REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS & TECHNOLOGIST BOARD
Make Testing a Safe Reality

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB REGULATORY POLICY ON POINT OF CARE TESTING (POCT)

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

KMLTTB QUALITY ASSURANCE SERVICES

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD *Make Testing a Safe Reality*	KMLTTB POLICY ON POINT OF CARE TESTING (POCT)		*DOCUMENT CONTROL* Serial: KMLTTB/POCT/POLICY/01
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A. KMLTTB REGULATORY POLICY ON POINT OF CARE TESTING (POCT)

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

Professional practice in the health sector requires consistent and ongoing commitment from all concerned with lifelong learning in order to update and develop the knowledge, skills and ethical attitudes that underpin competent practice. This perspective protects the public interest and promotes the health of all members of the Kenyan society.

Guided by the principle of beneficence, medical laboratory Sciences profession aspire to standards of excellence in health care provision and delivery.

KMLTTB policy on Point of Care Testing (POCT) is primarily governed by standards.

B. Core KMLTTB Standards

The national framework for POCT quality and competence is anchored by two primary ISO standards:

i. **ISO 15189:2022**: This is the overarching standard for medical laboratories. The latest 2022 revision now directly incorporates requirements for POCT, superseding the previously separate ISO 22870.

ii. **ISO 22870:2016**: Formerly the specific standard for POCT, it is now being phased out as its requirements (governance, quality assurance, and training) are integrated into the revised ISO 15189.

C. KMLTTB Guidelines & "ASSURED" Criteria

For National health and infectious disease control, KMLTTB mandates that POCT to follow the **ASSURED** criteria to be effective in resource-limited settings:

i. **A**ffordable

ii. **S**ensitive

iii. **S**pecific

iv. **U**ser-friendly

v. **R**apid and robust

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vi. **Reagents and E**quipment- Use of invitro diagnostics 0(IVDs) that are scientifically validated and verified in approved medical laboratories.

vii. **D**eliverable to end-users

D. Key Policy Principles

Medical laboratory sciences professional bodies, such as the AKMLA, AKMLS and MLSK, emphasize several primary principles for POCT policy:

i. **Medical laboratory sciences Governance**: POCT must be integral to a quality system and overseen by a registered and licensed medical laboratory.

ii. **Operator Competency**: Mandatory training and regular competency assessments are required for all Medical laboratory sciences staff performing tests. Non-medical laboratory staff are not authorized to conduct any form of analysis and investigation or acting as medical laboratory professionals

iii. **Quality Control**: Systems must include both **Internal Quality Control (IQC)** and **External Quality Assessment (EQA)** or proficiency testing.

iv. **Data Integration**: Results should be documented in the patient's electronic medical record and clearly identified as POCT-derived.

E. BLOOD GAS ANALYSIS (POCT) PRACTICAL LESSON FOR MEDICA LABORATORY SCIENCES MLS PROFESSIONALS.

This lesson is designed for a 60–90 minute practical training session on Point-of-Care (POC) capillary blood glucose testing, suitable forum nursing MLS professionals, healthcare assistants, or clinical staff.

Lesson Plan: Practical Blood Glucose Determination (POC Testing)

Duration: 60–90 Minutes

Setting: Clinical Skills Lab

F. Learning Objectives

By the end of this session, trainees will be able to:

a. Understand the principles of Capillary Blood Glucose (CBG) monitoring and its significance in managing diabetes.
b. Identify the necessary equipment for POC blood glucose testing.
c. Perform a capillary blood glucose test following aseptic technique and safety protocols.

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d. Calibrate a glucometer and interpret normal vs. c…

This practical lesson is designed for Medical Laboratory Sciences (MLS) Diploma MLS professionals to master point-of-care testing (POCT) for blood gas analysis .It focuses on the transition from traditional medical laboratory based analysis to bedside technology, emphasizing pre-analytical integrity and quality control.

Lesson Overview Topic:

Point-of-Care Testing (POCT) for Arterial Blood Gas (ABG) Analysis.

Target Audience:

Medical laboratory professionals' assigned to POCT.

Duration:

2.5–3 Hours (60 minutes Theory/Demo, 90 minutes in the demonstration Laboratory).

Learning Objectives:

a. Explain the clinical significance and normal ranges of pH, (ePOC {2}), and (pO {2}).
b. Identify and mitigate pre-analytical errors specific to POCT (e.g., air bubbles, sample mixing).

Demonstrate proficiency in operating a handheld or benchtop POCT analyser (e.g., Stat Profile Prime Plus or ePOC).

Perform and document daily Quality Control (QC) and calibration.

Part 1:

Theoretical Foundation & Demonstration (60 Mins) Clinical Significance:

a. Discuss the roles of the lungs (respiratory) and kidneys (metabolic) in maintaining acid-base balance.
b. POCT Advantages: Rapid turnaround time (results in <1 minute) and minimal sample volume requirement.

Pre-Analytical Critical Success Factors:

Anti-coagulation:

Use only heparinized syringes; excess liquid heparin can falsely dilute results.

Anaerobic Handling:

Immediate removal of air bubbles to prevent gas exchange with room air.

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Homogenization:

Roll the syringe between palms for 10 seconds and invert 10 times to ensure a homogeneous sample.

Demonstration:

Instructor performs a sample run on a POCT analyser, showing cartridge insertion, sample aspiration, and result printing.

Part 2:

Practical teaching medical Laboratory Session (90 Mins) MLS professionals should rotate through the following stations:

Station 1:

Analyser Setup and Quality Control Activity: Perform "Electronic QC" or run liquid control ampules.

Task:

Verify that QC results fall within the manufacturer's provided range before testing "patient" samples.

Station 2:

Sample Preparation and Analysis Activity:

Using "simulated" heparinized blood samples (provided by the medical laboratory), MLS professionals must prepare the sample for analysis.

Steps:

I. Expel any air bubbles and cap the syringe.
II. Gently mix the sample by rolling and inverting. Inject/aspirate into the analyser cartridge/sensor.
III. Record results for pH, (pCO {2}), and (pO {2}).

Station 3:

Pre-Analytical Error Simulation Activity: MLS professionals test two identical samples—one handled correctly and one deliberately "mishandled" (e.g., left uncapped for 10 minutes or containing a large air bubble).Task: Compare the results to see how (pO{2}) and (pCO_{2}) values shift due to atmospheric exposure.

Part 3:

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Interpretation and Assessment (30 Mins) Interpretation Exercise:

Use the "Tic-Tac-Toe" method to determine if a set of results indicates respiratory or metabolic acidosis/alkalosis.

Post-Lab Quiz:

Focus on:

I. Normal pH range (7.35–7.45).
II. Troubleshooting common analyser error codes.
III. Standard sample transport limits (analyse plastic syringes within 30 minutes at room temperature).

Required Equipment & Materials Analyzers:

POCT Blood Gas System (e.g., Siemens ePOC or Nova Stat Profile).

Consumables:

Test cards/cartridges, heparinized syringes, and waste containers.

Samples:

QC ampules (Level 1, 2, 3) and simulated blood samples.

Safety:

Gloves, lab coats, and eye protection (standard PPE).

G. PRACTICAL TRAINING FOR MEDICAL LABORATORY SCIENCES PROFESSIONALS ASSIGNED TO POCT FASTING LIPID PROFILE (POCT)

This practical lesson for MLS professionals covers the principles and procedures of point-of-care (POCT) testing to determine a fasting lipid profile. The lesson includes a theoretical overview, practical demonstrations, and hands-on activities, culminating in result interpretation and quality control.

Learning Objectives

Upon completion of this lesson, MLS professionals will be able to:

a. Explain the clinical significance of a fasting lipid profile and the advantages of POCT.
b. Outline the correct patient preparation requirements, specifically a 9-12 hour fast.

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c. Perform a capillary blood collection (finger stick) using aseptic technique.
d. Operate a POCT lipid analyzer (e.g., Cholestech LDX or CardioChek PA) according to manufacturer instructions.
e. Analyze and record results for total cholesterol (TC), high-density lipoprotein (HDL-C), triglycerides (TG), and calculated low-density lipoprotein (LDL-C).
f. Recognize potential interfering factors and implement appropriate quality assurance procedures.

Lesson Plan

Session 1:

a. Theory and Preparation (45 minutes)
b. Lecture & Discussion:

I. Introduction to Lipids and POCT: Discuss the role of lipids in the body, the importance of screening for cardiovascular disease (CVD) risk, and the benefits of POCT, such as rapid turnaround time and smaller blood volume requirements.
II. Patient Preparation: Emphasize the crucial need for a 9-12 hour fast (water only) to ensure accurate results for the full lipid panel, especially triglycerides. Mention other factors that can affect results (e.g., recent illness, medication).
III. Equipment Overview: Introduce the POCT devices, explaining their components (analyzer, test strips/cassettes, lancets, etc.) and the basic testing process (finger stick, sample application, results in 2-5 minutes).

Demonstration:

Trainer demonstrates proper handling and storage of test strips, calibration procedures, and the process of running a quality control sample as per manufacturer guidelines.

Session 2:

a. Practical Application (1 hour 45 minutes)
b. Hands-On Activity: Simulated Patient Interaction and Sample Collection:
c. MLS professionals' pair up (or use synthetic models) to practice explaining the procedure and confirming fasting status with a "patient".
d. MLS professionals perform mock or actual capillary blood collection via finger stick under supervision, ensuring proper antiseptic technique and correct application of blood to the test cassette.

Hands-On Activity:

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a. Sample Analysis and Result Interpretation:
b. MLS professionals load the test cassettes into the POCT analyzer and wait for results (2-5 minutes).
c. MLS professionals record the results (TC, HDL-C, TG, LDL-C estimate) on a standardized lab form.
d. Trainer guides discussion on normal ranges and how to flag abnormal results, noting when non-fasting samples might yield less complete data.

Assessment

Practical Competency Checklist: Trainer uses a checklist to evaluate MLS professionals ' performance during sample collection, instrument operation, and quality control procedures.

Written Quiz:

A short quiz covering theory (e.g., fasting requirements, clinical significance, sources of error).

Case Study Review:

MLS professionals analyze mock patient lipid profiles and suggest appropriate follow-up actions or potential interfering factors.

H. PRACTICAL TRAINING FOR MEDICAL LABORATORY PROFESSIONALS ASSINED TO POCT FASTING LIPID PROFILE (POCT)

This practical lesson for MLS professionals covers the principles and procedures of point-of-care (POCT) testing to determine a fasting lipid profile. The lesson includes a theoretical overview, practical demonstrations, and hands-on activities, culminating in result interpretation and quality control.

Learning Objectives

Upon completion of this lesson, MLS professionals will be able to:

g. Explain the clinical significance of a fasting lipid profile and the advantages of POCT.
h. Outline the correct patient preparation requirements, specifically a 9-12 hour fast.
i. Perform a capillary blood collection (finger stick) using aseptic technique.
j. Operate a POCT lipid analyzer (e.g., Cholestech LDX or CardioChek PA) according to manufacturer instructions.
k. Analyze and record results for total cholesterol (TC), high-density lipoprotein (HDL-C), triglycerides (TG), and calculated low-density lipoprotein (LDL-C).

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I. Recognize potential interfering factors and implement appropriate quality assurance procedures.

Lesson Plan

Session 1:

c. Theory and Preparation (45 minutes)
d. Lecture & Discussion:

IV. Introduction to Lipids and POCT: Discuss the role of lipids in the body, the importance of screening for cardiovascular disease (CVD) risk, and the benefits of POCT, such as rapid turnaround time and smaller blood volume requirements.
V. Patient Preparation: Emphasize the crucial need for a 9-12 hour fast (water only) to ensure accurate results for the full lipid panel, especially triglycerides. Mention other factors that can affect results (e.g., recent illness, medication).
VI. Equipment Overview: Introduce the POCT devices, explaining their components (analyzer, test strips/cassettes, lancets, etc.) and the basic testing process (finger stick, sample application, results in 2-5 minutes).

Demonstration:

Trainer demonstrates proper handling and storage of test strips, calibration procedures, and the process of running a quality control sample as per manufacturer guidelines.

Session 2:

e. Practical Application (1 hour 45 minutes)
f. Hands-On Activity: Simulated Patient Interaction and Sample Collection:
g. MLS professionals' pair up (or use synthetic models) to practice explaining the procedure and confirming fasting status with a "patient".
h. MLS professionals perform mock or actual capillary blood collection via finger stick under supervision, ensuring proper antiseptic technique and correct application of blood to the test cassette.

Hands-On Activity:

e. Sample Analysis and Result Interpretation:
f. MLS professionals load the test cassettes into the POCT analyzer and wait for results (2-5 minutes).
g. MLS professionals record the results (TC, HDL-C, TG, LDL-C estimate) on a standardized lab form.

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h. Trainer guides discussion on normal ranges and how to flag abnormal results, noting when non-fasting samples might yield less complete data.

Assessment

Practical Competency Checklist: Trainer uses a checklist to evaluate MLS professionals ' performance during sample collection, instrument operation, and quality control procedures.

Written Quiz:

A short quiz covering theory (e.g., fasting requirements, clinical significance, sources of error).

Case Study Review:

MLS professionals analyze mock patient lipid profiles and suggest appropriate follow-up actions or potential interfering factors.

I. PRACTICAL TRAINING OF MEDICAL LABORATORY PROFESSIONALS ASSIGNED TO POCT TO PERFORM POCT AS ANTENATAL SCREENING FOR HEMOGLOBIN (HB), HIV, AND SYPHILIS.

This lesson is designed for Medical Laboratory Sciences (MLS) professionals to gain practical competency in performing antenatal screening for Hemoglobin (Hb), HIV, and Syphilis.

Lesson Overview

a. **Target Audience:**

Medical laboratory professionals assigned to POCT.

b. **Duration:**

4 Hours (1 hour theory refresh, 3 hours practical).

c. **Learning Objectives:**

d. By the end of this session, MLS professionals will be able to:

i. Correctly collect capillary and venous blood samples following safety protocols.

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ii. Perform and interpret Hb, HIV, and Syphilis tests using point-of-care (POCT) and rapid diagnostic tests (RDTs).

iii. Understand the importance of Triple Elimination of Mother-to-Child Transmission (EMTCT).

1. Introduction & Theory (60 Minutes)

- **Significance of Screening:**

  Discuss the standards for screening at the first antenatal visit (ideally before 12 weeks) to prevent transmission.

- **Triple Elimination Strategy:**

  Review the integrated testing for HIV, Syphilis, and Hepatitis B (HBsAg) as recommended by WHO.

- **Test Methodologies:**

  a. **Hb:** Use of HemoCue or equivalent POC systems for immediate results.

  b. **HIV/Syphilis:** Use of **dual RDTs** which allow for simultaneous detection from a single finger-prick.

2. Practical Demonstration & Simulation (90 Minutes)

- **Preparation:**

  Ensure availability of dual HIV/Syphilis RDT kits, Hb cuvettes/strips, lancets, alcohol swabs, and biohazard waste bins.

A. **Step 1:**

Patient Interaction: Demonstrate professional communication and obtaining informed consent.

B. **Step 2:**

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Sample Collection: Guided practice on aseptic finger-prick technique and handling of whole blood.

C. **Step 3:**

Test Execution:

I. Perform **Hb** test and record results in g/dL.

II. Inoculate dual HIV/Syphilis RDT; demonstrate proper buffer addition and timing.

3. Interpretation & Documentation (60 Minutes)

a. **Reading Results:**

MLS professionals must practice identifying non-reactive, reactive, and invalid results on RDTs.

b. **Data Management:**

Emphasize the 2026 requirement for accurate recording in ANC registers and electronic health records.

C. Quality Control (QC):

Discussion on running known positive and negative controls to ensure kit integrity.

4. Competency Assessment & Wrap-up (30 Minutes)

a. **Proficiency Testing:**

Each Student perform the three tests on blind samples and are graded on technique and accuracy.

b. **Post-Test Counseling Basics:**

Brief overview of referring reactive cases for treatment (e.g., Benzathine Penicillin for Syphilis, ART for HIV).

c. **Feedback:**

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Review common errors such as improper sample volume or misreading faint test lines.

Practical HIV POCT Training for Medical laboratory professionals' assigned to POCT

Duration: 3–4 hours

Level: Medical Laboratory Sciences (DMLS)

Mode: Practical laboratory session with demonstrations and supervised practice

1. Learning Objectives

By the end of the session, MLS professionals should be able to:

a. Explain the principles of HIV POCT and its role in diagnosis.
b. Demonstrate correct specimen collection, handling, and storage.
c. Perform HIV rapid tests according to national guidelines.
d. Interpret and record results accurately.
e. Apply biosafety and infection prevention measures.
f. Communicate results ethically and maintain confidentiality.

2. Required Materials & Equipment

a. HIV rapid test kits (approved by national guidelines, e.g., Determine™, Uni-Gold™, First Response™)
b. Personal protective equipment (PPE): gloves, lab coats, masks
c. Lancets, alcohol swabs, capillary tubes
d. Biohazard waste containers & sharps disposal bins
e. Timer/stopwatch
f. Job aids & SOPs
g. Laboratory register/logbook

3. Lesson Outline

A. Introduction (20 min)

a. Brief overview of HIV epidemiology and importance of POCT.
b. National HIV testing algorithm.
c. Ethical considerations: informed consent, confidentiality, and counseling.

B. Demonstration (40 min)

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- Trainer demonstrates:

  a. Donning PPE.
  b. Preparing the testing area.
  c. Finger-prick blood collection.
  d. Performing the rapid test step-by-step.
  e. Reading and interpreting results within the correct time frame.
  f. Recording results in the logbook.
  g. Safe disposal of biohazard waste.

C. Supervised Student Practice (90 min)

- MLS professionals work in individually to:

  a. Prepare the workstation.
  b. Collect specimens (using simulated or volunteer samples).
  c. Perform the HIV rapid test.
  d. Interpret and record results.
  e. Trainer observes and provides feedback.

D. Troubleshooting & Quality Control (30 min)

  a. Discuss common errors (e.g., incorrect timing, insufficient sample).
  b. Demonstrate use of control samples.
  c. Emphasize documentation and adherence to SOPs.

E. Assessment & Reflection (30 min)

- **Practical assessment:**

  Each student performs a complete test independently.

  a. **Oral Q&A:**

     MLS professionals explain the rationale for each step.

  b. **Reflection:**

     MLS professionals share challenges and learning points.

4. Assessment Criteria

  a. Correct use of PPE and biosafety measures.

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b. Accurate specimen collection and handling.
c. Adherence to testing protocol.
d. Correct interpretation and documentation of results.
e. Professional conduct and ethical handling of patient information.

5. Follow-Up / Homework

a. Review national HIV testing guidelines.
b. Prepare a short report on the role of POCT in early HIV detection.
c. Read about external quality assessment (EQA) in HIV testing.

J. PRACTICAL TRAINING ON PERFORMING POINT-OF-CARE TESTING (POCT) FOR BILIRUBIN ESTIMATION TO MEDICAL LABORATORY PROFESSIONALS ASSIGNED TO POCT.

This lesson is designed for MLS professionals in a Medical Laboratory Science to gain practical proficiency in performing Point-of-Care Testing (POCT) for bilirubin estimation, primarily for neonatal jaundice screening.

Lesson Overview

- **Target Group:**

  Medical laboratory professionals' assigned to POCT

- **Duration:**

  3 Hours (1 Hour Theory/Demonstration, 2 Hours Practical)

- **Methodology:**

  Hands-on practical training, demonstration, and clinical correlation.

1. Learning Objectives

By the end of this session, MLS professionals will be able to:

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i. Explain the principle of POCT bilirubin measurement (e.g., reflectance spectroscopy or transcutaneous bilirubinometry).

ii. Perform a heel-prick sample collection following aseptic protocols.

iii. Operate a POCT bilirubinometer/strip reader accurately.

iv. Identify critical values and understand when to confirm results with laboratory serum bilirubin.

2. Required Materials & Equipment

i. **Devices:**

   a. POCT Bilirubin Reader (e.g., Bilistick or Jaundice Meter).

ii. **Consumables:**

   a. Sterile lancets, test strips, transfer pipettes, and alcohol swabs.

iii. **Safety Gear:**

   a. Gloves and a sharps container.

iv. **Specimen:**

Whole blood (heel prick) or simulator controls.

3. Training Procedure

Phase	Content/Activity	Key Points
Preparation	**Pre-analytical Steps**	Ensure test strips are not expired; protect samples from light to prevent photo degradation.
Sampling	**Heel Prick Technique**	Warm the heel for blood flow; disinfect the outer edge to avoid nerves; use 25-50 µL of whole blood.
Testing	**Device Operation**	Insert strip into the reader *before* applying the sample; apply blood to the collection pad.

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Analysis	**Reading Results**	Results are typically available within 2 minutes; read the display directly.

4. Technical Precautions & Troubleshooting

a. **Light Sensitivity:**

Bilirubin is light-sensitive; keep the reader and strips away from direct sunlight during testing.

b. **Interference:**

Haemolysed samples or high hematocrit (>65%) can cause errors on many POCT devices.

c. **Critical Thresholds:**

If POCT results are >250 µmol/L (approx. 14.6 mg/dL), MLS professionals must know to order a laboratory-based serum bilirubin test for confirmation.

5. Assessment & Evaluation

1. **Practical Skill Check:**

MLS professionals must demonstrate a successful "clean" sample application without causing hemolysis or under-saturating the strip.

2. **Case Study:**

Provide a set of POCT results (e.g., 320 µmol/L in a 24-hour-old infant) and ask the student to state the next clinical step (e.g., immediate medical laboratory confirmation and referral for phototherapy).

3. **Documentation:**

MLS professionals must correctly record the result in a POCT log form, including the device ID and patient identifiers

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