REPUBLIC OF KENY
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB REGULATORY POLICY, FRAMEWORK, AND GUIDELINES FOR PHLEBOTOMY TRAINING AND PRACTICE

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

KMLTTB QUALITY ASSURANCE SERVICES

	KMLTTB REGULATORY POLICY, FRAMEWORK, AND GUIDELINES FOR PHLEBOTOMY TRAINING AND PRACTICE		DOCUMENT CONTROL Serial: KMLTTB/FRAMEWORK/GUIDE/POL/01 Version 001 Date: 2ND, NOVEMBER, 2026
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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.

Phlebotomy is a core component of medical laboratory science regulated by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) under the Medical Laboratory Technicians and Technologists Act (Cap 253A). This document establishes the standard regulatory framework, training curriculum requirements, licensing protocols, and

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the scope of practice for phlebotomists and medical laboratory professionals practicing phlebotomy in Kenya.

1. Policy & Regulatory Framework

Legal Authority

A. Cap 253A Mandate: KMLTTB holds the statutory authority to approve institutions for training, register and license practitioners, and regulate standard operating procedures (SOPs) for all medical laboratory processes, including pre-analytical specimen collection.
B. Compliance Requirement: No individual shall practice phlebotomy or collect blood specimens for diagnostic purposes in Kenya without a valid, annual KMLTTB practice license or an explicit board-recognized certification.

2. Objectives

A. Standardize Pre-Analytical Care: Minimize pre-analytical laboratory errors, which account for up to 70% of diagnostic discrepancies.
B. Patient & Practitioner Safety: Enforce strict adherence to infection prevention and control (IPC) protocols.
C. Quality Assurance: Align Kenyan phlebotomy practices with International Organization for Standardization (ISO 15189) requirements for medical laboratories.

3. Scope of Practice

The scope of practice dictates the authorized clinical boundaries based on the practitioner's tier of KMLTTB registration.

Practitioner	Authorized Phlebotomy Procedures	Clinical Boundaries & Restrictions
Registered Medical Laboratory Technician / Technologist and officers Who are also Certified Phlebotomist (Short-Course Holder)	1. Routine venipuncture (vacutainer, syringe)	Restricted from cannulation or central line accessing Generally Prohibited from administering
	2. Capillary skin punctures (finger, heel)	

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	3. Blood culture collection	intravenous medication or fluids. accessing indwelling central venous catheters (CVCs) or peripherally inserted central catheters (PICCs) unless specialized institutional and KMLTTB-approved training is certified
	4. Point-of-Care Testing (POCT) capillary collection	
	5. All routine venipuncture & capillary collections	
	6. Therapeutic phlebotomy (under medical order)	
	7. Neonatal heel sticks and specialized pediatric collection	

4. CORE CURRICULUM MODULES

A. Anatomy and Physiology: Circulatory system, comprehensive vascular anatomy, selection of appropriate veins, and nervous system complications.
B. Infection Prevention & Control (IPC): Hand hygiene, appropriate Personal Protective Equipment (PPE) utilization, needle-stick injury protocols, and biohazard waste segregation.
C. Pre-Analytical Variables: Correct Order of Draw, patient identification protocols, prevention of hemolysis, lipemia, and specimen contamination.
D. Technical Skills & Equipment: Master of evacuated tube systems (ETS), winged infusion sets (butterflies), syringes, and skin puncture devices.
E. Ethics, Law, and Communication: Informed consent, patient confidentiality (Data Protection Act compliance), and management of adverse patient reactions (syncope, hematomas).

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Make Testing a Safe Reality

5. PRACTICAL / CLINICAL PRACTICUM REQUIREMENTS

A. Minimum Logged Collections: Trainees must complete a minimum of 100 successful, unassisted venipunctures and 20 capillary punctures logged in an official KMLTTB logbook.
B. Clinical Rotation: Minimum of 160 hours in a KMLTTB-accredited tier 4, 5, or 6(Class D, E and F) Medical (clinical) laboratory facility under the direct supervision of a registered and licensed Medical Laboratory Superintendent.

6. Professional Practice & Operational Guidelines

Licensed practitioners must conform to the following national technical standards:

A. Patient Verification: Implement a strict dual-identifier verification process (e.g., full name and date of birth/hospital number) matching the Medical laboratory requisition form before any puncture.
B. Standard Order of Draw: Enforced to prevent cross-contamination of additives:
   i. Blood culture bottles
   ii. Non-additive / Serum tubes (e.g., Red, Gold/SST)
   iii. Coagulation tubes (Light Blue - Sodium Citrate)
   iv. Heparin tubes (Green)
   v. EDTA tubes (Lavender/Pink)
   vi. Glycolytic inhibitor tubes (Grey - Sodium Fluoride)
C. Specimen Labeling: All tubes must be labeled at the patient's bedside immediately after collection. Pre-labeling is a critical regulatory violation.
D. Waste Management: Immediate disposal of sharps into functional, puncture-resistant biohazard sharps containers located at arm's reach. Needle recapping is strictly illegal.

7. Quality Assurance and Continuous Professional Development (CPD)

A. CPD Requirements: To renew an annual KMLTTB practicing license, phlebotomists Medical Laboratory Technicians, technologists and officers must accumulate a minimum of 20 CPD points annually, with at least 5 points dedicated specifically to pre-analytical quality control, patient safety and infection control.
B. Competency Assessments: Health facilities must conduct and document annual direct-observation competency assessments for all staff performing phlebotomy.

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