REPUBLIC OF KENY
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB REGULATORY POLICY, FRAMEWORK, AND GUIDELINES ON IVDs POST MARKET SURVAILANCE

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

KMLTTB QUALITY ASSURANCE SERVICES

	REGULATORY POLICY, FRAMEWORK, AND GUIDELINES ON IVDs POST MARKET SURVAILANCE		DOCUMENT CONTROL Serial KMLTTB/QAS/PMS-CPD/01 Version 001 Date: 11TH NOVEMBER, 2026
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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

Pursuant to the **Medical Laboratory Technicians and Technologists Act, CAP 253A of the Laws of Kenya**, the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) establishes TRAINING STANDARDS which are a comprehensive regulatory framework. This standard governs medical laboratory operations for the diagnosis, treatment, clinical management, treatment monitoring, and prevention of all diseases, within the Republic of Kenya.

The main goal of the MLS services is to ensure provision of safe, professional, competent and ethical Medical Laboratory Services in accordance to Cap 253A of the Laws of Kenya.

The **Standards for Medical Laboratory Services in Food and Nutrition Diseases** is one of the guidelines prepared by the KMLTTB prescribing mandatory clinical practice and competencies professionals shall practice in the course of their duty.

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.

REGULATORY POLICY FRAMEWORK AND GUIDELINES ON CONFERMENT OF CONTINUING PROFESSIONAL DEVELOPMENT (CPD) POINTS FOR QUARTERLY POST-MARKET SURVEILLANCE (PMS) REPORTS OF IN VITRO DIAGNOSTICS (IVDs)

1.0 POLICY STATEMENT AND RATIONALE

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1.1 Background

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is mandated under **Cap 253A of the Laws of Kenya** to regulate the training, practice, business, and employment of medical laboratory professionals, and to validate In Vitro Diagnostics (IVDs) under **Legal Notice No. 113 of 2011**. While pre-market validation ensures IVDs meet performance standards before entering the Kenyan market, continuous **Post-Market Surveillance (PMS)** is essential to detect lot-to-lot variations, reagent degradation, unauthorized kits, and adverse diagnostic events across clinical facilities.

1.2 Policy Objective

This policy establishes a structured framework to incentivize, standardize, and enforce quarterly IVD market surveillance reporting by **County Medical Laboratory Coordinators (CMLCs)** and **Medical Laboratory Superintendents (MLSs)** nationwide. In recognition of the technical rigor required for surveillance, compliant practitioners shall be conferred **five (5) CPD points per verified quarterly submission** (up to **20 CPD points annually**) toward their mandatory annual 50-point licensure renewal requirement.

2.0 STATUTORY AND REGULATORY ALIGNMENT

This framework operates pursuant to and in harmony with:

A. **The Medical Laboratory Technicians and Technologists Act (Cap 253A)** — General supervision and control over Medical laboratory practice and quality assurance.
B. **Legal Notice No. 113 of 2011** — Regulations governing the validation and authorization of medical laboratory equipment and reagents.
C. **The Medical Laboratory Technicians and Technologists (CPD) Regulations:** Classification of structured work-based learning, quality audits, and regulatory reporting as credit-bearing professional activities.
D. **ISO 15189:2022 and ISO 13485** — Standards for medical laboratory quality management and post-market vigilance.

3.0 SCOPE AND ELIGIBILITY

3.1 Eligible Cadres

Conferment of the five (5) quarterly CPD points applies strictly to:

A. **Medical Laboratory Superintendents (MLSs):** Registered and licensed practitioners officially designated to oversee technical operations, quality management, and regulatory compliance in public, private, or faith-based medical laboratories (Classes B–G).
B. **County Medical Laboratory Coordinators (CMLCs):** Designated officers responsible for coordinating diagnostic services, commodity security, and regulatory oversight within any of the 47 Counties.

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3.2 Conditions for Eligibility

To qualify for CPD point conferment, the applicant must:

A. Hold a **valid KMLTTB registration and active annual practicing license** for the reporting year.
B. Be formally registered in the KMLTTB Portal as the designated Superintendent of a licensed laboratory or verified as a CMLC.
C. Submit a complete, accurate, and verifiable **Quarterly IVD Post-Market Surveillance Report** within the stipulated statutory timelines.

4.0 ROLES AND RESPONSIBILITIES

4.1 Medical Laboratory Superintendents (Facility Level)

A. **Routine Surveillance:** Monitor daily internal quality control (IQC), external quality assessment (EQA) trends, reagent lot performance, and cold-chain integrity at the facility level.
B. **Verification of Authorization:** Ensure all IVDs, rapid diagnostic tests (RDTs), and analyzers in use bear a valid **KMLTTB Validation Certificate**.
C. **Incident Documentation:** Log all kit failures, false-positive/false-negative clusters, packaging defects, or expired/unregistered products in the facility Occurrence Register.
D. **Quarterly Reporting:** Compile and submit the Facility Quarterly IVD PMS Report via the KMLTTB Online Portal, with a copy routed to the respective CMLC.

4.2 County Medical Laboratory Coordinators (County Level)

A. **County-Wide Aggregation and Spot Audits:** Consolidate facility-level PMS reports across the county and conduct random market sweeps of public, private, and point-of-care testing (POCT) sites.
B. **Supply Chain Vigilance:** Track distributor compliance, batch recalls, and distribution of unauthorized IVDs within county borders.
C. **Escalation of Critical Alerts:** Immediately flag severe diagnostic failures (e.g., compromised HIV, Malaria, TB, Blood Transfusion, or VHF test kits) to KMLTTB within 24 hours.
D. **Quarterly Synthesis Report:** Submit the County Consolidated IVD Market Surveillance Report to KMLTTB

4.3 KMLTTB Quality Assurance and CPD Directorate

A. **Technical Review:** Audit submitted quarterly reports for completeness, data integrity, and actionable intelligence.

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B. **Regulatory Enforcement:** Initiate product recalls, distributor sanctions, or laboratory inspections based on surveillance findings.
C. **CPD Conferment:** Credit **5 CPD points** to the verified practitioner's KMLTTB CPD profile upon report approval.

5.0 REPORTING STANDARDS AND MANDATORY REPORT STRUCTURE

To qualify for the **5 CPD points**, a quarterly report must be submitted using the standardized **Form KMLTTB/PMS/IVD/01** and contain the following mandatory sections:

S.NO	SECTION	REQUIRED CONTENT AND TECHNICAL METRICS
1.	Administrative Metadata	Practitioner Name, KMLTTB Registration and License Number, Facility Name/License No. (for MLS) or County Name (for CMLC), and Reporting Quarter
2.	IVD Inventory and Validation Audit	Complete list of active IVDs/reagents in use or circulation, manufacturer/local distributor details, lot/batch numbers, expiry dates, and **KMLTTB Validation Certificate numbers**.
3.	Analytical Performance and QC Trends	Summary of IQC shifts/trends, EQA performance scores, invalid test rates (e.g., RDT control line failures), and sensitivity/specificity anomalies
4	Adverse Events and Non-Conformances	Detailed log of defective batches, cold-chain breaches, mislabeling, suspected counterfeit/unvalidated kits, and patient safety incidents.
5.	Corrective and Preventive Actions (CAPA)	Immediate containment actions taken (e.g., batch quarantine, vendor notification, repeat patient testing) and recommendations to KMLTTB.
6.	Attestation and Evidence	Signed declaration by the MLS/CMLC accompanied by supporting annexes (QC charts, batch photos, delivery notes, or quarantine logs).

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6.0 SUBMISSION TIMELINES AND CONFERMENT WORKFLOW

6.1 Quarterly Reporting Calendar

Reports must be submitted strictly within **fourteen (14) days** following the close of each calendar quarter:

A. **Quarter 1 (Jan – Mar):** Due on or before **14th April**
B. **Quarter 2 (Apr – Jun):** Due on or before **14th July**
C. **Quarter 3 (Jul – Sep):** Due on or before **14th October**
D. **Quarter 4 (Oct – Dec):** Due on or before **14th January**

6.2 Step-by-Step Conferment Process

A. **Digital Submission:** The MLS or CMLC logs into the KMLTTB Online Portal, selects *Post-Market Surveillance Reporting*, and uploads the completed report and supporting evidence.
B. **Automated Acknowledgment:** The system generates a timestamped Submission Tracking Number.
C. **Technical Vetting (Days 1–10 post-deadline):** KMLTTB Quality Assurance Officers evaluate the report against a standardized scoring rubric (minimum pass threshold: **70%** completeness and technical validity).
D. **Clarification Window (If Applicable):** If a report is incomplete, the officer issues a digital query; the practitioner has **5 working days** to rectify and resubmit.
E. **CPD Credit Conferment (Within 15 working days):** Upon approval, the system automatically posts **5 CPD Points** under Category 1 (*Work-Based Learning and Regulatory Quality Assurance*) to the practitioner's KMLTTB CPD Ledger and issues a downloadable digital CPD Certificate.

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7.0 GOVERNANCE, COMPLIANCE, AND SANCTIONS

7.1 Zero-Report Mandate

If a facility or county experiences zero IVD defects or adverse events during a quarter, the MLS or CMLC **must still submit a "Nil Defect Report"** accompanied by the routine IVD validation inventory and QC summary to earn the 5 CPD points.

7.2 Grounds for Rejection of CPD Points

KMLTTB shall withhold CPD conferment if:

A. The report is submitted after the 14-day grace period without prior written extension from the Registrar.
B. Data is plagiarized, copied from a previous quarter, or fabricated.
C. The practitioner's KMLTTB practicing license is expired or suspended.

7.3 Disciplinary Provisions

Knowingly falsifying surveillance data or concealing critical IVD failures that endanger public health constitutes professional misconduct under **Cap 253A** and shall attract disciplinary proceedings, including license suspension, fines, or facility closure.

8.0 MONITORING, EVALUATION, AND POLICY REVIEW

A. **Annual Impact Audit:** KMLTTB shall publish an annual *National IVD Post-Market Surveillance Bulletin* summarizing national diagnostic quality trends, recalled products, and county compliance rankings.
B. **Review Cycle:** This policy framework shall be reviewed every **two (2) years** by the KMLTTB Quality Assurance and Standards Committee, or earlier as necessitated by emerging diagnostic technologies and statutory amendments.

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