REPUBLIC OF KENY
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

IMPORTANT DISCUSSION ON NATIONAL LICENSING, CERTIFICATION, AND ACCREDITATION FRAMEWORKS FOR MEDICAL LABORATORY PROFESSIONALS.

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

KMLTTB QUALITY ASSURANCE SERVICES

	IMPORTANT DISCUSSION ON NATIONAL LICENSING, CERTIFICATION, AND ACCREDITATION FRAMEWORKS FOR MEDICAL LABORATORY PROFESSIONALS.	DOCUMENT CONTROL Serial KMLTTB/ MLS/IMPORT/DISCUSSION/01 Version 001 Date: 11TH NOVEMBER, 2026
	OWNERSHIP: REGISTRAR	

1st Ngong Avenue, ACK Garden Hse, 4th Floor|P.O.BOX 20889-00202 Nairobi Kenya| Tel: 0202731391; +254713553495; +254713554133; +254706110110;+254733430330|Email: info@kmlttb.org/labs@kmlttb.org| Web: www.kmlttb.org

INTRODUCTION

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

Pursuant to the **Medical Laboratory Technicians and Technologists Act, CAP 253A of the Laws of Kenya**, the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) establishes TRAINING STANDARDS which are a comprehensive regulatory framework. This standard governs medical laboratory operations for the diagnosis, treatment, clinical management, treatment monitoring, and prevention of all diseases, within the Republic of Kenya.

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.

The **Standards for Medical Laboratory Services in Food and Nutrition Diseases** is one of the guidelines prepared by the KMLTTB prescribing mandatory clinical practice and competencies professionals shall practice in the course of their duty.

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.

1st Ngong Avenue, ACK Garden Hse, 4th Floor|P.O.BOX 20889-00202 Nairobi Kenya| Tel: 0202731391; +254713553495; +254713554133; +254706110110;+254733430330|Email: info@kmlttb.org/labs@kmlttb.org| Web: www.kmlttb.org

IMPORTANT DISCUSSION ON NATIONAL LICENSING, CERTIFICATION, AND ACCREDITATION FRAMEWORKS FOR MEDICAL LABORATORY PROFESSIONALS.

From Kenya's perspective, we strongly believe that the foundation of a resilient diagnostic system is a competent, ethically grounded, and properly regulated Medical Laboratory workforce. We can invest in the most advanced diagnostic equipment and technologies, but without qualified professionals, effective regulation, and continuous competency development, these investments cannot deliver sustainable results.

In Kenya, the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), established under the Medical Laboratory Technicians and Technologists Act, Cap. 253A, laws of Kenya, provides the statutory framework for regulating Medical Laboratory education, registration, licensing, and professional practice.
Crucially, safeguarding diagnostic quality also requires ensuring that the scientific validation and verification of *in vitro* diagnostics (IVDs) rests squarely with specialized Medical Laboratory regulatory bodies rather than pharmaceutical regulators. Medical Laboratory professionals possess the distinct technical expertise needed to evaluate analytical performance, clinical utility, and post-market surveillance within actual testing environments, ensuring that only accurate, reliable diagnostics reach our laboratories and protect patient safety.

DISCUSSION

Q1: STRENGTHENING NATIONAL LICENSING AND TRAINING STANDARDS

A. **Focus:** How legislation ensures a competent workforce from the classroom to the bench.
B. **Talking Point:** "In Kenya, Cap. 253A empowers KMLTTB to regulate the entire lifecycle of a Medical Laboratory professional, starting from indexing students and accrediting training institutions to administering national licensing exams. A strong framework prevents unqualified personnel from entering the system. By enforcing strict entry-level standards, we guarantee that every licensed practitioner possesses the baseline competence required to generate accurate results."

Q2: CONTINUOUS COMPETENCY AND RAPID TECHNOLOGICAL CHANGE

A. **Focus:** Adapting to new diagnostic platforms and maintaining quality over time.
B. **Talking Point:** "Initial licensing is only the starting point. Diagnostic technologies are evolving rapidly, especially in molecular testing and point-of-care systems. Through mandatory Continuous Professional Development (CPD) and annual license

1st Ngong Avenue, ACK Garden Hse, 4th Floor|P.O.BOX 20889-00202 Nairobi Kenya| Tel: 0202731391; +254713553495; +254713554133; +254706110110;+254733430330|Email: info@kmlttb.org/labs@kmlttb.org| Web: www.kmlttb.org

renewal, we ensure our workforce stays current. Regulation must not be seen as punitive; it is a quality-assurance mechanism that protects both the patient and the integrity of the profession."

Q3: CROSS-BORDER HARMONIZATION AND REGIONAL HEALTH SECURITY

A. **Focus:** Aligning frameworks across Africa (e.g., East African Community, Nigeria, and Cameroon).
B. **Talking Point:** "Pathogens do not respect borders, which means our regulatory standards shouldn't either. When countries align their training curricula, licensing requirements, and accreditation benchmarks, we build regional resilience. Harmonization allows us to share expertise, recognize qualifications across borders during public health emergencies, and elevate the standing of Medical Laboratory medicine across the continent."

Q4: REGULATORY BOUNDARIES: MEDICAL LABORATORY VS. PHARMACEUTICAL REGULATORS

Institutional mandates, overlapping laws, on IVD oversight (KMLTTB vs. Kenya's Pharmacy and Poisons Board):

A. **Distinct Scientific Expertise:** Pharmaceutical regulators are structured to evaluate *in vivo* pharmacokinetics, drug toxicity, and chemical stability. *In vitro* diagnostics (IVDs) operate outside the body and require specialized expertise in analytical sensitivity, specificity, reagent stability, and calibration. Medical Laboratory scientists are uniquely trained to evaluate these parameters.
B. **Real-World Clinical Verification:** Paper-based dossier reviews are insufficient for IVDs. Medical Laboratory regulatory bodies oversee physical batch-to-batch testing and clinical verification using local patient samples and endemic disease profiles before an assay is approved for use.
C. **End-to-End Quality Oversight:** Medical Laboratory regulators already inspect and accredit the facilities where IVDs are deployed. Keeping IVD validation under the Medical Laboratory regulator creates a seamless link between pre-market approval, daily internal quality control, external quality assessment (EQA), and post-market surveillance.
D. **Preventing Substandard Diagnostics:** When IVDs are treated merely as commercial commodities under general pharmacy laws, substandard test kits can slip into the market, leading to misdiagnoses, wasted resources, and compromised outbreak responses. Dedicated Medical Laboratory oversight acts as a critical safeguard for public health. KMLTTB look toward the future of health security in Africa, let us remember that diagnostic systems are only as strong as the professionals behind the

1st Ngong Avenue, ACK Garden Hse, 4th Floor|P.O.BOX 20889-00202 Nairobi Kenya| Tel: 0202731391; +254713553495; +254713554133; +254706110110;+254733430330|Email: info@kmlttb.org/labs@kmlttb.org| Web: www.kmlttb.org

bench and the regulatory frameworks that govern them. By investing in strong statutory boards, continuous workforce competency, and dedicated Medical Laboratory oversight of *in vitro* diagnostics, we ensure that every test result is accurate, every patient is protected, and our health systems remain resilient.

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

1st Ngong Avenue, ACK Garden Hse, 4th Floor|P.O.BOX 20889-00202 Nairobi Kenya| Tel: 0202731391; +254713553495; +254713554133; +254706110110;+254733430330|Email: info@kmlttb.org/labs@kmlttb.org| Web: www.kmlttb.org