



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
STANDARDS OF SPECIALISED RENAL MEDICAL LABORATORY TO SUPPORT KIDNEY
TREATMENT UNIT AND KIDNEY TRANSPLANT PROGRAM

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

	COMPREHENSIVE SPECIALISED RENAL MEDICAL LABORATORY TO SUPPORT A RENAL TREATMENT UNIT AND KIDNEY TRANSPLANT PROGRAM		DOCUMENT CONTROL SERIAL: KMLTTB/SP/RENAL/LAB/01 Version: 001 Revision Date: 16 th September, 2026
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SPECIALISED RENAL MEDICAL LABORATORY TO SUPPORT A RENAL TREATMENT UNIT AND KIDNEY TRANSPLANT PROGRAM

CLASSIFICATION: CLASS F/G – SPECIALIZED RENAL MEDICAL LABORATORY

1.0 PREAMBLE AND LEGAL BASIS

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a statutory body mandated to oversee the training, practice, business, and employment of medical laboratory technicians and technologists and advises government on related matters as stipulated under Cap 253A of the Laws of Kenya. The Board also undertakes validation of in vitro diagnostics through Legal Notice No. 113 of 2011.

The Act gives the Board the responsibility of ensuring that all Medical Laboratories undertaking analysis and investigations meets the desired standards necessary for the delivery of quality Medical Laboratory services. These standards shall ensure the development of a robust Medical Laboratory services necessary to meet national and international health obligations that include sustainable development goals and Universal Health Coverage (UHC).

It is anticipated that compliance with the standards will enable Medical Laboratory run and sustain their analysis and investigations are ensuring the safety of the professionals, the patient and the environment.

1.1 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.

1.2 SCOPE

This standard sets the minimum requirements for any Medical Laboratory seeking to provide services in support of Renal Treatment and Kidney Transplantation.

No facility shall provide HLA typing for Kidney transplantation or related specialized testing without a KMLTTB Class F/G license.



2.0 CORE OBJECTIVES OF THE RENAL MEDICAL LABORATORY

To provide 24/7 support for:

- a) Early Chronic Kidney Disease (CKD) detection and staging
- b) Dialysis monitoring (hemodialysis and peritoneal)
- c) Pre-transplant workup and compatibility
- d) Post-transplant monitoring and rejection surveillance
- e) Management of complications

3.0 MEDICAL LABORATORY STRUCTURE - 8 INTEGRATED SECTIONS

3.1 Renal Clinical Chemistry and Biochemistry - The Workhorse

3.1 Routine Tests

UECs (Urea, Creatinine, Electrolytes $\text{Na}^+/\text{K}^+/\text{Cl}^-/\text{HCO}_3^-$), eGFR, Creatinine Clearance, BUN, Cystatin C, Uric Acid, Calcium-Phosphate-PTH axis and Magnesium

3.1.2 Dialysis Monitoring

- Pre/post dialysis Urea Reduction Ratio (URR)
- Kt/V
- Blood Gas Analyzer for acid-base.

3.1.3 Advanced analysis

- Urinalysis with microscopy
- Urine protein/creatinine ratio
- Microalbuminuria
- 24hr urine protein
- Beta-2 Microglobulin

3.1.4 Equipment

- Automated Chemistry Analyzer 600T/hr
- Electrolyte Analyzer ISE
- ABG Analyzer
- Automated Urine Chemistry Analyzer
- Osmometer

3.2 Hematology and Coagulation

Essential for anemia of CKD and transplant anticoagulation

3.2.1 Tests

- Full Haemogram
- Retic count, Iron studies (Ferritin, Total iron-binding Capacity (TIBC))
- Vitamin B12/Folate
- Coagulation profile (Prothrombin Time (PT/INR), Activated Partial Thromboplastin Time (aPTT))
- D-dimer



3.2.2 Equipment

- 5-part diff Hematology Analyzer
- Coagulation Analyzer

3.3 Immunology and Serology

3.3.1 Tests

Antinuclear Antibodies (ANA), ANCA (Antineutrophil Cytoplasmic Antibodies), Anti-CBM (Anti-glomerular basement membrane), Anti-PLA2R Antibodies, Complement C3/C4, Immunoglobulins, C - reactive protein (CRP).

3.2.3 Infectious screening for transplant

HIV Ag/Ab, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Cytomegalovirus (CMV) IgG/IgM, Epstein-Barr virus (EBV), Syphilis, TB QuantiFERON

3.4 HLA and Transplant Immunology Medical Laboratory - critical for transplant

This must be a separate clean room, ideally ISO 7/8 cleanroom.

3.4.1 HLA Typing

Low and High resolution HLA-A, B, C, DRB1, DQB1 by PCR-SSP and PCR-SSO / Next-Gen Sequencing

3.4.2 Crossmatching

Complement Dependent Cytotoxicity (CDC), Flow Cytometry Crossmatch (FCXM) - gold standard, Virtual Crossmatch

3.4.3 Antibody Screening

Panel Reactive Antibody (PRA), Single Antigen Bead Assay (Luminex) for Donor Specific Antibodies (DSA)

3.4.4 Immunosuppressive Drug Monitoring – Treatment drug monitoring (TDM)

Tacrolimus, Cyclosporine, Sirolimus, Mycophenolic Acid by LC-MS/MS or Immunoassay

3.5 Microbiology

Blood cultures, urine cultures (critical for UTI in transplant), peritoneal fluid cultures, screening for multi-drug resistant organisms. PCR for BK Virus, CMV viral load (Quantitative PCR).

3.6 Renal Histopathology and Immunofluorescence

For native kidney biopsy and transplant allograft biopsy; Light Microscopy, Immunofluorescence Microscopy (IgG, IgA, IgM, C3, C1q, Kappa/Lambda), Electron Microscopy.

Equipment: Cryostat, Tissue processor, automated stainer, Fluorescence microscope.



3.7 Molecular and Cytogenetics

BK virus, Cytomegalovirus (CMV) quantitative Polymerase Chain Reaction (PCR), Genetic testing for Autosomal Dominant Polycystic Kidney Disease (ADPKD), Alport syndrome

3.8 Point-of-Care Testing (POCT) in Renal Ward / ICU / Theatre

Handheld creatinine/electrolyte meters, ACT for heparin during dialysis/transplant, iSTAT for theatre.

4.0 INFRASTRUCTURE REQUIREMENTS

4.1 Space

Minimum 350-500 sqm, with unidirectional workflow

- Sample reception and phlebotomy
- Cold chain: 2-8°C fridges, -20°C and -80°C freezers for serum/DNA biobank
- Clean vs dirty separation
- Dedicated Transplant Medical Laboratory with positive pressure and HEPA filters

4.2 Support Systems

- LIMS (Laboratory Information Management System) integrated to Hospital Health Management Information System (HMIS) and dialysis machines
- 24/7 Power backup and Uninterrupted Power Supply (UPS) for analyzers and freezers
- Water treatment plant – Type I and II water for analyzers and molecular
- Bio-safety Level 2 with BSC Class II, autoclave, waste management per NEMA
- Blood Bank linkage – Must have immediate access to blood grouping and storage

5.0 KEY EQUIPMENT LIST

Speciality	Category	Essential Items
Analyzers	Clinical chemistry	Fully Automated Biochemistry
	Haematology and Immunology	Hematology 5-diff
		Chemiluminescence Immunoassay (CLIA), ABG, LC-MS/MS for TDM
		Flow Cytometer, Luminex 200
	Molecular Diagnostics	Real-Time PCR
Instruments and Equipment	Histology	Cryostat, Microtome



		Automated Tissue Processor
		Immunofluorescence (IF) Microscope
	General	Centrifuges (refrigerated)
		-80°C Freezer
		Automated Sample Storage

6.0 STAFFING STRUCTURE

DESIGNATION		REQUIREMENT
Medical Laboratory Director		Specialist Medical Laboratory Sciences (PhD/MSc)
Section Heads	Clinical Chemistry	Clinical Chemistry (PhD/MSc),
	Immunology	Immunologist (PhD/MSc.) with practical experience in HLA typing
	Microbiology	Medical Laboratory Sciences Microbiology Specialists (PhD/MSc)
	Histology/Cytology	Histotechnologist (PhD/MSc)
Technical Team		12-15 Medical Laboratory Technologists (shifts for 24/7) 2 Medical Laboratory Sciences Molecular Specialist 2 Histotechnologists (HND/BSc./MSc.)
Quality and Support		Quality Manager (ISO 15189) and LIMS Officer
Transplant Coordinator Liaison		Dedicated Medical Laboratory technologist for donor workup

7.0 WORKFLOW AND TAT PROTOCOLS

7.1 Pre-Transplant

Urgent Donor analysis and investigations:

ABO, HLA typing, Infectious screen, Crossmatch (CDC and Flow and Luminex)

Turnaround time (TAT): 6-8 hrs.

7.2 Post-Transplant Monitoring Schedule:

- **Day 0-30**

Daily Creatinine, Tacrolimus trough level, Complete Blood Count (CBC), Urine output analysis, Donor-Specific Antibody (DSA) - weekly

- **Month 1-12**

Creatinine, Therapeutic Drug Monitoring (TDM) twice weekly every weekly, BK Virus/Cytomegalovirus (CMV) – PCR, monthly.

- **Kidney biopsy if creatinine rises by more than 20% from baseline**

STAT histology within 24hr



8.0 QUALITY ASSURANCE AND ACCREDITATION

8.1 Internal QC

Levy-Jennings daily, Westgard rules

8.2 External Quality Assurance (EQA)

Participation in Proficiency Testing (PT); including KENAS, UK NEQAS for Histocompatibility and Immunogenetics (H and I) and Human Leukocyte Antigen (HLA)

8.3 Standard Operating Procedures (SOPs) – available for every assay per CLSI guidelines.

8.4 Accreditation - ISO 15189:2022 accreditation in 18 months, ASHI/EFI equivalent for HLA Medical Laboratory.

9.0 PHASED IMPLEMENTATION

9.1 Phase 1 (0-6 Months): Foundation

- Set up Chemistry, Hematology, Urinalysis, Serology, and Microbiology.
- Start dialysis support.
- Outsource HLA to reference Medical Laboratory.

9.2 Phase 2 (6-15 Months): Transplant Ready

Commission HLA Lab (Luminex and Flow), TDM by LC-MS/MS, Histopathology IF. Recruit HLA director. Validation and accreditation.

9.3 Phase 3 (15-24 Months): Advanced

NGS for high-res HLA, Biobank for research, Electron microscopy collaboration, live donor registry.

.....END.....

