



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

REGULATORY STANDARD GOVERNS MEDICAL LABORATORY OPERATIONS FOR THE DIAGNOSIS, TREATMENT, CLINICAL MANAGEMENT, TREATMENT MONITORING, AND PREVENTION OF VIRAL HEMORRHAGIC FEVERS (VHFS)

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

QUALITY ASSURANCE SERVICES

	STANDARD GOVERNS MEDICAL LABORATORY OPERATIONS FOR THE DIAGNOSIS, TREATMENT, CLINICAL MANAGEMENT, TREATMENT MONITORING, AND PREVENTION OF VIRAL HEMORRHAGIC FEVERS (VHFS)		DOCUMENT CONTROL Serial: KMLTTB/VHF/LABS/01 Version 001 Date: 14 TH OCTOBER, 2026
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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 this comprehensive regulatory framework. This standard governs medical laboratory operations for the diagnosis, treatment, clinical management, treatment monitoring, and prevention of **Viral Hemorrhagic Fevers (VHFs)**, including Ebola, Marburg, Rift Valley Fever, Dengue, and Lassa fever, within the Republic of Kenya.

1. STATUTORY AUTHORITY AND MEDICAL LABORATORY CLASSIFICATION

All facilities processing or referring specimens suspected of containing VHF agents must maintain strict alignment with KMLTTB diagnostic tiers:

- A. **Class F (Level VI - Referral/Molecular Medical Laboratories):** Authorized to perform molecular diagnostic techniques (e.g., RT-PCR, gene sequencing) and initial surveillance. Must maintain a minimum of **18 registered medical laboratory professionals**.
- B. **Class G (National/International Reference Medical Laboratories):** Authorized for definitive high-biosafety investigation, agent isolation, and national reference reporting. Must maintain a minimum of **25 registered medical laboratory professionals** and a verified **Biosafety Level 3 (BSL-3) or BSL-4** infrastructure.
- C. **Class B through E (Peripheral Care Medical Laboratories):** Strictly prohibited from opening or processing raw, un-inactivated specimens suspected of high-consequence VHFs. These tiers are restricted to utilizing point-of-care (POC) rapid strip tests or safe packaging for referral

2. PRE-ANALYTICAL PHASE & SPECIMEN MANAGEMENT

To protect Medical laboratory personnel and maintain sample integrity, strict adherence to the KMLTTB Standard Operating Procedure (SOP) for Mobile and Shipment of Medical Laboratory Specimens is mandatory:

- A. **Specimen Collection:** Blood collection must utilize a closed vacuum system (EDTA tubes preferred for molecular assays). Staff must wear full **Personal Protective Equipment (PPE)**, including fluid-resistant gowns, double gloves, N95/FFP3 respirators, and face shields.
- B. **Triple Packaging System:** Specimens must be enclosed using a compliant triple-packaging mechanism:
 - a. **Primary Leak-proof Receptacle:** Wrapped in sufficient absorbent material to absorb the entire liquid volume.
 - b. **Secondary Leak-proof Packaging:** Enclosing the primary receptacle.
 - c. **Rigid Outer Packaging:** Compliant with UN 2814 (Category A Infectious Substances) regulations, displaying appropriate biohazard labels.
- C. **Chain of Custody:** All samples must be tracked via the standardized KMLTTB Medical laboratory requisition form, documenting the precise time of collection, clinical history, and names of the handling licensed Medical Laboratory technologists/ officers.



3. ANALYTICAL PHASE: DIAGNOSTICS & TREATMENT MONITORING

Testing menus are strictly restricted based on facility risk categorization and the availability of certified containment equipment.

DIAGNOSTIC AND MONITORING MATRIX		
Clinical Intention	Approved Diagnostic Modalities	Minimum Required Containment
Definitive Diagnosis	Real-Time Reverse Transcription PCR (RT-PCR), Next-Generation Sequencing (NGS), Antigen-Capture ELISA.	Certified Class II Biosafety Cabinet (BSC) inside a Class F/G Facility
Differential Diagnosis	Rapid Diagnostic Tests (RDTs) for malaria ("VHF mimic"), full blood counts	Closed automated analyzers or Class II BSC
Treatment Monitoring	Clinical chemistry (Renal, Liver, Bone panels), Electrolytes, PT/INR Coagulation profiles	Point-of-Care (POC) micro-analyzers fitted with biohazard containment modifications.

IVD Validation Rule

In compliance with **Legal Notice No. 113 of 2011**, no reagent, kit, or In-Vitro Diagnostic (IVD) device shall be used for VHF testing unless it has undergone formal pre-market validation and possesses an official **KMLTTB Validation Certificate**.

4. POST-ANALYTICAL PHASE, BIOSAFETY & WASTE MANAGEMENT

- **Critical Value Reporting:** Confirmed or highly presumptive positive VHF results constitute a public health emergency. The Medical laboratory director must report results to the Ministry of Health Disease Surveillance Unit and KMLTTB within **30 minutes** of verification.
- **Decontamination:** All analytical workspaces must undergo mandatory decontamination using an EPA-approved, high-level disinfectant (e.g., 0.5% sodium hypochlorite solution or accelerated hydrogen peroxide) valid against enveloped viruses.
- **Bio-waste Disposal:** Liquid and solid Medical laboratory waste generated from VHF testing must be autoclaved on-site at 121°C for at least 30 minutes before transferring to a licensed high-temperature incinerator. Facilities must maintain a valid **KMLTTB-recognized waste management contract**.



5. Personnel Compliance and Quality Assurances

- A. **Licensure Requirement:** Only medical laboratory technologists holding a valid, current **KMLTTB Annual Practicing License** are legally permitted to handle or analyze suspected VHF samples.
- B. **Competency and CPD:** Staff assigned to high-containment suites must complete verified continuous professional development (CPD) modules covering VHF safety protocols. Training must be logged in the facility's quarterly returns.
- C. **Quality Control:** High-complexity testing labs must run daily Internal Quality Control (IQC) and participate in a KMLTTB-approved External Quality Assurance (EQA) proficiency testing program.

Facility Enforcement Notice

Non-compliance with these operational standards will result in the immediate revocation of the facility's operating license and legal prosecution under **Section 40 of CAP 253A**.

