REPUBLIC OF KENYA
MINISTRY OF HEALTH

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

THE HARMONISED AND MODERNISED MEDICAL LABORATORY SCIENCES PROFESSION IN KENYA

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a body corporate with statutory mandate 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

Professional practice in the health sector requires consistent and ongoing commitment from all concerned with lifelong learning in order to update and develop the knowledge, skills and ethical attitudes that underpin competent practice. This perspective protects the public interest and promotes the health of all members of the Kenyan society.

Guided by the principle of beneficence, medical laboratory Sciences profession aspire to standards of excellence in health care provision and delivery.

1. **Standardization Note: The Medical laboratory sciences profession** is the Kenya's official name from training to practice.

The profession is also referred to as **Medical laboratory Technicians, technologists, officer and scientists**; these titles are generally used interchangeably for the same professional role.

There is significant provisions for interprofessional collaboration between the **Medical laboratory Technicians and Technologists (MLTT) Act (Cap 253A)** and all other healthcare -related laws in Kenya. These laws function together to regulate health professionals, data, and institutional standards.

A. **The Health Act, 2017**

The Health Act, 2017 serves as the primary framework for the entire health system. It explicitly recognizes the **Kenya Medical laboratory Technicians and Technologists Board (KMLTTB)** as a key KMLTTBy body.

I. **KMLTTB Relationship:** Section 60 of the Health Act mandates that KMLTTBy bodies (read KMLTTB) must inspect and monitor professional standards, provided their functions do not conflict with the overall national health authority.

II. **Professional Conduct:** The MLTT Act's disciplinary functions are aligned with the Healthcare standards provisions under article 43(1) in constitution of Kenya 2010.

III. **Data and Digital Health Laws**

IV. There is an increasing interprofessional collaboration in how medical laboratory data is handled:

V. **Data Protection Act, 2019:** Medical laboratory heads must ensure that patient data collected during medical testing is handled in accordance with both the MLTT Act and the Data Protection Act.

VI. **Digital Health Act, 2023:** This newer act integrates with medical laboratory reporting requirements, specifically concerning the electronic filing of returns by training institutions.

2. INTERPROFESSIONAL COLLABORATION AND CONFLICT

The MLTT Act specifically regulates persons trained registered and licensed to perform medical laboratory tests. Interprofessional collaboration often eliminate a need for legal clarifications:

I. **Exclusivity of Practice:** Under Section 19(1) of the MLTT Act, only registered medical laboratory professionals can indulge in medical laboratory analysis and investigations in health institutions.

II. **Legal Precedent:** In *Association of Kenya Medical laboratory Scientific Officers v Ministry of Health (2019)*, the High Court ruled that policy guidelines (like the Task Sharing Policy) cannot allow non-medical laboratory individuals to conduct tests, as this would be inconsistent with the MLTT Act and the constitution of Kenya 2010.

3. SHARED INSTITUTIONAL OVERSIGHT

The KMLTT Board operates alongside other professional boards mentioned in Section 60 of the Health Act, including:

I. **Medical Practitioners and Dentists Council** (Cap 253)

II. **Nursing Council of Kenya** (Cap 257)

III. **Pharmacy and Poisons Board** (Cap 244)

IV. **Nuclear Regulatory Authority**

V. **Clinical officers council**

VI. **Physiotherapy council of Kenya**

VII. **Occupational Health council of Kenya**

VIII. **Radiography council of Kenya**

IX. **Kenya Nutritionist and Dieticians institute**

X. **Medical records officers and managers council**

These bodies often collaborate on the inspection of "health institutions" (hospitals, clinics, etc.) where multiple professional categories work together.

There is significant interprofessional collaboration between Medical laboratory Sciences (MlS) and other healthcare professions, primarily through shared **diagnostic goals**.
While medical laboratory scientists often work **"behind the scenes,"** their data is the foundation for approximately **70% of all medical decisions** made by physicians.

4. CORE AREAS OF INTERPROFESSIONAL COLLABORATION

Clinical Decision-Making: Medical laboratory sciences professionals' collaborate closely with **physicians** to diagnose, monitor, and treat diseases.
They provide critical data that guides therapy effectiveness and patient outcomes.

I. **Patient Care Coordination:** They work with **physicians** and **other healthcare professionals** to plan and implement patient care. For example, nurses identify patients for medical laboratory professional to collect samples (like blood or urine).

II. Medical laboratory professionals then analyze to provide the results needed for the nurse to administer the correct treatment.

III. **Point-of-Care Testing (POCT):** There is a functional interprofessional collaboration laboratory in bedside testing, where medical laboratory professionals perform or oversee rapid tests (like glucose monitoring) that are also frequently requested by other Healthcare professionals.

IV. **Public Health & laboratory bases disease surveillance:** Medical laboratory sciences professionals engage in interprofessional collaboration with **public health professionals** in tracking disease outbreaks, monitoring antimicrobial resistance, and conducting large-scale health screenings.

5. COMPARATIVE HEALTHCARE PROFESSIONAL LANDSCAPE

While roles are distinct, they often share similar educational foundations in hard sciences (microbiology, clinical chemistry, and immunology).

Feature	Medical laboratory Sciences	Other Healthcare professionals
Primary Focus	Diagnostic data and analytical integrity	Direct patient care and treatment implementation
Interaction	Primarily with the healthcare team (minimal patient contact)	Frequent, direct face-to-face patient interaction
Environment	Medical laboratories (hospitals, research, industry)	Bedside, clinics, and emergency rooms
Key Interprofessional collaboration	High-level data interpretation for diagnosis	Using that data to make clinical decisions

6. RISK-BASED PROFESSIONAL REGULATION BY KMLTTB

Risk-based professional regulation is a strategic framework where KMLTTB activities such as inspections, licensing, and enforcement are prioritized based on the level of risk that individuals or medical laboratory facilities pose to a KMLTTB's objectives.

Instead of a "one-size-fits-all" or "tick-box" approach, KMLTTBs target their finite resources toward the areas of greatest potential harm.

(a). CORE PRINCIPLES

1. **Risk Assessment**: KMLTTBs calculate risk by combining the **likelihood** of an event (e.g., professional misconduct) with the **impact** or severity of the resulting harm.
2. **Proportionality**: Intervention is tailored to the risk level. High-risk entities face more intrusive monitoring and stricter enforcement, while low-risk entities may benefit from "lighter-touch" regulation, such as self-assessment.
3. **Targeting**: Resources are focused on "priority risks" to protect the public interest more effectively.

(b). HOW IT WORKS IN PRACTICE

1. **Risk Identification**: Determining what could go wrong (e.g., unethical conduct, lack of competence, or financial crime).
2. **Risk Profiling**: Categorizing professionals or firms (low, medium, high) based on their compliance history, business model, or field of practice.
3. **Tiered Response**:
    a. **High Risk**: Frequent audits, mandatory reporting, and proactive investigations.
    b. **Low Risk**: Registration only, simplified due diligence, or educational guidance.

(C). COMMON APPLICATIONS

1. **Legal Services**: Organizations like the Solicitors Regulation Authority (SRA) and the Bar Standards Board use this model to identify threats to the rule of law and consumer protection.
2. **Health & Safety**: KMLTTB prioritizes inspections of workplaces with hazardous processes over those with historically high compliance.

(D). KEY BENEFITS VS. CHALLENGES

Benefit	Challenge
Efficiency: Directs "scarce resources" to where they matter most.	**Subjectivity**: Risk assessments can be influenced by the KMLTTB's auditor judgment.

Reduced Burden: Low-risk businesses face less "red tape".	**Data Dependency**: Requires high-quality, up-to-date data to be accurate.
Flexibility: Can adapt quickly to emerging threats like new technologies such as artificial intelligence (AI)	**Risk of Failure**: Public backlash can occur if a "low-risk" entity causes a major incident. This is common in Kenyan context

7. THE REGULATION OF MEDICAL LABORATORY SCIENCES PROFESSION.

The regulation of medical laboratory professions compared to single line disciplines varies significantly worldwide, primarily distinguished by whether a field is considered a **regulated health profession** (requiring a license to practice) or a **basic/pure science**.

(a) MEDICAL LABORATORY SCIENCES (MLS)

MLS, just like in Kenya, is strictly regulated field globally. In most jurisdictions, it is a protected profession requiring mandatory licensing or registration to perform diagnostic tests on human samples.

I. **Regulatory Bodies**: In Kenya medical laboratory sciences is regulated by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), created under section 3 of the mltt Act, Cap 253A laws of Kenya. In comparative jurisdictions, national councils like the Medical Laboratory Science Council of Nigeria (MLSCN) and the American Society for Clinical pathology (ASCP) Board of Certification in the U.S. oversee standards.

II. **Requirements**: Practice usually necessitates a specific professional degree, practical rotation in medical laboratories, and passing a national registration examination.

2. MEDICAL MICROBIOLOGY, BIOCHEMISTRY & PARASITOLOGY

These are core disciplines within MLS, they are often regulated as specialists when pursued as masters' degrees or Higher Diploma in medical laboratory sciences.
Those who holds standalone academic fields in either of these fields are required to undergo further training to meet the requirements to participate in analysis and investigations of diseases using human biological specimens. This training also include training on phlebotomy science and other specimen collection and management.
The training also include practical rotation in hospital laboratories and registration examinations.

3. **INTEGRATED PRACTICE**: specialists wishing to practice within Medical/clinical laboratory settings are typically regulated under the broad "Medical Laboratory

Sciences professionals" licensure protocol just like the general practitioners with recognition of specialty.

4. CLINICAL EMBRYOLOGY

Embryology is a highly specialized field with a multifaceted regulatory landscape. Assisted Reproductive Technology (ART) practitioners namely embryologists must be registered with specific health or reproductive authorities e.g. those involved in analysis and investigations using human biological specimens require to be licensed by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).

5. PHLEBOTOMY

The practice of phlebotomy is the critical "first step" in patient care, as approximately **70% of medical decisions** including diagnosis, treatment, and monitoring rely on medical laboratory test analysis derived from blood specimens. Because phlebotomy occurs during the **pre-analytical phase**, which accounts for **46% to 70% of all laboratory errors**, it directly determines the validity and accuracy of medical investigations.

(A). IMPACT ON SPECIMEN QUALITY AND ANALYSIS

Poor phlebotomy technique introduces "pre-analytical errors" that can lead to false results or specimen rejection:

I. **Haemolysis:** Improper collection (e.g., using too small a needle or shaking tubes) ruptures red blood cells, releasing intracellular contents. This can **falsely elevate** potassium, lactate dehydrogenase (LDH), and aspartate aminotransferase (AST) levels, potentially mimicking life-threatening conditions.

II. **Haemoconcentration:** Leaving a tourniquet on for more than one minute causes venous stasis, which can increase the concentration of proteins, cholesterol, and calcium by up to **15%**.

III. **Additive Contamination:** Failing to follow the correct **order of draw** can cause additive carryover (e.g., EDTA contaminating a citrate tube), leading to erroneous electrolyte or coagulation results.

IV. **Inadequate Volume:** Under filled tubes disrupt the critical blood-to-anticoagulant ratio, particularly in coagulation studies, resulting in artificially prolonged clotting times.

(b). IMPACT ON INVESTIGATIONS AND CLINICAL OUTCOMES

Errors in phlebotomy practice have far-reaching consequences for medical investigations:

I. **Diagnostic Delays:** Suboptimal specimens (e.g., clotted or haemolysed) are often rejected by the laboratory, requiring repeated draws that delay time-sensitive diagnoses.

II. **Misdiagnosis and Inappropriate Treatment:** Analytically precise results from compromised samples can mislead clinicians into ordering unnecessary further investigations or initiating potentially harmful therapies.

III. **Increased Healthcare Costs:** Re-testing and prolonged hospital stays due to specimen errors increase the financial burden on both patients and healthcare facilities.

(c). CRITICAL QUALITY CONTROLS IN PHLEBOTOMY

To ensure reliable analysis, phlebotomists must adhere to standardized procedures

I. **Patient Identification:** Verifying at least two permanent identifiers (e.g., full name and date of birth) is the most vital task to prevent catastrophic misidentification errors.

II. **Site Preparation:** Proper disinfection and allowing the alcohol to dry prevents bacterial contamination of blood cultures and interference with chemistry results.

III. **Sample Stability:** Correct handling, such as gentle inversion of tubes and timely transportation at appropriate temperatures, preserves analyte integrity.

IV. **Certification vs. Licensing**: In Kenya, phlebotomy is a licensed under medical laboratory profession al practice as pre analytical practice. The short course for phlebotomy practice is available for all persons registered as medical laboratory professional at any level. Nurses, clinical officers and medical officers desirous to practice as phlebotomists may also undergo a KMLTTB approved training course for recognition.

V. **Role and Scope of Practice**: KMLTTB Regulations typically limit phlebotomists derived from nursing, clinical medicine and medical officers to specimen collection, prohibiting them from performing analysis, investigations and diagnostic tests. Therefore phlebotomist is a healthcare professional specifically trained to perform **venipuncture** (drawing blood from veins), finger sticks, or heel

pricks. Globally, their role is essential for modern medical diagnosis, as blood analysis informs roughly 70% of medical decisions.

VI. **Blood Collection:** Performing safe and accurate draws for medical tests, transfusions, research, or donations.

VII. **Patient Interaction:** Verifying patient identity, explaining procedures, and calming anxious patients.

VIII. **Specimen Management:** Correctly labeling vials, processing samples (e.g., centrifuging), and maintaining the "chain of custody" for transport.

IX. **Sanitation and Safety:** Maintaining sterile work areas and properly disposing of biohazardous materials like used needles.

X. **Administrative Duties:** Entering patient data into Laboratory Information Systems (LIS) and managing supply inventories.

6. RELATIONSHIP BETWEEN MEDICAL LABORATORY SCIENCES (MLS) PRACTITIONERS AND MORTUARY SCIENTISTS.

While mortuary scientists handle the **collection** and **pre-analytical processing** of remains, Medical Laboratory Scientists (MLS) or technologists handle the **analytical testing**. www.mymortuarycooler.com +1

I. **Specimen Transfer:** Mortuary scientists collect and label fluids (toxicology) and tissues (histology), which are then logged into Laboratory Information Management Systems (LIMS) and sent to specialized labs staffed by MLS practitioners.

II. **Shared Scientific Foundation:** Both roles require knowledge of human anatomy, pathology, and microbiology to manage infectious risks and ensure sample viability.

III. **Collaborative Diagnostics:** MLS practitioners analyze the specimens (e.g., performing microbiological cultures or molecular diagnostics) to confirm findings that the mortuary scientist helped identify during the gross examination.

IV. **Safety Protocols:** Both professions strictly adhere to OSHA blood borne pathogen standards and use high-level Personal Protective Equipment (PPE) to manage the risk of handling infectious biological materials

7. SUMMARY OF REGULATORY STATUS

Profession	Kenya and Global Regulatory Status	Typical Requirement
Medical Laboratory Sciences	**High** (Mandatory)	Professional License + Degree or Diploma
Medical/Clinical Embryology	**Moderate to High**	Specialized ART Certification by appropriate regulatory body depending on function
Medical microbiology Parasitology/ Biochemistry	**Variable** (Context-dependent)	Master's Degree/ Higher National Diploma; License required to practice in a medical/clinical laboratory.
Phlebotomy	**Low to Moderate**	Require certification, registration and licensure by KMLTTB.
Mortuary scientist	**Low to moderate**	certification, registration and **Is essential.**

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