



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
Master of Science in Medical Laboratory Sciences (MSc MLS) Training Standards
Pursuant to the Medical Laboratory Technicians and Technologists Act,
CAP 253 A Laws of Kenya
Quality assurance services

	DEPARTMENT STANDARD REPORT		DOCUMENT CONTROL Serial: KMLTTB/MSc/TRN/STDS/01 Revision No. 001 Revision Date: 4 TH APRIL 2025
	OWNERSHIP	REGISTRAR	



INTRODUCTION

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a statutory body established under Section 3(2) of the Medical Laboratory Technicians and Technologists (MLTT) Act, 1999 (CAP 253A). Our mandate includes the general supervision and control over training, business, practice, and employment of medical laboratory technicians and technologists, as well as validation of in-vitro diagnostics (IVD) under Legal Notice No. 113 of 2011. The board recognises that specialised training in the medical laboratory sciences sector requires to align the profession and the professional towards the global health security so as to achieve patient safety and public trust in the regulation of laboratory medicine.

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.

1. PROGRAM STRUCTURE

Program Title: Master of Science in Medical Laboratory Sciences [MSc MLS]

Duration: 2 years full-time, 3-4 years part-time

Total Credits: 60-72 credits / 1800-2160 notional hours

Structure: Semester 1: Core Common | Semester 2: Specialisation Theory + Practicum | Year 2: Research, Advanced Practicum, Thesis

Thematic Areas of Specialisation:

- I. Clinical Chemistry / Chemical Pathology
- II. Haematology & Blood Transfusion Science
- III. Medical Microbiology - Bacteriology, Mycology
- IV. Medical Virology
- V. Clinical Parasitology
- VI. Medical Entomology
- VII. Histopathology
- VIII. Cytopathology
- IX. Medical Immunology



X. Molecular Diagnostics & Genomics

2. ADMISSION REQUIREMENTS CHECKLIST

A. Academic Requirements - Applicant must have ONE of:

BSc in Medical Laboratory Sciences

Foreign qualifications: Evaluated by KMLTTB and training institution recognised by CUE/KNQA as equivalent to Kenyan standards

B. Professional & Statutory Requirements:

Registration with Medical Laboratory statutory board - KMLTTB

Valid practicing license

Proof of 1 year internship / 2 years work experience in a recognized laboratory

Letter of recommendation: 2 academic + 1 professional supervisor

C. Research Prerequisites:

Concept note - 2-3 pages aligning with chosen thematic area

Basic Biostatistics and Research Methods certificate - if not covered in BSc

Computer literacy & Laboratory Information System proficiency

3. THEMATIC AREA SPECIFIC REQUIREMENTS

Each student must complete: Advanced Theory (12 credits), Advanced Lab Practicum (9 credits), Specialized Techniques (6 credits), and Thesis in specialisation.

Thematic Area	Core Advanced Competencies Mandatory Medical Laboratory Techniques Checklist
Clinical Chemistry	Pathophysiology of metabolic disorders, Endocrinology, Toxicology, Quality Assurance Automated chemistry analyzers, Immunoassays, ABG, Electrophoresis, LC-MS/MS principles
Haematology & Transfusion	Haemato-oncology, Haemostasis, Transfusion Medicine, Stem cell tech ,Bone marrow processing, Flow cytometry, Coagulation studies, Antibody ID, Apheresis
Medical Microbiology(Bacteriology, virology and Mycology)	AMR, Advanced Bacteriology, Mycology, Biosafety Level 3 practice Culture & AST automation - VITEK/MALDI-TOF, Anaerobic culture, Biofilm testing, Medical



	Virology, Parasitology & Entomology, Molecular parasitology, Vector biology, Neglected Tropical Diseases, Concentration techniques, Vector identification, In vitro culture, Antigen detection
Histopathology & Cytology	Oncopathology, Immunohistochemistry, Molecular pathology Microtomy, Special stains, IHC, Frozen section, Digital pathology
Molecular Diagnostics	Genomics, Pharmacogenomics, Bioinformatics DNA/RNA extraction, Conventional & Real-time PCR, NGS workflow, Sanger sequencing, Bioinformatics pipelines
Immunology Autoimmunity	Transplant immunology, Immunotherapy Nephelometry, Immunofluorescence, HLA typing, Cytokine assays

4. CURRICULUM REQUIREMENTS CHECKLIST

Common Core Courses - All specialisations [15 credits]:

Advanced Research Methodology & Biostatistics

Advanced Laboratory Management, Quality Management System ISO 15189

Bioethics, Biosafety & Biosecurity

Scientific Communication & Grant Writing

Advanced Pathophysiology & Laboratory Medicine Seminars

Assessment Requirements:

Continuous Assessment: 40% - Lab practicals, Journal clubs, Case studies

End of Semester Exam: 60%

Minimum 2 departmental seminars presented

Practicum Logbook: 600 hours in specialisation, signed by supervisor



Pass mark: 50% per unit, 60% for practicum

5. RESEARCH & THESIS REQUIREMENTS

Proposal development by end of Semester 2

Ethical approval: Institutional IREC + NACOSTI license if applicable

Supervisors: Minimum 2 - 1 with PhD in specialisation, 1 with MSc or above + 5 years' experience

Thesis: 15,000 - 25,000 words, original work in specialisation

Plagiarism check: <15% similarity

External examination + Viva voce

At least 1 manuscript submitted to peer-reviewed journal before graduation

6. INSTITUTIONAL & ACCREDITATION REQUIREMENTS

For university to mount the program:

Faculty:

Program Leader: PhD in Medical Laboratory Sciences + Associate Professor Level

At least 3 full-time PhD holders per thematic area offered

Medical Laboratory technologists: HND/BSc or MSc qualified for advanced laboratories.

Infrastructure:

Specialised Medical laboratories for each thematic area: BSL-2 minimum, BSL-2+ for Microbiology/Virology

Equipment: -Freezers, PCR machines, Flow cytometer, automated analyzers, Microtomes, Biosafety cabinets

Affiliation with Level 5/6 teaching hospital Laboratories of KMLTTB class F/G for clinical practicum.

Access to molecular Medical laboratory and research laboratories.



Physical and E-library with access to Science Direct, PubMed, and CLSI guidelines

Quality Assurance:

CLSI guidelines incorporated in SOPs

ISO 15189 aligned QMS in training labs

External examiner for each thematic area

Industrial advisory board with pathologists, lab directors

7. FINAL GRADUATION CHECKLIST

Student file must contain:

1. Proof of completed 60+ credits
2. Practicum logbook certified - 600 hours
3. Seminar presentation certificates - 2
4. Ethics approval letters
5. Thesis examiners reports - internal + external
6. Viva voce pass report
7. Manuscript submission proof
8. Clearance from department, library, finance
9. Board registration recommendation letter

Regulated Medical Laboratory Sciences Specialist Framework

This framework outlines specialist cadres with protected titles and defined scopes of practice. It aligns with ISO 15189, WHO Medical Laboratory Quality standards, and I KMLTTB structures. Areas of specialisation in Medical laboratory sciences include but NOT limited to the following:

- a. Clinical Chemistry
- b. Hematology
- c. Blood Transfusion Science
- d. Histopathology
- e. Clinical cytology/ Cytopathology
- f. Clinical Cytology
- g. Parasitology
- h. Medical Entomology



- i. Medical Microbiology - Bacteriology
- j. Medical Microbiology - Virology
- k. Medical Microbiology - Mycology
- l. Medical Immunology
- m. Molecular Diagnostics & Bioinformatics
- n. Pharmacogenetics
- o. Biosafety & Biosecurity
- p. IVD Verification & Validation / QMS

KMLTTB MAY INCLUDE OR REMOVE A SPECIALIST AREA AFTER DUE CONSULTATION WITH OTHER VERY IMPORTANT STAKE HOLDERS.

A. Scope at Higher Diploma Specialist:

Regulated Title: Specialist Medical Laboratory Technologist

- I. Perform and validate advanced tests in discipline
- II. Design and review SOPs, IQC/EQA management
- III. Verification of analyzers and reagents per KMLTTB IVD regulation
- IV. Train students, internship supervision
- V. First-line consultation on result interpretation
- VI. Manage pre-analytical, analytical, post-analytical errors

B. MSc LEVEL - Senior Specialist / Medical Laboratory Scientist

Entry: BSc MLS + Higher Diploma or direct MSc MLS in discipline + 3 years specialist experience + KMLTTB registration as Technologist/Specialist

Regulated Title: Senior Specialist Medical Laboratory Technologist / Medical Laboratory Scientist

Mandate: Reference Medical laboratory head, county/regional Medical laboratory manager, lecturer, method development.

1. Clinical Chemistry Specialist

Protected Title: Regulated Medical Laboratory Sciences Clinical Chemistry Specialist

Scope of Practice:

- I. Analytical: Performance, interpretation and reporting of biochemical analyses of blood, urine, CSF, and other body fluids including enzymes, electrolytes, metabolites, hormones, tumor markers, therapeutic drug monitoring
- II. Cardio-metabolic: Verification of lipid profiles, HbA1c, glucose tolerance, cardiac markers, and renal and liver function panels. Provide interpretive comments on cardio-metabolic risk and monitoring
- III. Instrumentation: Verification and validation of chemistry analyzers, reagents, calibrators and IVDs prior to clinical use



- IV. Quality: Design and oversight of internal QC, external QA, method evaluation, reference intervals
- V. Consultation: Advise clinicians on test selection, result interpretation, pre-analytical factors affecting chemistry results
- VI. Not limited to: Point-of-care chemistry, toxicology screening, newborn screening, and nutritional biochemistry
- VII. Processing metabolic panels, electrolytes, automated instrumentation operation, calibration, electrophoresis, immunoassay, handling serum, plasma, urine, CSF and recognizing pre-analytical errors
- VIII. Cardio-metabolic disorders: Design SOPs for dyslipidemia, diabetes, metabolic syndrome, HbA1c, cardiac biomarkers, CKD panels. Provide interpretive reporting and clinician consultation
- IX. Verification & Validation of IVDs: Scientific validation of chemistry reagents and equipment per KMLTTB mandate on IVDs

2. Haematology and Transfusion Medicine Specialist

Protected Title: Regulated Medical Laboratory Sciences Haematology Specialist and / or Regulated Medical Laboratory Sciences **Transfusion Medicine** Specialist

Scope of Practice:

- I. Cellular Analysis: Morphological examination of peripheral blood, bone marrow, body fluids. Automated and manual CBC, differentials, reticulocytes
- II. Hemostasis: Coagulation testing, D-dimer, platelet function, bleeding disorder workups
- III. Transfusion: Blood grouping, crossmatching, antibody identification, component therapy, adverse transfusion reaction investigation
- IV. Hemoglobinopathies: Screening and monitoring of sickle cell, thalassemia, and management labs for cardio-metabolic complications
- V. Quality: Validation of hematology analyzers, slide staining, flowcytometry protocols
- VI. Not limited to: Stem cell processing support, apheresis laboratory oversight
- VII. Hemoglobinopathies, leukemia/lymphoma workup support, transfusion reaction investigation
- VIII. Management of cardio-metabolic anemia, validation of haematology analyzers



3. Histopathology Specialist

Protected Title: Regulated Medical Laboratory Sciences Histopathology Specialist

Scope of Practice:

- I. Tissue Processing: Grossing, fixation, processing, embedding, microtomy, special stains, IHC
- II. Diagnostic Support: Preparation of slides for pathologist review, intra-operative frozen section support
- III. Bio banking: Tissue archiving, retrieval, and research specimen management
- IV. Quality: Validation of new histology methods, reagents, and equipment. Turnaround time monitoring
- V. Not limited to: Autopsy assistance, cytology specimen preparation, digital pathology workflows Frozen section support, IHC
- VI. Validation of Haematology IVDs, bio banking, digital pathology QA, grossing under supervision framework

4. Clinical Cytology Specialist

Protected Title: Regulated Medical Laboratory Sciences Clinical Cytology Specialist

Scope of Practice:

- I. Specimen Prep: Fine needle aspiration, gynecological and non-gynecological cytology preparation, liquid-based cytology
 - II. Screening: Preliminary screening of Pap smears and other cytology under supervision framework of regulatory council
 - III. Molecular Cytology: Cell block preparation for molecular and IHC studies
 - IV. Quality: Validation of stains, adequacy criteria, proficiency testing
 - V. Not limited to: Cancer screening programs, ROSE procedures
- Pap smear, FNA, liquid-based cytology, cell block for molecular studies

5. Medical Parasitology Specialist

Protected Title: Regulated Medical Laboratory Sciences Parasitology Specialist

Scope of Practice:

- I. Diagnosis: Microscopy, concentration methods, serology, molecular detection of protozoa, helminths, ectoparasites
- II. Surveillance: Monitoring of endemic parasites linked to cardio-metabolic and nutritional status
- III. Epidemiology Support: Outbreak investigation, prevalence surveys, vector-borne parasite mapping



- IV. Quality: Validation of rapid diagnostic tests and PCR assays for parasites
- V. Not limited to: Travel medicine diagnostics, neglected tropical diseases

6. Medical Entomology Specialist

Protected Title: Regulated Medical Laboratory Sciences Entomology Specialist

Scope of Practice:

- I. Vector Identification: Morphological and molecular identification of mosquitoes, flies, ticks, lice
- II. Surveillance: Vector density, insecticide resistance testing, and transmission risk assessment
- III. Control Support: Laboratory evaluation of vector control products, breeding site analysis
- IV. Epidemiology: Link lab data to disease transmission models for malaria, dengue, and arboviruses
- V. Not limited to: Biosafety assessment of arthropod colonies, research on vector competence

7. Molecular Diagnostics Specialist

Protected Title: Regulated Medical Laboratory Sciences Molecular Diagnostics Specialist

Scope of Practice:

- I. Nucleic Acid Testing: Extraction, amplification, sequencing for infectious disease, oncology, and inherited disorders
- II. Pharmacogenetics: Genotyping for drug metabolism, dosing guidance for anticoagulants, statins, and anti-cancer drugs
- III. Validation: Analytical and clinical validation of IVD molecular kits, LDTs, and NGS panels
- IV. Quality: Contamination control, biosafety level 2/3 molecular workflows
- V. Not limited to: Liquid biopsy, microbiome analysis, and companion diagnostics

8. Pharmacogenetics Specialist

Protected Title: Regulated Medical Laboratory Sciences Pharmacogenetics Specialist

Scope of Practice:

- I. Genetic Testing: CYP450 panel, VKORC1, TPMT and other clinically actionable variants



- II. Interpretation: Translate genotype to phenotype and provide therapeutic recommendations to prescribers
- III. Cardio-metabolic Focus: Warfarin, clopidogrel, statin response, diabetes drug pharmacogenomics
- IV. Validation: Verification of PGx assays and reporting algorithms
- V. Not limited to: Population pharmacogenomics research, education of health workers
- VI. CYP2C9, CYP2C19, VKORC1, TPMT, DPYD genotyping for anticoagulants, antiplatelet, statins, oncology
 - I. - Provide pharmacogenomics interpretation to prescribers, Support dose optimization in cardio-metabolic diseases

9. Biosafety and Biosecurity Specialist

Protected Title: Regulated Medical Laboratory Sciences Biosafety Officer

Scope of Practice:

- I. Risk Assessment: Pathogen risk grouping, activity risk assessment for BSL-1 to BSL-3 labs
- II. Compliance: Oversight of WHO, CDC, and national biosafety guidelines. Waste management, spill response
- III. Training: Competency in PPE, biosecurity, dual-use research of concern
- IV. Audit: Facility inspection, certification of BSCs, autoclaves, transport of infectious substances
- V. Not limited to: Incident investigation, emergency preparedness, laboratory security

10. Medical Laboratory Research Specialist

Protected Title: Regulated Medical Laboratory Sciences Research Scientist

Scope of Practice:

- I. Method Development: Design and validate new assays for clinical and public health use
- II. Clinical Trials: Lab component of trials, sample management, biomarker validation
- III. Data Analysis: Epidemiology, biostatistics, and laboratory data for disease burden
- IV. Grants and Ethics: Protocol design, ethical review submission for lab-based studies
- V. Not limited to: Translational research, implementation science

11. Health Professions Education Specialist in MLS

Protected Title: Regulated Medical Laboratory Sciences (MLS) Educator



Scope of Practice:

- I. Curriculum: Design and delivery of MLS programs at diploma, degree, and specialist level
- II. Competency Assessment: OSCE, practicum supervision, licensing exam development
- III. Continuing Education: CPD coordination, simulation training, mentorship
- IV. Accreditation: Support programs to meet regulatory council and academic standards
- V. Not limited to: E-learning, interprofessional education

12. IVD Verification and Validation Specialist

Protected Title: Regulated Medical Laboratory Sciences IVD Specialist

Scope of Practice:

- I. Pre-implementation: Verification of manufacturer claims: accuracy, precision, linearity, LoD, reference range
- II. Post-market: Surveillance of IVD performance, complaint handling, vigilance reporting
- III. Regulatory: Documentation for regulatory authority submission, method comparison studies
- IV. Quality: Manage lot-to-lot verification, stability studies
- V. Not limited to: Evaluation of POCT, AI-assisted IVDs

13. Public Health and Epidemiology Medical Laboratory Sciences Specialist

Protected Title: Regulated Medical Laboratory Sciences Public Health Specialist

Scope of Practice:

- I. Surveillance: Lab data for disease notification, outbreak detection, antimicrobial resistance
- II. Reference Testing: Confirmatory testing, strain typing, whole genome sequencing
- III. Epidemiology: Design lab components of surveys, link lab results to population health
- IV. Policy: Provide evidence for guidelines on screening and control programs
- V. Not limited to: Cardio-metabolic disease surveillance using lab biomarkers

14 Medical Microbiology – Bacteriology

- I. **Core Focus:** Bacterial morphology, physiology, pathogenicity, and antimicrobial resistance (AMR).



- II. **High-Yield Pathogens:** *Mycobacterium tuberculosis*, *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa*, Enterobacteriaceae (ESBL, Carbapenem-resistant).
- III. **Diagnostic & Clinical Pillars:**
 - a. Phenotypic identification (Gram stain, biochemical matrices, MALDI-TOF MS).
 - b. Minimum Inhibitory Concentration (MIC) testing via broth microdilution or E-tests.
 - c. Interpretation of phenotypic vs. genotypic resistance mechanisms (e.g., *mecA*, *blaCTX-M* genes).
- IV. **Protected Title:** Medical Laboratory Sciences Bacteriology Specialist.
 - a. **Core Competencies:** Bacterial pathogenicity and virulence dynamics. Phenotypic identification systems (MALDI-TOF Mass Spectrometry). Antimicrobial Resistance (AMR) tracking including broth microdilution Minimum Inhibitory Concentration (MIC) mechanics, E-tests, and genetic marker parsing (e.g., *mecA*, *blaCTX-M*, *vanA/B*).

15. Medical Microbiology – Virology

- I. **Core Focus:** Viral replication cycles, viral pathogenesis, and vaccine development
- II. **High-Yield Pathogens:** HIV-1/2, Hepatitis B & C, Influenza, Arboviruses (Dengue, Zika, Chikungunya), and filoviruses (Ebola).
- III. **Diagnostic & Clinical Pillars:**
 - a. Viral load monitoring (quantitative real-time PCR).
 - b. Serology profiling (HBsAg, anti-HBs, HBeAg to map chronic vs. acute states).
 - c. Next-Generation Sequencing (NGS) for genotype monitoring and viral resistance tracking (e.g., HIV antiretroviral resistance mutations).
- I. **Protected Title:** Regulated Medical Laboratory Sciences Virology specialist.
 - a. **Core Competencies:** Viral replication kinetics, latency models, and tissue tropism. Absolute viral load monitoring using quantitative real-time PCR and digital droplet PCR (ddPCR). Complex serological interpretation (e.g., acute vs. chronic HBV panels). Next-Generation Sequencing (NGS) for tracking viral antiretroviral resistance mutations.

15. Medical Microbiology – Mycology

- I. **Core Focus:** Classification, morphology, and clinical management of superficial, subcutaneous, and systemic fungal infections.
- II. **High-Yield Pathogens:** *Cryptococcus neoformans*, *Candida albicans* (and multidrug-resistant *Candida auris*), *Aspergillus fumigatus*, *Histoplasma capsulatum*.
- III. **Diagnostic & Clinical Pillars:**
 - a. Microscopic morphologic analysis (germ tube tests, KOH mounts, India ink for capsules).



- b. Biomarker diagnostics: Galactomannan assays and (1→3)-β-D-glucan detection.
 - c. Antifungal susceptibility testing (AFST) targeting azoles, echinocandins, and polyenes.
- IV. **Protected Title:** Regulated Medical Laboratory Sciences Mycology Specialist
- a. **Core Competencies:** Taxonomic profiling and morphologic differentiation of opportunistic deep-tissue fungi (*Cryptococcus neoformans*, *Candida auris*, *Aspergillus fumigatus*). Biomarker diagnostics using serum/BAL Galactomannan assays and (1→3)-β-D-glucan surveillance. Antifungal Susceptibility Testing (AFST) adhering to CLSI or EUCAST microdilution guidelines.

16. Medical Immunology

Core Focus: Cellular and humoral immunity, hypersensitivities, autoimmunity, and immunodeficiencies.

High-Yield Systems: Major Histocompatibility Complex (MHC/HLA) mapping, T-cell subpopulation dynamics, and cytokine signaling pathways.

Diagnostic & Clinical Pillars:

- b. Immunophenotyping via multicolour Flow Cytometry (e.g., absolute CD4+/CD8+ counts).
- c. Automated enzyme immunoassays (ELISA, CLIA) and Multiplex bead assays for autoantibodies (e.g., ANA, anti-dsDNA).
- d. Functional immune assays (NK cell activity, Lymphocyte transformation tests).

Protect Title: Regulated Medical Laboratory Sciences Immunology Specialist.

Core Competencies: Cellular and humoral equilibrium, hypersensitivities, autoimmunity, and immunodeficiencies. High-dimensional multicolour Flow Cytometry Immunophenotyping (e.g., CD4+/CD8+ subsets, Treg profiling). Automated autoantibody screening matrices via Chemiluminescent Immunoassays (CLIA), ELISA, and high-resolution HLA typing (MHC Class I/II) for transplantation.

14. POST-DOCTORAL LEVEL - Distinguished Fellow / Medical Laboratory Sciences Research Professor

Entry: PhD MLS + 2-4 year post-doctoral fellowship + significant research output + KMLTTB retention

Regulated Title: Post-Doctoral Fellow / Distinguished Specialist -

Mandate: Highest level - national/international reference, research and training.[Discipline]

Scope at Post-Doctoral:

- I. Translational research, advanced genomics, proteomics, metabolomics
- II. National lab strategic planning, health system strengthening



- III. International guideline development (WHO, Africa CDC)
- IV. Mentor PhD candidates, lead centers of excellence in molecular diagnostics, pharmacogenomics, biosafety
- V. Validation of emerging technologies: CRISPR diagnostics, point-of-care molecular IVDs, data science and AI application
- VI. Advanced epidemiology: predictive modeling using lab big data

C. Cross-cutting Competencies for All Specialists

- I. Quality Management: ISO 15189, GLP, documentation and audit
- II. Ethics and Professionalism: Confidentiality, scope boundaries, referral pathways
- III. Digital Health: LIS management, data governance, cybersecurity
- IV. Leadership: Supervision, laboratory management, resource planning

D. Regulatory Notes

- 1. **Title Protection:** Only persons registered with the KMLTTB may use the specialist title
- 2. **Scope Limitation:** Practice must be within education, training, and competency. Additional scopes require documented CPD and KMLTTB approval
- 3. **Delegation:** Specialists may delegate technical tasks to Medical Laboratory technologists but retain professional responsibility for results and interpretation within scope.

KMLTTB Compliance for all levels:

- 1. Must be indexed, registered, and annually licensed by KMLTTB
- 2. Must only use KMLTTB-approved IVDs and equipment
- 3. Must adhere to KMLTTB CPD thematic areas - 27 areas including all above
- 4. Higher Diploma and above must demonstrate competence in consultation, education, research, and management as integral features

