



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB MANDATORY STANDARDS FOR SPORTS 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 MEDICAL LABORATORY ANALYSIS AND INVESTIGATIONS		DOCUMENT CONTROL Serial: KMLTTB/LABS/SPORTS/MED/01 Version 001 Date: 2 ND JANUARY, 2026
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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.

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 C (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.

I. 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, Sick 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.....

