



REPUBLIC OF KENYA

MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

COMPREHENSIVE KMLTTB REQUIREMENTS FOR A SPECIALISED CRITICAL CARE MEDICAL LABORATORY

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

	COMPREHENSIVE KMLTTB REQUIREMENTS FOR A SPECIALISED CRITICAL CARE MEDICAL LABORATORY		DOCUMENT CONTROL CODE: KMLTTB/SP/CCU/LAB/01 Version: 001
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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.

VISION, MISSION AND CORE VALUES

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.

STANDARDS AND REQUIREMENTS

A specialised critical care Medical Laboratory should adhere to the following standards and requirements.

I. Design and Location

a) Location

Adjacent to Intensive Care Unit (ICU) or within 30 seconds walking distance. Dedicated pneumatic tube system from ICU to the central Medical Laboratories.

b) Size

- 120-180 sqm for core stat Medical Laboratory (Emergency Medical Laboratory)
- 15 sqm satellite Point-of-Care Testing (POCT) Medical Laboratory inside ICU as per KMLTTB ICU recommendations.

c) Operational Model

Operational hybrid model - Dedicated ICU Stat Medical Laboratory and ICU Bedside POCT and main Hospital Medical Laboratory backup for complex tests.

d) Environment

- Heat, ventilation and air-conditioning with; 6 air changes per hour, 2 fresh, negative pressure for microbiology corner.
- Temperature of 18-24°C.
- Humidity level between 30-60%
- 100% uninterruptible power supply and generator backup and 12 electrical points per bench.



e) Workflow

A one-way sample flow: Reception > Processing > Analysis > Waste.

There should be separate dirty utility.

II. Test Menu

These test must be available.

A. STAT

These are analysis and investigations performed in less than 30 mins Inside ICU Medical Laboratory or POCT

- Blood Gases analysis and investigations: pH, pO₂, pCO₂, HCO₃, BE, lactate, electrolytes on ABG analyzer
- Electrolytes analysis and investigations: Sodium (Na⁺), Potassium (K⁺), Chloride (Cl⁻), Calcium (Ca²⁺), Magnesium (Mg²⁺) and Phosphate (PO₄³⁻)
- Metabolic analysis and investigations: Glucose, Urea, Creatinine, Bilirubin, Albumin, Ammonia
- Cardiac analysis and investigations: Troponin I/T, CK-MB, NT-proBNP, D-dimer
- Coagulation analysis and investigations: PT/INR, aPTT, Fibrinogen, ACT for ECMO/heparin
- Hematology analysis and investigations: CBC, Hb/Hct, Platelets - critical for phlebotomy anemia monitoring
- Sepsis markers analysis and investigations: Lactate, Procalcitonin, CRP, LDH
- Osmolality, ketones, ethanol analysis and investigations.

B. Urgent

These are analysis and investigations performed in less 2 hours in a Stat Medical Laboratory:

- LFTs, Arterial Blood Gas (ABG) electrolytes panel, Magnesium, Phosphate
- Renal: eGFR, Creatinine clearance
- Drug Levels: Vancomycin, Aminoglycosides, Phenytoin, Tacrolimus
- Toxicology: Paracetamol, Salicylate
- Microbiology rapid: Gram stain, Blood culture loading, Urine microscopy, Malaria, HIV rapid
- Transfusion: Group & Crossmatch, ABO/Rh

C. Routine

These are analysis and investigations performed in less than 6 hours – through the central Medical Laboratory Link:

- Microbiology culture and sensitivity, TB GeneXpert
- Endocrinology: Cortisol, Thyroid
- Immunology, Viral loads, Histopathology



III. Equipment List for 50 Beds

50 ICU beds = ~400-600 tests/day at peak occupancy.				
	Category	Equipment	Quantity	Key Spec
1.	Blood Gas	Critical Care ABG Analyzer with co-oximetry	3; 2 in ICU, 1 as a backup	pH, gases, lactate, electrolytes, Hb
2.	Chemistry	Automated Chemistry Analyzer 600-800 tests/hr	2; 1 in use and 1 as a backup	ISE module
3.	Hematology	5-part CBC Analyzer	2	Low-volume mode for ICU anemia
4.	Coagulation	4-channel Coagulometer	2	PT, aPTT, Fibrinogen, D-dimer
5.	Immunoassay	Immunoassay Analyzer	1	Troponin, Procalcitonin, BNP
6.	POCT at Bedside	1 Glucometer - per 5 beds	10	Connected to LIS
7.	POCT	Handheld ABG/electrolyte (iSTAT type)	4	For isolation/ECMO beds
8.	Microbiology	Blood culture system 40-bottle, Biosafety Cabinet Class II	1 each	
9.	Sample Handling	Refrigerated Centrifuge, Specimen Refrigerator 2-8°C, -20°C freezer	2, 2, 1	
10.	Support	Pneumatic tube, UPS 30KVA, Deionizer, Autoclave	1 SYSTEM	

MANDATORY: Continuous Renal Replacement Therapy (CRRT), ventilators and defibrillators in ICU itself as per critical care block standards, but Medical Laboratory must interface with them for anticoagulation and fluid balance data.

IV. Point-of-Care Testing (POCT) Governance

- Every ICU bay has: Glucometer, access to ABG within 1 minute.
- Central POCT committee must be chaired by Medical Laboratory Director.
- All POCT devices interfaced via POCT1-A2 middleware to Laboratory Information System (LIS)/Hospital Information System (HIS).



- d) QC must be run daily lockout if QC fails.

V. Staffing for 24/7 Operation

For 50 beds, 3 shifts:

- a) Medical Laboratory Director: 1 - Critical Care
- b) Medical Laboratory Sciences Specialists: 2 - Chemical pathology, Microbiology
- c) Medical Laboratory Technologists: 12; 4 per shift, 3 for main bench, 1 for POCT rounds
- d) Medical Laboratory Technologists (for sample collection): 6 to minimize diagnostic phlebotomy volume - critical for ICU anemia
- e) Medical Laboratory Sciences Quality Assurance Officer: 1

Ratio: 1 Medical Laboratory technologist per 12-15 ICU beds per shift.

VI. IT and Turnaround Time (TAT) System

- a) LIS and ICU patient data management system (PDMS) Integration: Required as per Level 3 ICU standards. Auto-alert critical values to ICU monitor.
- b) TAT Targets: ABG <10 min, Electrolytes/glucose <15 min, CBC <30 min, Coagulation <45 min, Lactate <20 min.
- c) Critical Value List: K^+ <2.8 or >6.5, Ca^{2+} <1.8, Glucose <2.2 or >25, pH <7.1 or >7.6, Lactate >4, Hb <6 g/dL.

VII. Infrastructure and Safety Requirements

- a) Bench Space: Adequate bench with sink, centrifuge, refrigerator, and intercom
- b) Power: Redundant circuits, automatic voltage regulator.
- c) Water: Type II purified water for analyzers.
- d) Biosafety: BSL-2 for microbiology area, spill kits, 4-color waste segregation.
- e) Storage: 30-day reagent stock for a 50-bed unit, cold chain monitored.

VIII. Quality and Accreditation

- a) Internal QC: 2 levels every 8 hours for all stat tests
- b) External QA: proficiency testing
- c) ISO 15189:2022 documentation: SOPs for all ICU tests, sample acceptance and rejection criteria, especially pre-analytical (tube types and volumes) to reduce phlebotomy loss
- d) Key Performance Indicators (KPIs): TAT compliance >95%, Sample rejection rate <2%, Critical value notification <15 min.

IX. Consumables Planning

Calculate monthly for 50 beds at 85% occupancy:

- a) ABG syringes: ~3,000/month
- b) Blood gas, chemistry, EDTA tubes: follow formula Total Volume = 1.0mL gas tubes and 3.0mL serum and 2.7mL citrate and 3.0mL EDTA



- c) Use pediatric low-volume tubes to prevent hospital-acquired anemia.

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