



REPUBLIC OF KENYA  
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD  
KMLTTB MANDATORY STANDARDS FOR SPORTS/ATHLETICS MEDICAL LABORATORY ANALYSIS AND INVESTIGATIONS.

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

QUALITY ASSURANCE SERVICES

|  |                                                                                                 |           |                                                                                                                                   |
|--|-------------------------------------------------------------------------------------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------|
|  | KMLTTB MANDATORY STANDARDS FOR SPORTS/ATHLETICS MEDICAL LABORATORY ANALYSIS AND INVESTIGATIONS. |           | <b>DOCUMENT CONTROL</b><br><br>Serial:<br>KMLTTB/LABS/SPORTS/MED/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.

## MODEL STANDARD MEDICAL LABORATORY FOR A SPORTS/ ATHLETES FACILITY

This is the permanent Medical laboratory that should be available and remain at National and International Sports Centres in Kenya

Designation: KMLTTB Class F - Sports Reference Medical Laboratory with a Capacity of 300-500 tests/day | 24/7 during championships

## 1. BUILDING SPECIFICATION - LEGACY DESIGN

Space: 320 sqm total - must be ground floor with 2 entries - Athletes Entry (clean) and Sample/Waste Exit (dirty). No stairs.

Zone Layout per KMLTTB and ISO 15189:

**Zone 1 - Reception and Registration - 30sqm:**



Glass partitioned, barcode system, privacy for doping control, AC, intercom to team doctors, CCTV.

**Zone 2 - Phlebotomy and Sample Collection - 40sqm:**

5 phlebotomy chairs, 2 doping control washrooms with blue dye - WADA compliant - no running water lock, 2 emergency beds, handwash, biohazard bins. Direct pass-through window to Medical Laboratory.

**Zone 3 - Hematology and Blood Bank - 40sqm:**

Bench 1: Hematology analyzers, Microscope station. Bench 2: Blood grouping, cross-match, 2 Blood fridges, and emergency O-ve Blood stock 10 units from KNBTs.

**Zone 4 - Clinical Chemistry and Cardiac / Emergency Medical Laboratory - 45sqm:**

Main analyzers, POCT dock, cardiac markers. Closest to emergency room. Direct result screen to resuscitation bay.

**Zone 5 - Microbiology and Molecular - 35sqm:**

BSC Class II A2, incubator, PCR cabinet, GeneXpert for TB/Flu/COVID, culture benches. Negative pressure -30Pa.

**Zone 6 - Immunology and Endocrinology / Anti-Doping Support - 35sqm:**

Immunoassay, hormone testing, sample integrity testing - pH, specific gravity for urine - handover bench to ADAK.

**Zone 7 - Support - 60sqm:**

Store and 2-8C cold room 10sqm, -20C and -80C freezer room for biobank, autoclave room, waste holding, RO plant 100L/hr, 40KVA generator room and 20KVA UPS room.

**Zone 8 - Staff and QA - 35sqm:**

Medical Laboratory Manager Office with LIS server, QA office, staff changing with shower, toilet, tea room, document archive.

**UTILITIES:** 100KVA mains and 40KVA Perkins auto generator and 20KVA UPS 4hrs. Medical AC 6 x 24,000 BTU with HEPA. Intercom to Stadium Medical Centre. Starlink and fiber and 5G.



## 2. COMPLETE EQUIPMENT LIST –

## Fixed Medical Laboratory Grade

| S.No. | Section              | Equipment                             | Model Spec                                                        | Qty      |
|-------|----------------------|---------------------------------------|-------------------------------------------------------------------|----------|
| 1.    | Hematology           | 5-Part Diff Analyzer                  | Sysmex XN-350                                                     | 1        |
|       |                      | ESR Analyzer                          | Vesmatic Cube 200                                                 | 1        |
|       |                      | Coagulation Analyzer                  | Sysmex CA-540                                                     | 1        |
|       |                      | Microscope with camera                | Olympus CX43 and imaging                                          | 2        |
|       |                      | Centrifuge refrigerated               | Thermo Megafuge 8R                                                | 1        |
| 2.    | Clinical Chemistry   | Fully Auto Chemistry                  | Beckman Coulter AU480 - 400T/hr                                   | 1        |
|       |                      | Electrolyte Analyzer                  | Roche AVL 9180                                                    | 1        |
|       |                      | Radiometer                            | ABL90 FLEX                                                        | 1        |
|       |                      | POCT Backup                           | Abbott i-STAT Alinity x2                                          | 2        |
| 3.    | Cardiac              | Cardiac Immunoassay                   | Roche Cobas h232 - Troponin, NT-proBNP, D-Dimer                   | 1        |
| 4.    | Immunology / Hormone | Chemiluminescence Immunoassay Mindray | CL-1000i - Ferritin, Vit D, Cortisol, Testosterone, TSH, HCG, CRP | 1        |
|       |                      | FIA Meter                             | Finecare III Plus                                                 | 1 backup |
| 5.    | Micro / Molecular    | BSC Class II A2                       | Esco AC2-4S                                                       | 1        |
|       |                      | Incubator 37C and CO2                 | Memmert                                                           | 2        |
|       |                      | GeneXpert IV                          | Cepheid 4-module                                                  | 1        |
|       |                      |                                       | Bio-Rad CFX96                                                     | 1        |
|       |                      | Urinalysis Analyzer                   | Sysmex UC-3500                                                    | 1        |



|    |            |                                            |                                         |        |
|----|------------|--------------------------------------------|-----------------------------------------|--------|
| 6. | Blood Bank | Blood Bank Fridge and Platelet agitator    | Helmer                                  | 1 each |
|    |            |                                            | Gel Card Centrifuge and Incubator Ortho | 1      |
| 7. | General    | Autoclave 75L                              | Tuttnauer                               | 1      |
|    |            | Medical Fridges 300L and Freezers - 20/-80 | Philipp Kirsch                          | 3      |
|    |            | RO Water System                            | 100L/hr                                 | 1      |
|    |            | LIS and Barcode                            | LabWare and Zebra printers x3           | 1 set  |

### 3. REAGENTS - 1 Month Championship and Legacy Stock

For 5000 tests/month:

|              |                           |                                                                                                                         |                                         |
|--------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Chemistry:   | AU480 reagent kit         | ALT, AST, ALP, Bilirubin, Urea, Creatinine, CK total, CK-MB, LDH, Glucose, Protein, Albumin, Ca, Mg, Phos - 2 kits each | Calibrators, Controls L1/L2/L3 x 2 sets |
| Hematology:  | XN-350                    | Cellpack, Sulfolyser, Cellclean - 4 sets each                                                                           | Controls Low/Normal/High                |
| Cardiac:     | Troponin I HS x 300 tests | NT-proBNP x 200, D-Dimer x 200, Myoglobin x 100                                                                         |                                         |
| Coagulation: |                           | PT, APTT, Fibrinogen x 200 each                                                                                         |                                         |
| Immunology:  |                           | Ferritin x 500, Vitamin D x 500, Cortisol x 300, Testosterone x 300, CRP x 400, TSH x 200, HCG x 200                    |                                         |



|            |  |                                                                                                                                          |  |
|------------|--|------------------------------------------------------------------------------------------------------------------------------------------|--|
| Blood Bank |  | : Anti-A, Anti-B, Anti-D, AHG cards, Coombs, Panel cells x 2 sets                                                                        |  |
| Micro:     |  | Blood Agar, Chocolate, MacConkey plates - 20 each, Urine CandS kits, Malaria RDT 500, HIV/HBV/HCV 300 each, COVID/Flu PCR cartridges 300 |  |
| Molecular: |  | GeneXpert Flu/RSV, COVID cartridges 200, TB cartridges 100<br>Controls: Daily IQC mandatory, EQA - KENAS/WHO                             |  |

#### 4. CONSUMABLES - 1 Month with 50% Buffer

EDTA tubes 3000, Plain 3000, Heparin 1500, Citrate 500, Sodium fluoride 500, Butterfly 21G 500, Needles 21G 2000, Alcohol swabs 5000, Gloves 50 boxes, PPE kits 200, N95 500, Sharps 5L 30, Biohazard bags 500, Micropipette tips, Slides, Coverslips, Cuvettes, Printer paper, Barcode labels 10,000.

#### 5. MEDICAL LABORATORY EMERGENCY PREPAREDNESS

##### A. Mass Casualty / Stampede Protocol - Level 1

**Activate MCI mode:** Only 4 tests - Hb, Group and Cross-match, Glucose, Lactate. All other tests suspended.

- I. Blood bank release O-ve without cross-match if needed with physician signed release.
- II. 2nd shift on standby, Call tree: Medical Laboratory Manager -> County Medical Laboratory Coordinator -> KNBTs (Medical Laboratory).

##### B. Clinical Emergency Protocols



- I. Exertional Heat Stroke: ABG, lactate, Na, K, creatinine, CK every 2 hrs. until stable. Cold chain for ice bath saline.
- II. Sudden Cardiac Death: Troponin HS, NT-proBNP, D-Dimer, K, Mg, ABG - STAT 10 min. Direct line to Hospital Cath Laboratory.
- III. Convulsion / Status: Glucose, Na, Ca, Mg, ABG, CK, toxicology sample hold.
- IV. Anaphylaxis / Bleeding: Fibrinogen, PT/APTT, Hb.

#### **C. Public Health Emergency**

- I. Outbreak Control: PCR isolation room, triple packaging, rider to National reference Laboratory within 2 hrs. Immediate notification to County Disease Surveillance Coordinator.
- II. **Biobank:** All outbreak samples stored at -80C with Material Transfer Agreement.

#### **D. Anti-Doping Integrity**

- I. No doping assay done. Medical Laboratory only does Sample Integrity: pH, SG, visual. Samples sealed, stored at 2-8C <24hrs, handed to ADAK DCO with chain of custody form. Fridge with double lock and CCTV.

#### **E. Technical Resilience**

- I. Power: Mains -> Generator auto 10 sec -> UPS sustains analyzers. If failure >4hrs - switch to POCT.
- II. Water: RO and 1000L overhead tank.
- III. Equipment failure: Service contract with Laborex, Hightech, Philips - 2hr response during championships. Backup POCT for every critical test.
- IV. Supply chain: Linked to KEMSA and Nairobi Hospital buffer stock and direct distributor.

#### **F. Waste and Biosafety**

- a. Autoclave on-site, waste contract - NEMA licensed incinerator, waste manifest, daily incineration during championships.

#### **6. STAFFING - Medical Laboratory - 24/7**

Day Shift (07:00-19:00): 1 Medical Laboratory Manager - MSc, 2 Technologists - Chemistry/Hematology, 1 Technologist - Micro/Molecular, 1 Technologist - Blood Bank, 2 Technicians - Phlebotomy, 1 Data Officer, 1 Biosafety Officer, 1 Lab Assistant/Cleaner

Night Shift (19:00-07:00): 2 Technologists - 1 Chemistry/Hematology, 1 General, and 1 Technician

All must be KMLTTB licensed, BLS trained, SCAT6 aware.



## KMLTTB - MODEL STANDARD MEDICAL LABORATORY FOR A SPORTS/ ATHLETES FACILITY (MMLF)

### VEHICLE and INFRASTRUCTURE

Chassis: Mercedes Sprinter 519 CDI 4x4, LWB, High Roof, 190HP Diesel. Reinforced suspension for 3.5T lab load. Ground clearance 250mm for Kasarani field.

Conversion: Aluminium insulated sandwich panels, anti-bacterial vinyl floor, and 4-zone negative pressure gradient. Epoxy workbenches chemical resistant.

Power: 3 sources - 1) 10KVA Perkins Silent Generator 2) 1.2KW Solar and 10KWh Lithium bank 3) 32A CEE shore power and 5KVA Online UPS. Auto-changeover <10sec.

Utilities: 250L Fresh and 250L waste, RO water system 20L/hr, 18,000 BTU Medical Inverter AC with HEPA, 6x 13A sockets and USB, LED shadow less lights 500 lux.

**In Kenya, sports doping investigations fall under a stringent dual-regulatory framework.** While the Anti-Doping Agency of Kenya (ADAK) enforces compliance with the World Anti-Doping Agency (WADA) Prohibited List, any Medical laboratory operating within Kenyan borders to collect, process, or analyze human biological specimens must be legally licensed and regulated by the **Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB)**.

Per the KMLTTB Laboratory Classification Schedule, basic medical Laboratory (Class B) are strictly restricted to specimen collection centers or preliminary screeners. Definitive anti-doping analysis and advanced screening are reserved exclusively for **Class G (International Referral Laboratories)**, or specialized units operating under strict international reference standards.

Below is the comprehensive medical laboratory analysis matrix and administrative framework required for sports doping investigations in Kenya.

## 7. Mandatory Testing Menu & Analytes

Anti-doping analysis is divided into screening and definitive confirmation, targeting Blood, urine, or alternative matrices (such as dried blood spots):

### A. Hematological Profiling (Athlete Biological Passport - ABP)

Monitors the markers of blood manipulation, erythropoiesis-stimulating agents (ESAs), or autologous blood transfusions over time:



1. **Complete Blood Count (CBC) with Full Differential:** Tracking baseline parameters like Hemoglobin (Hb) and Packed Cell Volume (PCV/Hematocrit).
2. **Absolute Reticulocyte Count:** Highly critical marker; sudden fluctuations flag bone marrow manipulation or synthetic erythropoietin (EPO) use.
3. **OFF-HR Score Calculation:** An algorithmic metric matching Hb and Reticulocyte percentages to catch blood doping.

#### B. Urine & Plasma Screening for Prohibited Classes

1. **Anabolic Androgenic Steroids (AAS):** Detection of exogenous testosterone, nandrolone, stanozolol, and their metabolites. Includes measuring the urinary Testosterone/Epitestosterone (T/E) ratio.
2. **Peptide Hormones & Growth Factors:** Screening for Human Growth Hormone (hGH), Erythropoietin (EPO) analogues, Insulin-like Growth Factor-1 (IGF-1), and Chorionic Gonadotrophin (hCG).
3. **Beta-2 Agonists & Diuretics/Masking Agents:** Identification of substances used to rapidly flush the system or reduce weight (e.g., furosemide, hydrochlorothiazide).
4. **Stimulants, Narcotics, and Glucocorticoids:** In-competition detection of performance enhancers such as amphetamines, cocaine, morphine, and systemic corticosteroids.

## II. Required Methodological & Technological Standards

KMLTTB mandates that technologies utilized for doping analysis must yield legally defensible data capable of withstanding scrutiny in international sports arbitration courts:

| ANALYTICAL CATEGORY     | KMLTTB APPROVED TECHNOLOGICAL MODALITY                                                                                                                                                        |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Initial Broad Screening | High-Performance Liquid Chromatography (HPLC), Ultra-Performance Liquid Chromatography (UPLC), and advanced Automated Immunoassays.                                                           |
| Definitive Confirmation | Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS). These provide the necessary molecular fingerprinting to eliminate false positives. |
| Isotope Ratio Analysis  | Gas Chromatography-Combustion-Isotope Ratio Mass Spectrometry (GC-C-IRMS) to conclusively differentiate natural (endogenous) steroids from synthetic (exogenous) counterparts.                |



|                          |                                                                                                                                   |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Protein & Hormone Assays | Isoelectric Focusing (IEF) and Polyacrylamide Gel Electrophoresis (PAGE) to distinguish endogenous EPO from recombinant variants. |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------|

### III. Strict Quality, Legal, and Chain-of-Custody Framework

Since doping investigations lead to legal sanctions, KMLTTB outlines uncompromising quality and security protocols:

1. **Watermarked Chain-of-Custody (CoC):** From the exact minute of sample collection (Split into Sample A and Sample B), every single handling Medical laboratory professional must sign a tamper-evident, legally binding custody log.
2. **Sample Integrity Matrix:** Before analysis, Medical laboratories must record urine specific gravity, pH, and sample temperature. Samples failing these baseline tests are flagged for potential athlete tampering.
3. **Specific B Code Personnel Licensing:** The physical extraction, batch execution, and analysis of anti-doping specimens can only be done by KMLTTB-licensed Medical Laboratory Professional who hold accredited specialized certifications in Forensic Toxicology or Advanced Mass Spectrometry.
4. **Quarterly Quality Returns and Double-Blind EQA:** The facility must submit exhaustive validation data to KMLTTB quarterly. It must maintain dual proficiency testing enrollment, complying with both WADA EQAS (External Quality Assessment Scheme) and KMLTTB-monitored local proficiency criteria.

The **Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB)** serves as a crucial partner in maintaining standards, anti-doping integrity, and medical diagnostic excellence for Kenyan athletes.

1. **Integrity in Sports Diagnostics & Anti-Doping:** Emphasizing the vital role of accredited medical laboratory practitioners in conducting clean, accurate, and uncompromised testing for local and international athletes to ensure sports integrity.
2. **Capacity Building and CPD Accreditation:** Highlighting the importance of sports medicine as an emerging niche for laboratory professionals. The KMLTTB Online Portal continuously coordinates Continuous Professional Development (CPD) points to ensure practitioners stay compliant with modern diagnostic technology in sports Medicine.
3. **Standards and Regulation Compliance:** KMLTTB reaffirms its strict stance on ensuring that sports-related diagnostics are handled exclusively by registered and licensed Medical Laboratory professionals using Scientifically validated kits and reagents.



4. **Inter-Agency Collaboration:** Strengthening partnership models between the Kenya Medical Laboratory Technicians & Technologists Board (KMLTTB) and sports administrators like **NOC-Kenya** to protect athlete well-being, injury prevention, and medical fitness tracking.

For a long time Kenyans have celebrated athletes who are physically fit. This standard reminds us that physical fitness without medical fitness is a risk.

An athlete should have available Medical Laboratory services so as to be screened, tested, cleared, monitored, and protected - before, during and after competition.

It is not just about winning. It is about safe participation, longevity of careers, and clean sport. This is where the medical laboratory becomes the gatekeeper of fitness.

## 2. What does medically fit sports men and women mean in the Medical Laboratory?

As KMLTTB - the regulator of medical laboratory practice in Kenya - medical fitness is not a guess. It is a verifiable Medical laboratory result.

We define a medically fit athlete through:

- a) **Pre-Participation Medical Examination (PPME):** Every athlete must have documented baseline Medical laboratory work ups - Full Haemogram, Sickle Cell status, Blood Group, Renal and Liver function, Fasting Glucose, HbA1c, Lipid profile, Urinalysis, and for endurance athletes, Cardiac biomarkers and ECG correlation.
- b) **Infection and Risk Screening:** HIV, Hepatitis B/C, and other infectious screens for contact sports, with strict confidentiality and counseling as per our ethical code.
- c) **Female Athlete Health:** Hemoglobin, Ferritin, Vitamin D, Hormonal profile and Relative Energy Deficiency in Sport (RED-S) assessment. We cannot have our champions collapsing from preventable anemia.
- d) **Clean and Safe Sport:** Integrity of samples for anti-doping, Therapeutic Use Exemptions (TUE) verification, and supplement contamination screening. A medically fit athlete is a clean athlete.

No clearance should be given without quality-assured Medical laboratory evidence.



### 3. The Quality Standard Behind Medically Fit

Medically fit decision is only as good as the Medical laboratory that produced it.

At KMLTTB we enforce:

- A. **ISO 15189 Aligned Testing:** Every lab supporting NOC-K activities must be licensed, use validated SOPs for pre-analytical, analytical and post-analytical phases, and maintain traceability.
- B. **Competency, Not Just Qualification:** No trainee or unlicensed personnel will handle athlete samples. We require logbook verification and direct supervision until competency is signed off.
- C. **IQC and EQA:** Daily internal quality control with Westgard rules, and mandatory External Quality Assessment. KMLTTB shall not allow a false negative or false positive to end a career.

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

