



REPUBLIC OF KENYA  
MINISTRY OF HEALTH



# KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

## KMLTTB MANDATORY TESTING MENU FOR AUTOIMMUNE WORKUP

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

### QUALITY ASSURANCE SERVICES

|                                                                                    |                                                     |           |                                                                                                                                  |
|------------------------------------------------------------------------------------|-----------------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------|
|  | KMLTTB MANDATORY TESTING MENU FOR AUTOIMMUNE WORKUP |           | <b>DOCUMENT CONTROL</b><br><br>Serial:<br>KMLTTB/LABS/OUTO/IMMU/01<br><br>Version 001<br><br>Date: 2 <sup>ND</sup> JANUARY, 2026 |
|                                                                                    | OWNERSHIP                                           | REGISTRAR |                                                                                                                                  |



## INTRODUCTION

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, as stipulated under Cap 253A of the Laws of Kenya. The Board also provides government advisories on related matters, including the validation of in vitro diagnostics through Legal Notice No. 113 of 2011.

The Act gives the Board the responsibility of ensuring that students undertaking medical laboratory sciences (MLS) training and practising professionals acquire the desired knowledge and skills that are necessary for the delivery of medical laboratory services.

These standards will ensure the development of a robust human resource for health necessary to meet national and international health obligations that include sustainable development goals and universal health coverage. The implementation of these standards will no doubt contribute to achievement of the right to the highest attainable standard of health as outlined in the constitution of Kenya 2010 as well as achievement of Vision 2030. This shall be the hallmark of quality Healthcare and patient safety.

## 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.

## MANDATORY MEDICAL LABORATORY ANALYSIS INVESTIGATIONS FOR HAEMOPHILIA A AND B DIAGNOSIS AND MANAGEMENT IN KENYA

Aligned to MOH, Kenya Haemophilia Association, and WFH Guidelines for Management of Hemophilia 2023

This is the Minimum Mandatory Panel for diagnosis, treatment, monitoring and prevention. No Medical Laboratory facility Class C TO G should manage bleeding disorders without this framework. It is auditable by KMLTTB and should inform other institutions such as SHA to ensure Quality Health care and patient safety in the republic of Kenya.

**The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) regulates the scope of medical laboratory analysis and diagnostic testing based on a strict facility tiering schedule.** In Kenya, comprehensive investigations for complex conditions like autoimmune diseases are primarily designated for **Class C (which may be found in KMPDC**



**Level III/Health Centre/Medical Centres)** up to specialized high-tier reference and critical care Medical Laboratory facilities. Because no single Medical laboratory test definitively establishes an autoimmune diagnosis, KMLTTB mandates a strict framework combining generic baseline testing, advanced immunological assays, and stringent quality systems.

The following detailed framework covers the mandatory Medical laboratory analyses, testing menus, technologies, and regulatory requirements stipulated under the KMLTTB Guidelines.

## 1. Mandatory Testing Menu for Autoimmune Workup

KMLTTB separates testing capabilities by laboratory class. A facility investigating autoimmune diseases must offer a multi-tiered array of investigations:

### A. Baseline & Inflammatory Markers (Class B & C Requirements)

These tests evaluate overall systemic inflammation, cytopenias, or organ involvement associated with flares:

- a. **Total Blood Count (TBC) / Complete Blood Count (CBC):** To assess for autoimmune hemolytic anemia, leukopenia, or thrombocytopenia commonly seen in diseases like Systemic Lupus Erythematosus (SLE).
- b. **Peripheral Blood Film (PBF) Reporting:** Crucial for identifying schistocytes, spherocytes, or abnormal white cell morphology.
- c. **Erythrocyte Sedimentation Rate (ESR):** A key acute-phase reactant used to track disease activity.
- d. **C - reactive protein (CRP) Qualitative & Quantitative:** For monitoring acute inflammatory responses.
- e. **Rheumatoid Factor (RF):** Core screening test for Rheumatoid Arthritis.
- f. **Synovial Fluid Analysis:** Examining increased white blood cells to differentiate septic arthritis from autoimmune arthropathies.

### B. Advanced Immunological Studies & Serologies (Class C and Above)

To perform definitive autoimmune investigations, laboratories utilize specialized immunoassay configurations:



- a. **Antinuclear Antibodies (ANA):** Typically performed via indirect immunofluorescence (IIF) as a high-sensitivity screening test, or ELISA.
- b. **Anti-Extractable Nuclear Antigens (Anti-ENA panel):** Targeted follow-up testing following a positive ANA.
- c. **Anti-double-stranded DNA (anti-dsDNA):** High-specificity diagnostic marker for SLE.
- d. **Anti-Neutrophil Cytoplasmic Antibodies (ANCA):** Essential for diagnosing ANCA-associated vasculitides.
- e. **Complement Measurement (C3 and C4):**
- f. Quantified to monitor complement consumption during active immune complex-mediated disease.
- g. **Organ-Specific Autoantibodies:** Including Islet autoantibodies (GADA, IAA) for Type 1 Diabetes and thyroid antibodies for Graves/Hashimoto's.
- h. **C. Immunophenotyping & Genetic Studies**
  - i. **CD4/CD8 and CD45 Counts:** Evaluated via flow cytometry to assess cellular immune profiles and rule out primary immunodeficiencies mimicking or co-existing with autoimmunity.
  - j. **HLA Typing:** Genetic associations such as HLA-B27 (Ankylosing Spondylitis) or HLA-B51 (Behçet's disease).



## 2. KMLTTB Technology & Methodological Standards

As Per the KMLTTB classification schedule, Class C and specialized laboratories must be equipped with and validated to use advanced techniques to guarantee diagnostic precision:

| Technology Layer                       | Medical Application in Autoimmunity                                                |
|----------------------------------------|------------------------------------------------------------------------------------|
| Indirect Immunofluorescence (IIF)      | Gold standard screening for ANA and ANCA patterns.                                 |
| Chemiluminescence & Spectrophotometry  | Quantitative autoantibody and complement measurement (C3, C4, anti-dsDNA).         |
| Flow Cytometry                         | Cellular subsetting (CD4/CD8 ratios) and cytokine profiles.                        |
| Immunoagglutination / Hemagglutination | Rapid qualitative/semi-quantitative detection of Rheumatoid Factor.                |
| Digital Microscopy with AI             | Advanced automated reading of immunofluorescent patterns to limit technician bias. |

## 3. Regulatory compliance & Quality Framework

For a medical laboratory to officially operate and report these investigations in Kenya, it must fulfill structural mandates laid down by the board:

- 1. Reagent Validation and Registration:** All autoantibody kits, controls, and equipment must undergo **Conformity Assessment** and clinical evaluation. The facility must maintain a comprehensive **Technical Dossier** approved by KMLTTB before using any diagnostic reagent commercially.
- 2. Personnel Licensing:** Investigations can only be performed, analyzed, and signed off by validly licensed Medical Laboratory Technologists or Specialists registered under KMLTTB who have fulfilled continuous professional development (CPD) points.
- 3. Total Quality Management (TQM):** Laboratories are legally required to participate in External Quality Assessment (EQA) programs / Proficiency Testing specifically targeting serological markers (such as ANA and RF) and maintain rigid internal quality controls (IQC).
- 4. Reporting Limitations:** Results must state reference intervals. Per clinical consensus adopted by the board, laboratory data must explicitly act as diagnostic adjuncts rather than standalone screeners for asymptomatic unselected populations.

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

