



REPUBLIC OF KENYA

MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

**KMLTTB TRAINING CURRICULUM AND MANUAL FOR VERIFICATION AND
VALIDATION OF IVDS FOR AUTHORIZATION IN KENYA**

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

	KMLTTB TRAINING CURRICULUM AND MANUAL FOR VERIFICATION AND VALIDATION OF IVDS FOR AUTHORIZATION IN KENYA		DOCUMENT CONTROL SERIAL: KMLTTB/VAL/TRN/MANU/01 Version: 001
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KMLTTB TRAINING CURRICULUM AND MANUAL FOR VERIFICATION AND VALIDATION OF IVDs FOR AUTHORIZATION IN KENYA

1.0 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 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.

2.0 MANUAL STRUCTURE

Compliance: ISO 15189:2022 | KMLTTB Standards

2.1 Quality Policy and Objectives

This is pursuant to Cap 253A, Legal Notice No. 113 of 2011, and The Medical Laboratory (Equipment and Reagents Validation) Regulations and KMLTTB Procedure KMLTTB/VER/VAL/PROCEDURE/01

2.2 PART A: Core Manual Text

Module 1: Quality Management System and ISO 15189:2022

Objective – To ensure technical competence and ethical patient care.

All training Medical laboratories operate under ISO 15189:2022 management and technical requirements. Quality Manual defines 12 QMS essentials.

Module 2: Documented Quality Policy

Quality Manual, Organogram Chart, Job Descriptions, Document Control Procedure

Versioning, Approval, Distribution, Retention (5 years)

Module 3: Phase-Specific SOPs

Trainees must follow Standard Operating Procedures (SOPs) for entire testing cycle/process; Pre-analytical, Analytical, Post-analytical. No step should be skipped.

Module 4: Internal Quality Control (IQC) and Proficiency Testing (PT)/EQA

IQC

- Daily for two (2) levels.
- Plot on Levey-Jennings.
- Apply Westgard multi-rules: 1-2s, 1-3s, 2-2s, R-4s, 4-1s, 10x
- Corrective action log (mandatory)

EQA



- Monthly blind samples
- Processed with certified staff

Module 5: Training Standards

KMLTTB approved curriculum with milestones Mentorship - 1:5 supervisor to trainee ratio.

Direct supervision until Phase 4 clearance. Independent testing or result release before competency verification is prohibited

Module 6: Assessment and Verification

4-Phase Model

- Phase 1 Knowledge – Written quiz minimum of 50%
- Phase 2 Observation – Trainer demonstration walkthrough
- Phase 3 Practice – Supervised testing, IQC/EQA handling
- Phase 4 Verification – Direct observed practical, logbook sign-off, and independent clearance this Includes; Critical value communication <30 min, Biosafety personal protective equipment (PPE) audit, Annual re-assessment.

2.3 PART B: SOP Library - 15 Core SOPs

SOP No	Title
SOP 001	Document Control and Quality Manual Management
SOP 002	Personnel Training, Roles and Competency
SOP 003	Specimen Collection, Identification and Transport
SOP 004	Specimen Reception, Rejection and Storage
SOP 005	Analytical Testing – Hematology
SOP 006	Analytical Testing – Clinical Chemistry
SOP 007	Analytical Testing – Microbiology
SOP 008	Analytical Testing – Histopathology
SOP 009	Internal Quality Control and Westgard Rules
SOP 010	External Quality Assessment and Proficiency Testing
SOP 011	Critical Value and STAT Reporting
SOP 012	Biosafety, PPE and Waste Management
SOP 013	Internal Audit and Non-conformity Management
SOP 014	Logbook Maintenance and Verification
SOP 015	Equipment Calibration and Maintenance

SOP Template for each:

1. Purpose
2. Scope
3. Responsibilities/Authorization



4. Materials
5. Procedure (step-by-step)
6. Quality Checks
7. Safety
8. References
9. Revision History

Example SOP 009; Steps include Run controls, Plot, Interpret Westgard, if 1-3s fail STOP, Investigate, Correct, Document, and Rerun.

2.4 PART C: Annex Templates

Annex 1: Trainee Logbook

Date	Department	Test Performed	Specimen ID	Supervisor Initials	Remarks

Annex 2: Competency Assessment Form

Trainee: Module:

Criteria:	Knowledge 25%,	Technical skill 25%,	IQC/EQA 20%,	Biosafety 15%,	Communication 15%
Score:					
Pass/Fail					
Assessor; Name and Sign KMLTTB Reg. No.					

Annex 3: IQC Levey-Jennings Chart Template

Test:		
Lot:		
		Rule violation column
Mean:		
SD:		
Daily values table		
Chart area		



Annex 4: EQA / Blind Sample Log

1.	Sample ID	
2.	Date Received	
3.	Results (Trainee)	
4.	Results (Medical Laboratory)	
5.	Concordance Y/N	
6.	Corrective Action	

Annex 5: Critical Value Communication Log

1.	Test	
2.	Critical Value	
3.	Notified To	
4.	Time Detected	
5.	Time Notified	
6.	Notified By	

Annex 6: Internal Audit Checklist

Area:		
1.	Training adherence	
2.	SOP compliance	
3.	PPE	
4.	Documentation	
5.	Logbook	
6.	NC Y/N	
7.	Evidence	

Annex 7: Non-conformity & Corrective Action Report (NCAR)

1.	Description	
2.	Root Cause	
3.	Correction	
4.	Preventive Action	
5.	Closed by Date	



Annex 8: Direct Observation of Practical Skills (DOPS)

1.	Procedure observed	
2.	Steps done correctly	
3.	Errors	
4.	Global Rating	

Annex 9: Mentorship Supervision Record

1.	Week	
2.	Goals	
3.	Activities	
4.	Feedback	
5.	Supervisor Sign	

3.0 CURRICULUM DOCUMENT

KMLTTB Training Curriculum and Manual for Verification and Validation of IVDs for Authorization in Kenya

Title: Certified Training on Verification and Validation of In Vitro Diagnostics (IVDs) for Market Authorization in Kenya

Owner: Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) - Quality Assurance Services

Target Cadre: Registered Medical Laboratory Technologists, Laboratory Managers/Directors, Quality Assurance (QA) Officers, IVD Evaluators working in KMLTTB-recognized Validation Laboratories.

Pre-requisite: Diploma/Higher Diploma/BSc or MSc in Medical Laboratory Sciences, valid KMLTTB practicing license, one (1) year experience in Clinical Chemistry, Hematology, Microbiology, Virology, Mycology, Parasitology, Blood Transfusion Science, Histopathology, Clinical Cytology, Immunology or any other speciality recognised by KMLTTB through registration and licensure.

Course Duration:

40 Hours Theory (5 days residential) 24 Hours Practicum in designated Validation Medical Laboratory

3 Months Supervised Field Assignment (1 IVD Dossier)



Overall Goal:

To build capacity of Medical Laboratory professionals to conduct scientifically valid verification and validation of IVDs to confirm safety, efficacy, quality and economic value before authorization for use in Kenya, as required under Section 5(e), 25(2) (a) and 40(d) of Cap 253A.

Learning Outcomes: By end, learner will be able to:

1. Differentiate verification vs validation as per KMLTTB and ISO 15189:2022
2. Interpret manufacturer claims: precision, accuracy, linearity, sensitivity, specificity
3. Design and execute CLSI-based verification/validation protocols
4. Analyze performance data and make authorization recommendation
5. Prepare a KMLTTB-compliant Validation Report and Dossier

4.0 MODULE BREAKDOWN**MODULE 1 – Regulatory Framework for IVDs in Kenya (4 Hrs.)**

Role of KMLTTB, Cap 253A and Equipment and Reagents Validation Regulations:

definition of equipment, reagents, validation Procedure

KMLTTB/VER/VAL/PROCEDURE/01 and Application Form

KMLTTB/APL/ML/IVD/VAL/01

Categories of IVDs: Class A-D per GHTF/IMDRF risk

Ethics and penalties for illegal validation

MODULE 2: Fundamentals – Verification vs Validation (4 Hrs.)

- Verification – Confirming manufacturer claims in your Medical laboratory (CLSI EP15-A3, EP05)
- Validation – Establishing performance for novel, modified, or off-label IVDs (ISO 15189:2022 clause 5.3.2.3)

When to verify, when to validate, when to do both

MODULE 3: Analytical Performance Characteristics (6 Hrs.)

- Precision – Repeatability, intermediate precision (EP05-A3, 20x2x2 protocol)
- Accuracy/Trueness – Comparison with reference method/material (EP09-A3)
Linearity, Measuring interval (EP06)
- Detection capability – LoB, LoD, LoQ (EP17-A2)
- Diagnostic sensitivity, specificity, PPV, NPV (EP12, EP24) Interference, cross-reactivity, stability and carry-over
- Equipment – wavelength, resolution, linearity, voltage, workload, environmental stability



MODULE 4: Pre-Analytical Requirements for Validation Lab (4 Hrs.)

KMLTTB Inspection Checklist KMLTTB/VALIDATION/LAB/01, ISO 15189, ISO 15190
Biosafety, ISO 23640 stability, ISO 18113 labeling

Sample management: reference panels, negative/positive, traceability

Documentation: SOPs, package size, labeling, batch numbers scribd.com

MODULE 5: Designing the Verification/Validation Protocol (6 Hrs.)

Writing objective, scope, acceptance criteria Sample size calculation (CLSI, WHO/TDR)
Statistical plan

Template: KMLTTB Protocol Template

MODULE 6: Practical Execution (24 Hrs. Medical Laboratory Practicum)

Exercise 1: Verification of HIV Rapid Kit (sensitivity/specificity vs gold standard)

Exercise 2: Verification of Automated Chemistry Analyzer (precision, linearity, method comparison)

Exercise 3: Validation of new Malaria RDT - full performance

Data capture in Excel / MedCalc / SPSS

MODULE 7: Data Analysis and Interpretation (4 Hrs.)

CV%, SD, Bland-Altman, Passing-Bablok, Cohen's Kappa, ROC curves

Establishing if acceptance criteria met

Dealing with non-conformance

MODULE 8: Reporting and Dossier for Authorization (6 Hrs.)

Structure of Final Validation Report per KMLTTB Certificate of Validation - duration, batch vs equipment relevance

Rejection handling and CAPA

Post-market surveillance and lot verification scribd.com

MODULE 9: Quality Management and Professionalism (2 Hrs.)

QMS, document control, data integrity

Professional conduct during validation³.

5.0 TRAINING MANUAL OUTLINE FOR FACILITATORS

Each module in the Manual should contain:

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1. Session Plan: Objectives, Time, Method (Lecture, Demo, Group Work)
2. Content Notes: Detailed notes
3. CLSI Guideline Quick Reference Table
4. Performance Claim
5. CLSI Guideline
6. Minimum Sample Requirement
7. Precision EP05-A3 / EP15-A3 20 days x 2 runs x 2 replicates
8. Accuracy
9. EP09-A340 patient samples across range
10. Linearity
11. EP06-Ed27-11 levels, duplicate
12. LoB/LoDEP17-A260 blank + 60 low-level samples
13. Sensitivity/Specificity
14. EP12-A2 / EP24

WHO recommends 250 positive / 250 negative for HIV

Standard Templates (Annexes):

Annex 1: IVD Verification Protocol Template

Annex 2: Sample Size Calculator

Annex 3: Raw Data Sheets

Annex 4: Final Validation Report Template (aligned to KMLTTB/VER/VAL/PROCEDURE/01)

Annex 5: Medical Laboratory Inspection Readiness

Checklist4. ASSESSMENT & CERTIFICATION

- a) Formative: 40% (Medical Laboratory practicum logs) Summative: 60% (Written exam + Dossier defense)
- b) Pass mark: 70% (KMLTTB CPD standard)
- c) Certification: KMLTTB Certificate of Competence as IVD Evaluator + 20 CPD points
- d) On successful completion, participant can be co-opted into KMLTTB validation Medical laboratory team via Form KMLTTB/APL/ML/IVD/VAL/01

6.0 IMPLEMENTATION PLAN

Week 1: Residential training

Week 2-3: Medical Laboratory practicum at 3 KMLTTB-designated Medical laboratories

Month 2-4: Each trainee conducts 1 real IVD verification under mentorship and submits to KMLTTB for review



Annex 10: Document Control Master List

Doc No | Title | Version | Effective Date | Owner | Location

Annex 11: Annual Competency Reassessment Form

Same as Annex 2 + Previous NC closure review

Annex 12: Independent Clearance Certificate

The CLSI EP17-A2 consensus standard provides the formal guidelines used by clinical laboratories and IVD manufacturers to establish and verify the detection capabilities of quantitative measurement procedures. It defines three distinct lower-end performance thresholds

- Limit of Blank (LoB).
- Limit of Detection (LoD),
- Limit of Quantitation (LoQ)

The three thresholds progressively answer different analytical and clinical questions.

The differences between these three vital metrics, their mathematical calculation according to the **EP17-A2 protocol**, and their clinical significance are detailed below.

The Three Lower Performance Thresholds

Metric	Core Question Answered	Definition	Statistical Determination Basis
LoB <i>(Limit of Blank)</i>	Is there background noise?	The highest apparent analyte concentration expected when a sample containing no analyte is tested.	95th percentile of replicate measurements on blank samples (5% false-positive risk).
LoD <i>(Limit of Detection)</i>	Is the analyte actually present?	The lowest concentration that can be reliably distinguished from the LoB and detected.	Concentration at which the analyte is truly present and detected 95% of the time (5% false-negative risk).
LoQ <i>(Limit of Quantitation)</i>	What is the actual concentration?	The lowest concentration at which the analyte can be measured with an acceptable, predefined precision/accuracy.	Determined via precision profiles, often targeting an intermediate precision CV $\leq 20\%$.



EP17-A2 Mathematical Calculations

The limits are hierarchical and stack upwards along the concentration axis: $LoB < LoD \leq LoQ$.

1. Limit of Blank (LoB)

If the distribution of blank measurements is normal (Gaussian), the parametric equation is used:

$LoB = \text{blank} + 1.645 \text{ times sigma blank}$

Where blank is the mean and sigma blank is the standard deviation of blank replicates. The multiplier 1.645 represents the 95th percentile of a one-tailed normal distribution, accepting a 5% Type I error (false positive).

Note: If the blank data shows floor effects or skewed distributions, a non-parametric percentile method must be substituted.

2. Limit of Detection (LoD)

The LoD builds upon the LoB by adding a buffer that handles the statistical dispersion of true low-concentration samples:

The second multiplier of 1.645 accounts for a 5% Type II error (false negative), confirming a 95% detection success rate.

- **LoD (Limit of Detection)**

The smallest amount of analyte in a sample that can be detected, though not necessarily quantified as an exact value.

- **LoB (Limit of Blank)**

The highest apparent analyte concentration expected to be found when replicates of a blank sample (containing no analyte) are tested. It is typically calculated as:

$LoB = \text{blank} + 1.645 \text{ times sigma \{blank\}}$

- **1.645**

The multiplier derived from the standard normal distribution corresponding to a **95% confidence limit** (one-tailed test, where $\alpha = 0.05$ and $\beta = 0.05$).

- **Sigma low sample**

The pooled standard deviation of repeated measurements from samples with a known, minimal concentration of the analyte.

Conceptual Relationship

The relationship between the blank distribution and the low-concentration sample distribution ensures two critical statistical protections:

- **Type I Error (alpha = 0.05)**

A 5% maximum probability of falsely claiming a substance is present when it is actually absent (False Positive).

- **Type II Error (beta = 0.05)**

A 5% maximum probability of failing to detect the analyte when it is actually present at the LoD level (False Negative).

Comparison of Laboratory Analytical Limits

Limit	Definition	Purpose	Key Inputs
Limit of Blank (LoB)	Highest apparent signal expected from analyte-free samples.	Defines the noise threshold.	Mean and SD of blank replicates.
Limit of Detection (LoD)	Lowest concentration reliably distinguished from the LoB.	Confirms presence vs. absence.	LoB and SD of low-concentration samples.
Limit of Quantitation (LoQ)	Lowest concentration measured with acceptable bias and precision.	Confirms reliable quantitative value.	Total analytical error budget.

3. Limit of Quantitation (LoQ)

Unlike LoB and LoD, which are constrained by statistical noise boundaries, the **LoQ is bounded by clinical utility goals** (Total Error or Precision limits). It requires running a panel of low-level samples to chart a precision profile.

- The LoQ is defined as the concentration where the assay achieves the target precision threshold (e.g., Coefficient of Variation $\leq 20\%$).
- Under **CLSI EP17-A2**, the LoQ can be equivalent to the LoD if the precision goals are met exactly at the detection point, but it can never be lower than the LoD ($LoQ \geq LoD$).

Study Requirements for Validation

To establish these values under CLSI Guidelines:

- **Blanks**

Minimum of 60 replicates (e.g., 3 lots $\times$ 4 replicates $\times$ 5 days) using true matrix blank materials.

- **Low-Level Samples**

Minimum of 60 replicates of native, low-concentration patient pools spanning the expected detection cutoff

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

