REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

OVERVIEW OF THE OFFICIAL KMLTTB IVD VERIFICATION & VALIDATION TRAINING PROTOCOL

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

KMLTTB QUALITY ASSURANCE SERVICES

	OVERVIEW OF THE OFFICIAL KMLTTB IVD VERIFICATION & VALIDATION TRAINING PROTOCOL		DOCUMENT CONTROL Serial: KMLTTB/VERI/VAL/IIVD/01 Version 002 Date: 2ND SEPTEMBER, 2026
	OWNERSHIP	REGISTRAR	

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Overview of the Official IVD Verification & Validation Training Protocol

The generated document provides an exhaustive, structurally rigorous framework tailored for the **Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB)** to train laboratory professionals and govern operations within accredited validation medical laboratories.

The protocol incorporates standard guidelines (such as CLSI and ISO 15189) adapted to the regulatory context of Kenya. It is divided into the following key sections:

I. **Purpose & Scope:** Establishes the regulatory mandate for IVD evaluation, covering all rapid diagnostic tests (RDTs), molecular testing, point-of-care testing (POCT) systems, and automated analyzers within Kenya.

II. **Conceptual Separation (Verification vs. Validation):** Provides an explicit educational breakdown distinguishing between *Verification* (confirming a manufacturer's claims for pre-cleared, WHO-prequalified, or FDA/CE-approved tests) and *Validation* (proving performance for novel, laboratory-developed, or modified tests).

III. **Core Evaluation Parameters & Statistical Metrics:** A detailed, scannable matrix defining the technical criteria, mandatory benchmarks, and statistical evaluation approaches for:
   a. Diagnostic Sensitivity and Specificity
   b. Precision (Repeatability & Reproducibility via 20-day nested designs)
   c. Analytical Sensitivity (Limit of Detection)
   d. Analytical Specificity & Interference Testing (Confounders like bilirubin, lipids, hemolysate)
   e. Linearity & Dynamic Range (Regression Coefficient $R^2 \geq 0.98$)

IV. **Step-by-Step Validation Workflow:** An operational 8-phase timeline mapping out the validation lifecycle:
   a. *Phase I to III:* Administrative review, Personnel Competency Logs, and Environmental Monitoring.
   b. *Phase IV to V:* Panel selection (characterized bio-specimens/ATCC strains) and Wet-Bench Runs.
   c. *Phase VI to VIII:* Discrepant Resolution pathways (e.g., PCR/Sequencing arbitration), Biostatistics, and a mandatory **10-year archival data retention policy**.

V. **Biosafety, Quality Control, and Ethical Considerations:** Sets mandates for physical bio-containment (BSL-2/BSL-3), institutional review board (IRB/ERC) patient de-identification approvals, and Internal Quality Control (IQC) execution.

VI. **Reporting Structure & Technical Templates:** Standardizes the final dossier layout required for submission to the board.

VII. **Institutional Sign-Off Authority:** Incorporates formal signature blocks for the Lead Validation Officer, Laboratory Technical Director, and the **KMLTTB Registrar / CEO** to grant official market authorization.

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"For any IVD targeting HIV, Malaria, or TB, the validation team shall not accept any manufacturer claim that falls below the current Kenyan MoH clinical management thresholds. If the validation cohort yields a lower 95% confidence interval boundary below the defined national benchmark, the device shall be flagged as ***'Not Recommended for Routine Clinical Deployment'*** *and escalated to the KMLTTB Board for regulatory review."*

KMLTTB Advanced Competency Assessment: IVD Verification & Validation Protocol

Under ISO 15189 standards, what is the fundamental regulatory and procedural distinction between the verification and the validation of an in vitro diagnostic (IVD) examination procedure?

A.
Verification applies exclusively to qualitative molecular tests, whereas validation applies only to quantitative clinical chemistry assays.

B.
Validation is performed internally by the clinical laboratory for unmodified commercial assays, while verification is performed exclusively by the regulatory body (KMLTTB).

C.
Verification confirms that a commercial, unmodified assay meets the manufacturer's claimed performance specifications in the user's environment, whereas validation establishes performance characteristics for laboratory-developed or substantially modified assays.

D.
Verification requires a 20-day dual-run protocol, whereas validation requires only a single-day proficiency panel run.

Show hint
Consider who originally established the performance specifications of the assay being tested and whether the assay has undergone any modifications or is being used entirely off-label.

Field / Requirement Log Details & Verification Criteria	
Trainee Name	_____
KMLTTB Registration No.	_____ (Must hold a valid annual practicing license)
Laboratory / Facility	_____

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Assigned IVD System	**Equipment / Kit Name:** _____
Theoretical Assessment	Passed Interactive Competency Quiz above (Minimum Score: **80%**)
Wet-Bench Evaluation	Successfully completed 5 blind panel runs with 100% expected concordance.
Pipetting & Safety Audit	Verified correct usage of BSL-2/3 safety cabinets and micro-pipette calibration.

Official Training Sign-Off

I. **Trainer / Validation Lead:** I certify that the candidate has demonstrated full technical competence according to the KMLTTB protocol.
   a. *Signature:* _____ | *Date:* ____/____/2026

II. **Laboratory Director:** Authorized to perform independent IVD validations.
   a. *Signature:* _____ | *Date:* ____/____/2026

🎯 High-Burden Disease Diagnostic Benchmarks

MINIMUM ACCEPTANCE THRESHOLDS		
Disease / Assay	Diagnostic Sensitivity	Diagnostic Specificity
HIV 1/2 RDTs	≥ 99.5%	≥ 98.5%
HIV Viral Load	≥ 95.0% (at 1000 copies)	≥ 99.0%
Malaria RDTs	≥ 95.0% (at 200 p/µL)	≥ 98.0%
TB Molecular	≥ 90.0% (Overall Smear-)	≥ 98.0%
Arbovirus IgM/IgG	≥ 90.0%	≥ 95.0%

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- Disease-Specific Wet-Bench Validation Requirements

I. **HIV 1/2 Diagnostic Assays (Serology & Molecular)**

II. **Regulatory Context:** Follows the KMLTTB -approved Medical Laboratory testing services.

III. **Rapid Diagnostic Tests (RDTs):**

a. **Sensitivity Benchmark:** ≥ 99.5% (Lower confidence limit ≥ 98.0%).

b. **Specificity Benchmark:** ≥ 98.5% (Lower confidence limit ≥ 97.0%).

c. **Panel Requirement:** Minimum **200 true positive** and **200 true negative** well-characterized plasma/serum samples.

IV. **Molecular Viral Load (VL) & Early Infant Diagnosis (EID):**

a. **Analytical Sensitivity (LoD):** Must reliably detect ≤ 50 copies/mL for plasma.

b. **Linearity Range:** 1.0×10^2 to 1.0×10^7 copies/mL ($R^2 \geq 0.98$).

c. **Cross-Reactivity Challenge:** Must prove zero cross-reactivity against Hepatitis B (HBV), Hepatitis C (HCV), and elevated rheumatoid factor.

2. Malaria Diagnostic Assays (RDTs & Microscopy)

I. **Regulatory Context:** Aligned with the KMLTTB and National MOH targets for elimination.

II. **Antigen-Detecting RDTs (HRP2 / pLDH):**

a. **Sensitivity Benchmark:** ≥ 95.0% for *Plasmodium falciparum* samples with parasite densities **≥ 200 parasites/µL**.

b. **Specificity Benchmark:** ≥ 98.0% against non-malaria febrile illness controls.

c. **Panel Requirement:** 100 confirmed *P. falciparum* positives, 50 *P. vivax/ovale/malariae* (if validating multi-species kits), and 100 febrile negative controls.

d. **Prozone Effect Challenge:** Must include at least 5 high-density samples (>100,000 parasites/µL) to rule out false negatives caused by hook/prozone effects.

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3. Pulmonary Tuberculosis (TB) Assays

I. **Regulatory Context:** Driven by the KMLTTB/ MOH

II. **Molecular/NAAT Platforms (e.g., GeneXpert, Truenat):**

a. **Sensitivity Benchmark (Smear Positive):** ≥ 98.0%

b. **Sensitivity Benchmark (Smear Negative, Culture Positive):** ≥ 70.0% to ≥ 90.0% (Target threshold for upgrading molecular networks).

c. **Specificity Benchmark:** ≥ 98.0% against non-tuberculous mycobacteria (NTM).

d. **Drug-Resistance Marker Validation (Rifampicin/Isoniazid):** Validation panels must contain at least **30 genotypically confirmed resistant strains** to verify mutation detection accuracy.

4. Emerging Arboviruses (Dengue, Chikungunya, Zika)

I. **Regulatory Context:** Outbreak response guidelines for endemic coastal, western, and urban areas (e.g., Mombasa, Mandera, Nairobi).

II. **Serological Assays (IgM/IgG ELISA or RDT):**

a. **Sensitivity Benchmark:** ≥ 90.0% during the convalescent phase (>7 days post-onset).

b. **Specificity Benchmark:** ≥ 95.0%

c. **Cross-Reactivity Challenge (Critical):** Due to high structural homology, the validation panel **must** explicitly include cross-reactivity sub-panels containing:

i. Yellow Fever vaccine-induced antibodies

ii. West Nile Virus positive sera

iii. Rheumatoid Factor (RF) positive sera (to check for false IgM positives)

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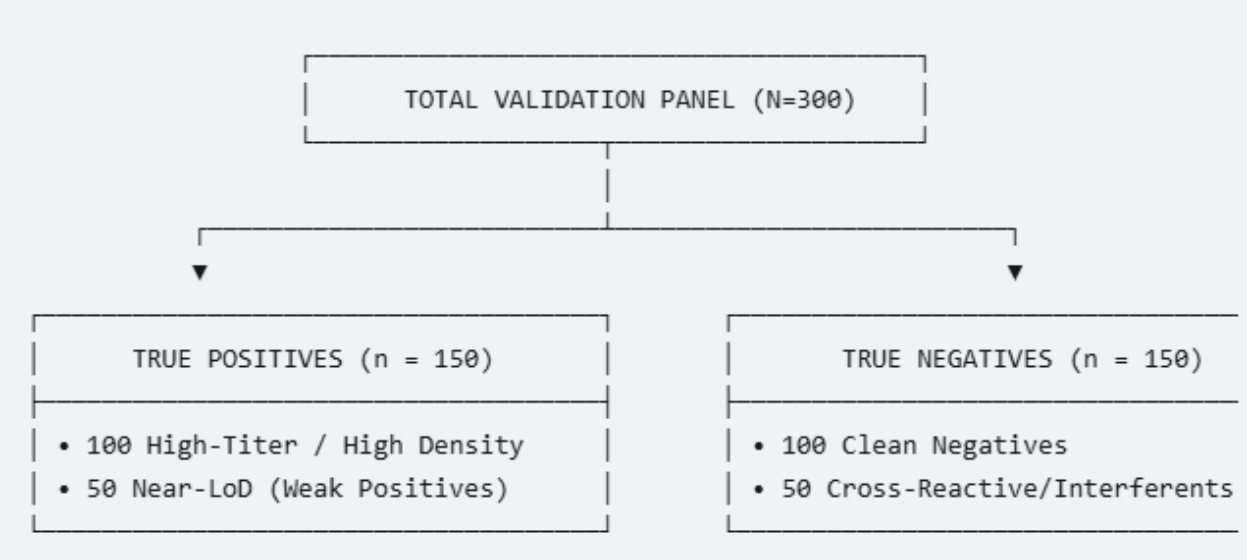
📊 Validation Panel Composition Guide for Trainees

When setting up a wet-bench validation run under KMLTTB oversight, trainees must construct their evaluation panel using a **nested reference grid**:



📝 Modified Action Item for the KMLTTB Report Dossier

Spreadsheet Architecture and Calculation Guidance

Because standard CSV (Comma-Separated Values) files store flat text and do not preserve live, functional macros or formatting across different software environments, this file acts as a structured blueprint. It includes dedicated sections for metadata tracking, a **2x2 contingency matrix table**, and explicit instructions for setting up your calculations.

To make the sheet live and automate the math within Microsoft Excel, Google Sheets, or Libre Office Calc, follow these formulas after opening the file:

1. Basic Performance Metrics

Set up your 2x2 table cells such that your raw counts are stored in specific cells (e.g., cell B19 for True Positives, B20 for False Positives, B21 for False Negatives, and B22 for True Negatives). Use these spreadsheet formulas:

I. **Diagnostic Sensitivity:** =B19 / (B19 + B21)

II. **Diagnostic Specificity:** =B22 / (B22 + B20)

III. **Positive Predictive Value (PPV):** =B19 / (B19 + B20)

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IV. **Negative Predictive Value (NPV):** =B22 / (B22 + B21)

2. Implementing the Wilson Score 95% Confidence Interval (CI)

The Wilson Score interval is highly recommended over the traditional Wald (Asymptotic) method for clinical validations. It does not break down at extreme values (near 0% or 100% sensitivity/specificity), which are common in high-burden disease testing (e.g., HIV diagnostic kits).

For a calculated proportion \(p\) (e.g., Sensitivity) and total trials \(n\) (e.g., Total Diseased, \(TP + FN\)), using a standard critical \(Z\)-value of **1.96** for a 95% confidence level, program these advanced formulas into your spreadsheet cells:

I. **Lower Bound Formula:**

= ((p + (1.96^2 / (2 * n))) - 1.96 * SQRT ((p * (1 - p) / n) + (1.96^2 / (4 * n^2)))) / (1 +

(1.96^2 / n))

II. **Upper Bound Formula:**

= ((p + (1.96^2 / (2 * n))) + 1.96 * SQRT ((p * (1 - p) / n) + (1.96^2 / (4 * n^2)))) / (1 +

(1.96^2 / n))

Excel Workbook Architecture & Live Implementation

The generated workbook has been meticulously structured using python code to serve as an authoritative, audit-ready validation tool for **KMLTTB-accredited medical laboratories**. It features a **Classic Navy** high-contrast corporate layout designed to align with strict laboratory documentation standards.

The workbook is split into two primary operational worksheets:

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1. Worksheet: Validation Dashboard

This is the primary analysis sheet where performance statistics are dynamically computed based on your raw wet-bench matrix input.

I. **Administrative Profile (Rows 4–10):** Structured spaces for inputting data regarding the laboratory facility, target pathogen, kit lot tracking, reference standards, and the responsible validation officer.
II. **Contingency Matrix (Rows 12–17):** A live 2x2 table tracking raw counts for **True Positives (TP)**, **False Positives (FP)**, **False Negatives (FN)**, and **True Negatives (TN)**. The marginal totals are completely automated via standard mathematical =SUM () formulas.
III. **Automated Wilson Score 95% CI Engine (Rows 19–26):** Contains live cells pre-programmed with nested formulas to calculate point estimates alongside the lower and upper statistical limits of the **Wilson Score Interval** simultaneously.
IV. **KMLTTB Quality Status Flag (Column F):** Integrates live logic checking (=IF ()) comparing point estimates against Kenyan Ministry of Health targets. It dynamically yields a **PASS** or **FAIL** notification based on the high-burden diagnostic thresholds established during our protocol tailoring (e.g., flagging any HIV screening assay whose point sensitivity dips below 99.5%).

2. Worksheet: Raw Data Log

This sheet is dedicated to logging live patient/specimen entries during wet-bench evaluation runs.

I. **Specimen Tracing Variables (Columns A–D):** Collects details like Unique Specimen IDs, patient demographics, and the biological matrix source (e.g., Plasma, Serum, Whole Blood).
II. **Diagnostic Cross-Referencing (Columns E–F):** Logs the raw, explicit qualitative answers generated by the Reference Standard and the Candidate IVD.
III. **Concordance Classification Automation (Column G):** Utilizes an advanced nested string formula to parse input pairs and automatically classify the specimen into its diagnostic quadrant:

=IF (AND (E4="Positive", F4="Positive"),"True Positive", IF (AND (E4="Negative", F4

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```
=IF(AND(E4="Positive",F4="Positive"),"True Positive",
IF(AND(E4="Negative",F4="Negative"),"True Negative",
IF(AND(E4="Negative",F4="Positive"),"False Positive", "False Negative")))
```

Use code with caution.

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This string classification directly matches the requirements needed to feed the 2x2 matrix dashboard via standard =COUNTIF () queries.

🚀 Next Steps to Advance Your Protocol Implementation

If you want to expand this automated training system, let me know if you would like to:

1. Integrate **built-in VBA macros or advanced data validation rules** that automatically protect cell formulas from being altered or corrupted by lab technicians during field audits.
2. Develop a **graphical summary component** (e.g., instructions for drawing point/whisker plots to visually graph the 95% confidence intervals).
3. Draft a written **Standard Operating Procedure (SOP)** that outlines the step-by-step procedure for troubleshooting a **FAIL** evaluation tag on the dashboard.
   Develop a graphical summary component (e.g., instructions for drawing point/whisker plots to visually graph the 95% confidence intervals
   📊 Visualizing 95% Confidence Intervals (Wilson Score)

   To visually report validation data to the **KMLTTB Board**, point estimates must be presented with their surrounding uncertainty bounds. A standard bar chart is insufficient because it hides the margin of error at the extremes.

   Instead, clinical trials utilize a **Point/Whisker Plot** (also called a Forest Plot variant) to graph the calculated value against national minimum acceptance thresholds.

🛠️ Step-by-Step Construction in Microsoft Excel

Since Microsoft Excel does not have a native "Forest Plot" template, you can construct a clean, publication-ready Point/Whisker chart using **Custom Error Bars** and a **2D Scatter Plot**.

Phase 1: Set Up the Graph Data Table

In a new area of your spreadsheet (or on a dedicated summary sheet), create a helper table structured exactly like this:

Metric (Y-Axis Label)	Value (X-Axis Position)	Y-Value (Spacing)	Minus Error (Left Whisker)	Plus Error (Right Whisker)
Diagnostic Sensitivity	=B19 *(Point value)*	2	=B19 - B20 *(Point - Lower Bound)*	=B21 - B19 *(Upper Bound - Point)*

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Diagnostic Specificity	=B23 *(Point value)*	$_1$	=B23 - B24 *(Point Lower Bound)*	- =B25 - B23 *(Upper Bound - Point)*

I. **Why Y-Value Spacing?** Giving Sensitivity a 2 and Specificity a 1 plots them on separate horizontal tracks, stacking them neatly over each other.

II. **Phase 2: Insert the Scatter Plot**

1. Highlight your data in the **Value** and **Y-Value** columns.
2. Go to the top ribbon and select **Insert → XY (Scatter) →** Choose **Scatter with Only Markers** (no lines connecting the dots).
3. Right-click the chart area, choose **Select Data**, and click **Edit** on your data series.
   I. Set **X values** to your point estimates (Value column).
   II. Set **Y values** to your vertical tracking numbers (Y-Value column).

Phase 3: Add the Horizontal Confidence Whiskers

1. Click on one of the plotted data dots inside your chart.
2. Go to the **Chart Design** tab at the top ribbon → Click **Add Chart Element** (far left).
3. Hover over **Error Bars** and select **More Error Bars Options...**
4. Excel will automatically add both vertical and horizontal lines. Clean this up by clicking on the **Vertical Error Bars** and hitting **Delete** on your keyboard.
5. Click on the remaining **Horizontal Error Bars** to open the formatting side pane:
   a. Under **Direction**, select **Both**.
   b. Under **End Style**, select **Cap** (creates the clean vertical boundary lines).
   c. Under **Error Amount**, click the radio button for **Custom**, then click **Specify Value**.

II. A small dialog window will pop up with two input fields:
   a. Clear the **Positive Error Value** field and highlight your calculated **Plus Error** cells.
   b. Clear the **Negative Error Value** field and highlight your calculated **Minus Error** cells.
   c. Click **OK**.

Phase 4: Format and Polish for the KMLTTB Dossier

I. **Fix the X-Axis Limits:** Right-click the horizontal axis → **Format Axis**. Change the **Minimum** bound from 0.0 to 0.90 (or 90%). This zooms the graph in on the critical performance window, making small confidence intervals visible.

II. **Clean Up the Y-Axis:** Delete the numerical Y-axis gridlines. Use **Data Labels** or insert manual text boxes next to the tracks labeled **"Diagnostic Sensitivity"** and **"Diagnostic Specificity"**.

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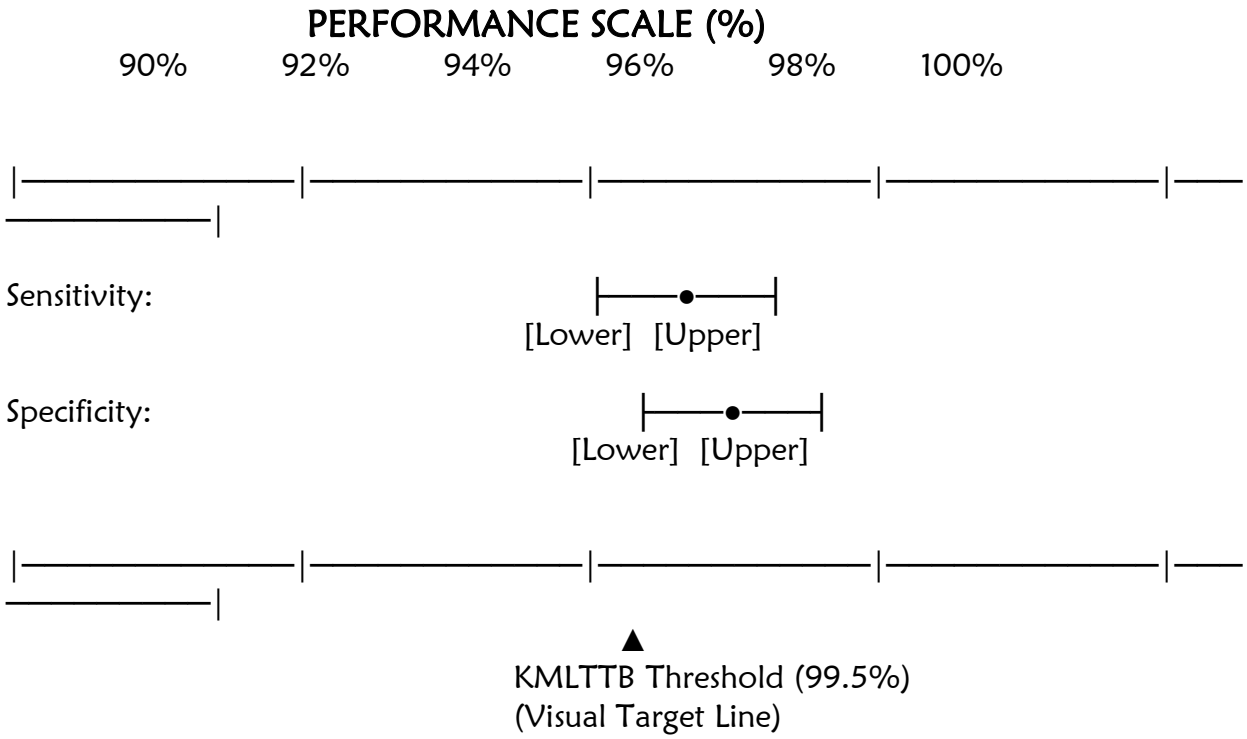
Once constructed, your final visualization provides an instant overview of clinical acceptability:



🛡 **Compliance Inspection Rules:**

1. **Passing Assay:** The entire point **and its left whisker** sit completely to the right of the vertical national threshold marker line.
2. **Failing Assay:** Even if the center point (●) is above 99.5%, if the left whisker extends across the line into the lower percentage zone, the sample size was too small or the variance was too high.
   The assay fails the audit.

Section: Quality Assurance

STANDARD OPERATING PROCEDURE (SOP): MANAGING METHOD VALIDATION FAILURES & UNACCEPTABLE STATISTICAL CONFIDENCE INTERVALS

1. PURPOSE

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This Standard Operating Procedure (SOP) defines the mandatory corrective actions and diagnostic investigation pathways required when an In Vitro Diagnostic (IVD) medical device fails to meet the performance criteria authorized by KMLTTB. Specifically, it addresses scenarios where the point estimate or the **Lower Bound of the 95% Wilson Score Confidence Interval (the left whisker)** crosses below the defined national regulatory threshold.

2. SCOPE

I. This SOP is legally binding for all Medical laboratory personnel, validation officers, quality managers, and Medical laboratory technical directors operating within KMLTTB-accredited, authorized, or licensed validation medical laboratories in Kenya. It applies to all validation and verification evaluations for:

II. Rapid Diagnostic Tests (RDTs)
III. Molecular Diagnostics / NAAT (e.g., PCR, GeneXpert)
IV. High-throughput automated clinical analyzers
V. Point-of-Care Testing (POCT) devices

3. RESPONSIBILITIES

I. **Validation Officer / Medical Laboratory Technologist:** Executes the wet-bench testing, inputs raw data, constructs the Point/Whisker plot, identifies failures, and immediately ceases testing upon confirmation of an out-of-specification (OOS) statistical event.
II. **Laboratory Quality Manager:** Logs the formal Non-Conformance (NC), initiates the Root Cause Analysis (RCA) portfolio, locks affected electronic master spreadsheets, and ensures the quarantine of candidate validation test kits.
III. **Laboratory Technical Director:** Reviews the final RCA report, signs off on the corrective actions, and formally communicates the validation failure or re-testing request to the KMLTTB Registrar/CEO.

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4. TECHNICAL OPERATIONAL WORKFLOW

[WHISKER CROSSES FAILURE THRESHOLD]
|
▼
[PHASE I: IMMEDIATE HALT & LOCK]
• Stop validation runs.
• Freeze master spreadsheets & log files.
• Quarantine all candidate IVD reagents.
|

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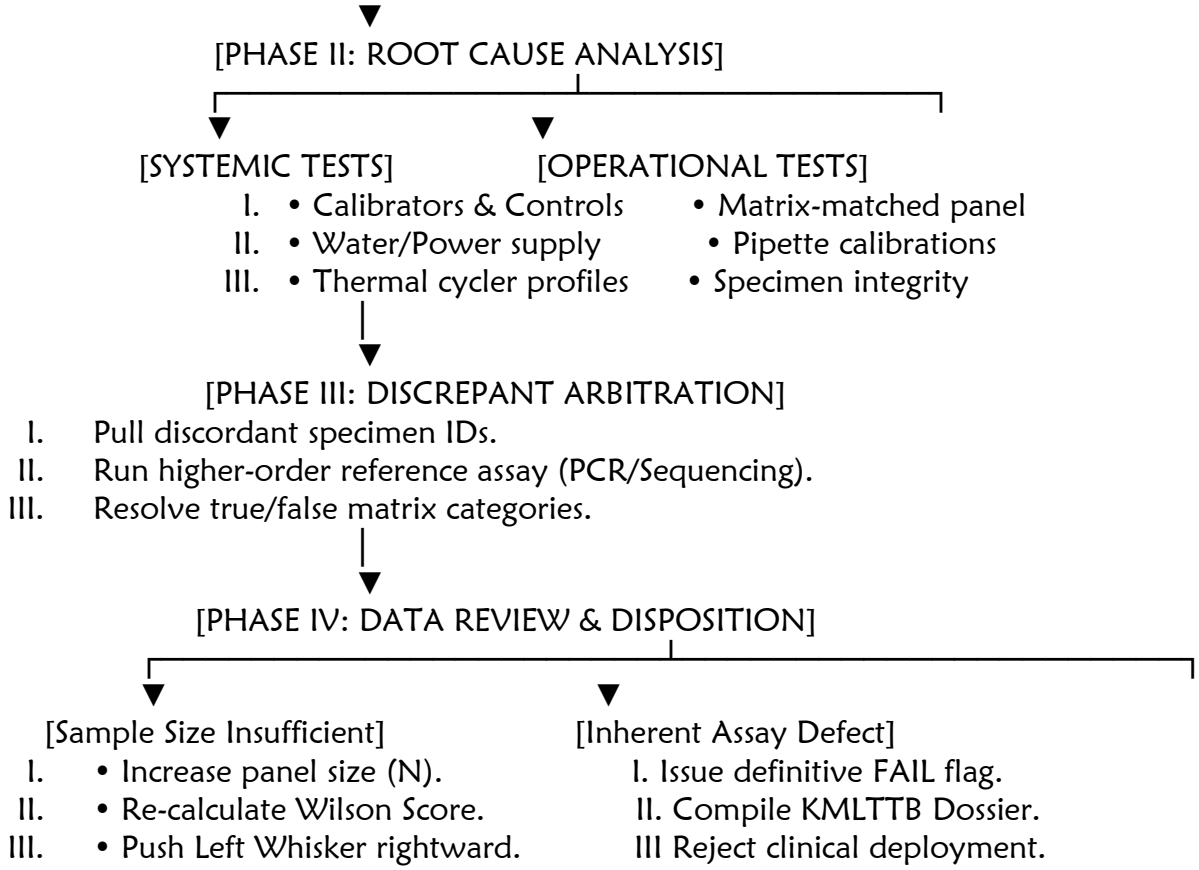

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5. DETAILED PROCEDURAL STEPS

PHASE I: IMMEDIATE HALT AND QUARANTINE

I. **Trigger Condition:** If the lower boundary line (left whisker) of the 95% Wilson Score confidence interval for Diagnostic Sensitivity or Diagnostic Specificity falls below the mandated national threshold (e.g., <98.0% for HIV sensitivity), the evaluation must be flagged as **OOS (Out-of-Specification)**.

II. **Cease Operations:** Stop all ongoing wet-bench runs associated with the candidate device immediately. No further clinical samples or evaluation panel specimens may be processed.

III. **Data Lock:** Lock the electronic data repository sheet (KMLTTB_IVD_Wilson_Score_Validator.xlsx) to prevent unauthorized entries or manual overwriting of automated =IF () failure flags.

IV. **Physical Quarantine:** Place all remaining candidate IVD test kits, chips, cartridges, or reagents into a dedicated quarantine cold chain storage unit labeled: **"CAUTION: FAILED VALIDATION PROTOCOL – DO NOT USE FOR CLINICAL TESTING."**

PHASE II: INITIAL TECHNICAL ROOT CAUSE ANALYSIS (RCA)

The Quality Manager must convene an investigation team within **24 hours** to complete the KMLTTB RCA Checklist across two primary pillars:

A. Operational & Environmental Variables

I. **Pipetting Calibration:** Verify the calibration certificates of all micro-pipettes used in sample preparation. Perform an immediate gravimetric calibration check if manual pipetting was involved.

II. **Cold Chain Integrity:** Extract the continuous temperature log data for both the specimen storage freezers and the candidate reagent refrigerators. Check for any temperature spikes outside the manufacturer's instructions for use (IFU).

III. **Operator Competency Log:** Cross-reference the operator's KMLTTB registration and internal training assessment logs to rule out unauthorized or uncertified personnel errors.

2. Systemic Analyzer Variables

I. **Thermal Cycling Calibration:** For molecular amplification platforms (PCR), extract the optical and thermal calibration logs to rule out edge-effect failures or baseline cycler drift.

II. **Water & Power Quality:** Check the resistance log of the laboratory's deionized/distilled water purification system. Verify that the Uninterruptible Power Supply (UPS) did not experience micro-surges during the validation runs.

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PHASE III: SPECIMEN INTEGRITY & DISCREPANT ARBITRATION

I. **Identify Discordant Entries:** Isolate the precise Specimen Tracking IDs from the Raw Data Log that generated the "False Positive" or "False Negative" classifications.
II. **Matrix Evaluation Check:** Audit the extracted serum/plasma/whole-blood samples for signs of severe hemolysis, icterus, or lipemia that could cause optical or chemical interference.
III. **Reference Standard Verification:** Re-test the discordant specimens using a higher-order, gold-standard alternative method (e.g., if a candidate Malaria RDT yielded a discordant result against routine microscopy, arbitrate using quantitative nested Polymerase Chain Reaction [PCR]).
IV. **Update Matrix:** If the arbitration protocol confirms that the initial reference standard result was incorrect, update the 2x2 matrix dashboard accordingly. If the reference standard was correct, the candidate IVD's failure status stands.

PHASE IV: DATA EXTENSION VS. ASSAY REJECTION

The investigation team must determine if the left whisker violation is due to a small sample size or an inherent biological defect in the assay.

Scenario A: Sample Size Insufficiency (Wide Confidence Interval)

I. **Indication:** The point estimate meets the threshold (e.g., Sensitivity = 99.6%), but the left whisker crosses below the threshold because the total sample size (\(N\)) was too small, widening the statistical margin of error.
II. **Corrective Action:** With authorization from the Technical Director, expand the validation panel by adding a minimum of **50 well-characterized, near-LoD weak positive samples** and **50 true negatives**.
III. **Re-evaluation:** Re-run the expanded panel and recalculate the Wilson Score. The increased denominator (\(n\)) will shrink the interval, pulling the left whisker rightward into the passing zone if the assay is truly high-performing.
IV. **Scenario B: Inherent Assay Defect (Failed Point Estimate)**
V. **Indication:** The center point estimate itself falls below the national threshold, or the left whisker remains in the failure zone despite an expanded, statistically robust panel.
VI. **Corrective Action:** Terminate the evaluation permanently. The Quality Manager will compile the final non-conformance portfolio.

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6. DOCUMENTATION & MANDATORY KMLTTB ESCALATION

I. **Log Non-Conformance:** Register the incident in the laboratory master quality ledger within 48 hours of failure detection.
II. **Dossier Preparation:** Complete the *KMLTTB Comprehensive IVD Validation Rejection Form*, attaching the raw data logs, the failed Point/Whisker visualization, and the completed Root Cause Analysis file.
III. **Board Notification:** Submit the official dossier electronically and via registered post to the **KMLTTB Registrar / CEO** at the Board Headquarters in Nairobi.
IV. **Archival Mandate:** Retain all raw data files, physical printouts, calibration traces, and arbitration logs in the laboratory's secure quality archive for a minimum statutory period of **10 years** from the date of the failure log.

7. ASSOCIATED REFERENCE DOCUMENTS

I. **KMLTTB-IVD-M-001:** National Framework for In Vitro Diagnostics Verification & Validation Protocols.
II. **ISO 15189:2022:** Medical Laboratories — Requirements for Quality and Competence (Clause 7.3: Verification and Validation of Methods).
III. **CLSI EP05-A3:** Evaluation of Precision Performance of Quantitative Measurement Procedures.

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8. SOP APPROVAL AND SIGN-OFF BLOCKS

Role	Name	Signature	Date
Prepared By:			
KMLTTB Quality Manager	_____	_____	____/____/202..
Reviewed By:			
Validation Technical Director	_____	_____	____/____/202..
Authorized By:			
KMLTTB Validation officer	_____	_____	____/____/202..

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