experience, education, and demonstrating competence. Specific knowledge and experience is common to all three areas; none is mutually exclusive of the other. Demands of the health care environment often require an individual to practice in more than one area, thereby performing at different levels of practice.

The *scientific function* includes the production of test data, monitoring the accuracy, precision and utility of laboratory testing, the correlation and interpretation of test data, and the design, evaluation and implementation of new laboratory test methods.

The *managerial function* includes managing all aspects, technical, fiscal, workflow, and human resources, of medical laboratory operations.

The *educational function* includes the establishment and management of educational programs for new and current medical laboratory practitioners, other healthcare providers and consumers.

Qualifications for Practice

KMLTTB has prescribed standards for ALL personnel including directors, superitendents, medical laboratory officers to ensure the accuracy and reliability of test performance.

KMLTTB has developed curricula for both diploma and degree level of medical laboratory sciences education and training at universities and colleges. These curricula forms the bases for basic training for one to join medical laboratory sciences profession in Kenya. Further, KMLTTB has set minimum standards of training in terms of physical facilities (Medical Laboratory Sciences Demonstration Laboratories, medical Library and lecture rooms. This standards also include academic profile where the requirement

for one to join **diploma training** is expected to have completed secondary school education and obtained, in one sitting, a minimum of mean grade of C plain at KCSE and cluster subject that consist of

English/Kiswahili- C plain
Mathematic /Physics- C plain,
Biology- C plain
Chemistry- C plain

for one to join **degree training** is expected to have completed secondary school education and obtained, in one sitting, a minimum of mean grade of C+ (plus) at KCSE and cluster subject that consist of

English/Kiswahili- C+ plus
Mathematics/Physics- C+ plus,
Biology- C+ plus
Chemistry- C+ plus

The Board has also made it mandatory for institutions to present all selected trainees in medical laboratory sciences to KMLTTB 30 days post admission for scrutiny of their

qualification and they are thereby indexed for future reference in training and practical areas allocations
KMLTTB has also ensured approved medical laboratory sciences training institutions are equipped with human resource capacity that is composed of registered and licensed medical laboratory science professionals who are specialised in the areas that they teach. These areas are mainly the core units of medical laboratories sciences as indicated as the basic discipline.

Persons not qualified in the basic Medical Laboratory Sciences subjects are not allowed to participate in teaching the core areas.

In accordance with MLTT Act and this regulations, KMLTTB has requires that all invitro Diagnostics(Medical Laboratories reagents and equipment's) are validated and verified to ascertain their quality to ensure all medical laboratory test are accurate. This should be done by qualified medical laboratory professionals in certified medical laboratory institutions. The process is scientific excises that determines validity of invitro diagnostics information as claimed by the manufactures and establishes precision specify, specificity and linearity among other attributes required for specific testing.
KMLTTB requires all qualified medical laboratory technician and technologist to have sat and passed registration examinations offered just before registration.
KMLTTB requires practitioners to maintain CPD points for every year of practices in accordance with the CPD guidelines KMLTTB/GEN/03

KMLTTB requires that all medical laboratory Technicians and technologist in both public and private practice to observe medical laboratory quality improvement and implement ISO 15189:2022 and any subsequent version to ensure quality of medical laboratory service and not necessary for accreditation. All reference medical laboratory should ensure accreditation status

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is the statutory regulatory body established under Cap 253A of the Laws of Kenya to govern the training, registration, licensing, and professional practice of Medical Laboratory Sciences (MLS).

Advanced clinical specialization under KMLTTB regulations typically occurs at the Higher Diploma, Postgraduate Master of Science (MSc) levels Doctor of Philosophy (PhD) and Post-Doctoral level. The following matrix details the primary board-approved areas of specialization, core testing focus, specific diagnostic procedures, and required regulatory compliance parameters.

KMLTTB Medical Laboratory Sciences Specialist Matrix

Approved Specialization Area	Core Diagnostic Focus & Scope	Sample Procedures / Technical Interventions	KMLTTB Regulatory & Quality Mandates
Clinical Chemistry	Analysis of body fluids (serum, plasma, CSF) to	• Quantitative assaying of renal/liver	• Strict calibration logs for fully

	evaluate metabolic, endocrine, and systemic organ function.	function tests. • Specialized endocrine testing (thyroid panels, reproductive hormones). • Therapeutic Drug Monitoring (TDM) and toxicology screening.	automated chemistry analyzers. • 95% target adherence to Westgard Rules on daily Internal Quality Control (IQC).
Haematology & Haemostasis	Investigation of cellular blood components and blood coagulation pathways to diagnose anemias, leukemias, and bleeding disorders.	• Bone marrow aspirate processing and morphologic evaluation. • Full Blood Counts (FBC) and differential reviews. • Coagulation screening (PT, APTT, D-Dimer assays).	• Regular verification of automated hematology profiles via cell control matrices. • Participation in designated External Quality Assessment (EQA) for blood film identification.
Blood Transfusion Sciences	Immunohaematological safe matching of blood products, ensuring compatibility and screening for transfusion-transmissible infections.	• ABO / Rhesus forward and reverse blood grouping. • Antibody screening, identification, and crossmatching. • Component preparation (packed cells, FFP, platelets).	• Full cold-chain maintenance tracking and blood bank storage logging. • Mandatory adverse transfusion reaction reporting protocols.
Medical Microbiology (Bacteriology, Mycology, Virology)	Isolation, identification, and susceptibility profiling of infectious micro-organisms (bacteria, fungi, and viruses).	• Automated and manual blood/urine bacterial cultures. • Antimicrobial Susceptibility Testing (AST) profiling. • Viral load quantitation and fungal cultures.	• Bio-risk and biosafety level compliance checkmarks. • Verification of media batch sterility before diagnostic usage. • Standardized Reporting of Critical Values.
Histopathology & Cytology	Microscopic evaluation of tissue biopsies and cellular smears to detect malignancies, chronic inflammation, and cellular abnormalities.	• Tissue processing, embedding, and microtomy. • H&E structural staining and Immunohistochemistry	• Documented chemical hygiene logs for volatile handling (Formalin/Xylene). • Double-blind

		(IHC). • Fine Needle Aspiration Cytology (FNAC) and Pap smear screening.	review mandates for abnormal malignant screenings.
Medical Parasitology & Entomology	Detection of parasitic infestations, vector identification, and management of neglected tropical diseases (NTDs).	• Expert malaria microscopy and quantitation. • Concentration techniques for stool parasites. • Identification of disease-carrying vectors (mosquitos, snails).	• Validation of stain batches (Giemsa/Leishman). • Maintenance of standard reference slide library for proficiency monitoring.
Molecular Diagnostics & Biotechnology	Advanced amplification and analysis of nucleic acids (DNA/RNA) for genetic disorders, infectious pathogens, and forensic applications.	• Polymerase Chain Reaction (PCR) assays. • Gene sequencing and viral genotyping. • Hybridization techniques.	• Specialized infrastructure segregation (Pre-PCR vs Post-PCR zones) to prevent cross-contamination. • Method validation protocols for open molecular platforms.

Approved Specialty Area	Higher Diploma (HDip)	Master of Science (MSc)	Doctor of Philosophy (PhD) & Post-Doc
Cytopathology	**Technical Cytotechnologist** • Performs advanced cellular preparation and routine staining (e.g., Pap smear, FNAC processing). • Identifies and marks abnormal cells for review.	**Clinical Cytopathology Specialist** • Conducts primary diagnostic evaluation of liquid-based cytology and complex tissue smears. • Validates diagnostic screening workflows.	**Consultant Pathologist / Researcher** • Establishes national cervical cancer screening guidelines. • Leads digital cytopathology innovation and clinical research.
Histopathology	**Advanced Histotechnologist** • Manages grossing assistance, microtomy, embedding, and standard H&E or special stains. • Troubleshoots artifact issues.	**Anatomical Pathology Scientist** • Operates advanced Immunohistochemistry (IHC) profiling. • Manages the tissue repository and frozen section setups.	**Principal Expert in Morphological Sciences** • Directs comparative pathology tumor boards. • Spearheads molecular pathology oncogenic biomarker research.
Biosafety & Biosecurity	**Facility Biosafety Officer** • Enforces daily waste decontamination protocols, PPE logs, and chemical hygiene. • Monitors autoclave efficacy.	**Director of Bio-risk Management** • Designs safety containment criteria for BSL-3 facilities. • Formulates institutional emergency spill response guidelines.	**National Bio-Defense Advisor** • Drafts nationwide pandemic response, biosecurity, and select agent control policy frameworks for the Ministry of Health.
Validation of In Vitro Diagnostics (IVDs)	**Technical Evaluator** • Runs parallel precision and accuracy testing benchmarks for new reagents, test kits, or equipment panels.	**IVD Performance Scientist** • Drafts Validation Master Plans (VMP). • Reviews cross-reactivity, clinical sensitivity, and specificity limits.	**KMLTTB IVD Committee Chairperson** • Enforces final legal authorization for import/market placement under **Legal Notice No. 113 of 2011**.

Public Health	**Epidemiological Lab Tech** • Handles sample collection, field screening, and data uploads during disease outbreaks. • Manages local diagnostic outreach.	**Epidemiology Laboratory Officer** • Manages laboratory-backed surveillance networks. • Analyzes spatial antimicrobial resistance (AMR) maps.	**Global Health Strategist (WHO/CDC)** • Designs regional disease eradication programs. • Directs large-scale genomic tracking for emerging public health threats.
Health Professions Education	**Clinical Preceptor / Instructor** • Leads bench instruction, logbook signing, and practical skills mentorship for interns.	**Medical Laboratory Educator** • Designs academic curricula aligned with KMLTTB requirements. • Implements modern assessment methodologies.	**Dean of Faculty / Academic Visionary** • Leads institutional program accreditation reviews. • Shapes regional workforce training and educational policy models.
Clinical Embryology	**IVF Laboratory Technologist** • Performs basic semen analysis, sperm preparation, and handles media inventory tracking. • Monitors incubators.	**Senior Clinical Embryologist** • Performs Intracytoplasmic Sperm Injection (ICSI), blastocyst grading, and embryo verification. • Runs QA for IVF suites.	**Director of Reproductive Sciences** • Coordinates pre-implantation genetic testing (PGT) programs. • Advances research on innovative cell culture models and fertility treatments

Essential Professional Compliance Checklist

To practice as a licensed specialist in any of the areas above, KMLTTB enforces several legal guidelines:

[1] **Active Registration & Licensure:** A professional must hold a valid, yearly practicing license mapped explicitly to their level of qualification.
[2] **Continuous Professional Development (CPD):** Personnel must acquire a minimum of **50 CPD points** annually from KMLTTB accredited providers to qualify for license renewal.
[3] **Quality Management Systems (QMS):** Specialists must oversee facility compliance following **ISO 15189 standards**, submitting mandatory quarterly returns highlighting IQC performance, EQA scores, and critical value timelines to the board.
[4] If you are setting this up for a specific institution, let me know:

[5] The **tier of your health facility** (e.g., Class B, C, or D laboratory)
[6] The specific **academic level** you are targeting (e.g., Higher Diploma curriculum development vs Hospital laboratory structure)
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[11] The **tier of your health facility** (e.g., Class B, C, or D laboratory)
[12] The specific **academic level** you are targeting (e.g., Higher Diploma curriculum development vs Hospital laboratory structure)
[13] I can further customize the matrix with precise staffing dynamics and infrastructural equipment metrics tailored to your needs.

Higher Diploma, Postgraduate Master of Science (MSc) levels Doctor of Philosophy (PhD) and Post-Doctoral level
To advance your professional registry with the **Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB)**, it is essential to understand the board's official educational hierarchy. In accordance with **Cap 253A of the Laws of Kenya**, KMLTTB maintains specialized registers for practitioners upgrading their qualifications from basic competencies (Certificate/Diploma/BSc) to elite advanced tiers.

The expanded matrix below outlines the scope of practice, expected institutional placement, and regulatory expectations across the **Higher Diploma, Master of Science (MSc), Doctor of Philosophy (PhD), and Post-Doctoral levels**.

Academic & Registry Level	Primary Scope of Practice	Focus of Clinical / Research Interventions	Institutional Tier & Placement (Kenya)
Higher Diploma (HDip / HND)	**Advanced Technical Specialist** • Execution of specialized bench procedures. • Routine laboratory department management. • Troubleshooting advanced automation.	• Running specialized diagnostic assays (e.g., bone marrow processing, advanced cultures). • Managing internal quality control (IQC) data. • Supervising basic diploma/certificate interns.	• Sub-County & County Referral Laboratories (Tiers 3 & 4). • Core private reference laboratories.
Master of Science (MSc)	**Clinical Scientist & Lab Director** • Analytical validation of complex methodologies. • Design of Quality Management Systems (QMS). • Academic lecturing and operational research.	• Designing multi-department validation protocols. • Troubleshooting complex diagnostic anomalies. • Serving as an ISO 15189 Internal Auditor. • Directing biosafety and biosecurity setups.	• National Referral Hospitals (Kenyatta National Hospital, KU-RTH). • Universities as Lecturers. • Research institutes (KEMRI).
Doctor of Philosophy (PhD)	**Principal Investigator & Consultant** • Design and funding of public health research. • Strategic health policy formulation. • Subject-matter expert consultation for the Ministry of Health (MoH).	• Leading clinical trials and breakthrough genomic profiling. • Authoring national testing guidelines. • Supervising MSc and PhD level research dissertations. • Heading institutional review boards (IRB).	• Senior Faculty / Professors at Universities. • Principal Scientists at research institutions such as KEMRI or international NGOs (CDC, WHO).
Post-Doctoral Level	**Global Research Leader & Innovator** • Patenting new in-vitro diagnostics (IVDs). • Driving high-impact translational medicine. • Spearheading national pandemic	• Designing next-generation molecular diagnostic tools. • Securing multi-million shilling international research grants. • Advisory tasks for the KMLTTB IVD validation committee.	• Specialized international reference laboratories. • Advanced Biotech/Pharmaceutical companies. • University research centers of excellence.

response frameworks.