REPUBLIC OF KENYA

MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB PHLEBOTOMY, SPECIMEN COLLECTION AND REFERAL MANAGEMENT POLICY.

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

KMLTTB QUALITY ASSURANCE SERVICES.

	KMLTTB PHLEBOTOMY, SPECIMEN COLLECTION AND REFERAL MANAGEMENT POLICY		DOCUMENT CONTROL Serial: KMLTTB/PHREB/POLICY/01 Version 001 Date: 1ST DECEMBER, 2025
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KMLTTB PHLEBOTOMY, SPECIMEN COLLECTION AND REFERAL MANAGEMENT POLICY

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 acquire the desired knowledge and skills that are necessary for the delivery of medical laboratory services.
This policy 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 policy 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.
It is anticipated that compliance with the standards will enable training institutions run and sustain their training programs thereby equipping medical laboratory professionals with the necessary skills and competencies to provide medical laboratory services in diverse settings\ that include the pre analytical phase of analysis and investigations.

All medical laboratory training institutions and other key actors are required to adhere to this policy to ensure their training programmes and institutions are accredited to provide holistic training of students with requisite skills, competences and professionalism that guarantees the public of their right to highest attainable standards of health, patient safety as well as safety for medical laboratory professionals and the environment.

Any institution offering a course in phlebotomy, specimen collection and their referral shall do so under the auspices of KMLTTB.

The training leading to the award of any certification in medical laboratory phlebotomy, specimen collection and management shall be designed in a way to meet the diagnostic and health needs of the people of Kenya as well as the professional needs of the practitioners. All medical laboratory phlebotomy, specimen collection and management training shall be **ACCREDITED** after meeting the following standards set out by the KMLTTB policy.

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In accordance with CAP 253A laws of Kenya section 5. The mandate of KMLTTB is to exercise general supervision and control over the training business, practice and employment of Medical laboratory technicians and technologists Kenya and to advise the government on all matters thereof. The board also oversees the Validation of in vitro diagnostics.

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.

1.0 Policy Statement

This policy establishes the procedures for the standardized and safe collection, labeling, handling, processing, and transport of patient specimens to ensure the quality and validity of diagnostic test results, and to protect the safety of patients and healthcare workers. Strict compliance with these procedures is mandatory.

Subsequently, the Board endorsed CPD as the means for maintaining and updating professional competence in order to ensure that the public interest will always be promoted and protected, as well as ensuring the best possible service to the community. The purpose of CPD is not only to acquire new knowledge and skills, but also to improve attitude and ultimately the competency of the medical laboratory professional with an end benefit to the client.

1.2. Target audience:

This document is aimed at: All people (medical laboratory staff, nurses, clinicians, phlebotomists, health trainees) who perform or supervise phlebotomy in both the private and public health care facilities, including those involved in home-based care; Health

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trainers, and educators; Administrators and procurement officials (who need to be aware of which equipment and supplies are safe and cost effective)

2.0 Scope

This policy applies to all personnel who perform specimen collection shall exclusively only medical laboratory professionals registered by KMLTTB, registered nurses, registered clinical officers and registered physicians.

Phlebotomy science involves the art and science of drawing blood from a patient for diagnostic testing, transfusions, donations, or therapeutic purposes.

Specimen collection and management encompasses the entire process of obtaining, handling, processing, storing, and transporting various biological samples (including blood, urine, tissue, etc.) to ensure their integrity for accurate laboratory analysis and diagnosis.

Phlebotomy is a critical procedure in healthcare, primarily performed by trained professionals called phlebotomists. The "science" aspect refers to the underlying knowledge and technical precision required, including:

- **Anatomy and Physiology:** Understanding the circulatory system, especially the location and characteristics of veins suitable for puncture.
- **Infection Control and Safety:** Adhering to standard precautions and safety regulations to prevent the spread of blood borne pathogens.
- **Equipment Knowledge:** Selecting and using appropriate equipment (needles, vacuum tubes, lancets, etc.) based on the patient and test requirements.
- **Procedural Technique:** Performing venipuncture or capillary punctures with precision to collect adequate, high-quality samples while minimizing patient discomfort and complications.

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2.1 Specimen Collection and Management

This is a broader field that includes phlebotomy as a primary collection method. It involves a systematic process to ensure the reliability of laboratory results, as the integrity of the sample directly affects the accuracy of the diagnosis. Key steps include:

- **Patient Preparation:** Verifying patient identity, explaining the procedure, and ensuring specific requirements (e.g., fasting) are met.
- **Collection:** Obtaining the biological sample using proper techniques and sterile equipment.
- **Labeling and Handling:** Accurately labeling specimens immediately after collection and following specific handling instructions (e.g., mixing with proper additives in the correct order of draw, maintaining specific temperatures).
- **Processing:** Preparing the sample for analysis (e.g., centrifugation to separate plasma or serum).
- **Storage and Transport:** Storing samples under appropriate conditions and transporting them to the laboratory using leak-proof containers and established protocols to prevent contamination or degradation.

In essence, phlebotomy is the *act* of drawing blood, while specimen collection and management is the comprehensive *system* that ensures all biological samples are viable for medical testing and diagnosis.

The regulatory framework for phlebotomy science, specimen collection, and management involves the Kenya Medical Laboratory Technician and Technologists Board (KMLTTB) and medical laboratory sciences professional organizations. Regulatory and guidelines ensure **accuracy, safety, and patient privacy** throughout the pre-analytical phase of medical laboratory testing (analysis and investigations).

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International organizations like the World Health Organization (WHO) and the International Organization for Standardization (ISO) also offer global best practices. Key areas of regulation include proper patient identification, specimen labeling and handling, safety and infection control, and required training and competency for phlebotomists

Phlebotomy science and the associated practices of specimen collection and management shall be governed by a robust regulatory framework designed to ensure patient safety, worker protection, and the accuracy and reliability of medical laboratory results. This framework primarily comprises guidelines, standards, and laws established by KMLTTB.

3.0 Definitions

- **Phlebotomy:** The process of obtaining blood from a patient's vein or capillary.
- **Specimen:** A sample of bodily fluid (e.g., blood, urine) for medical laboratory analysis.
- **Order of Draw:** The specific sequence for collecting blood into different tubes to avoid cross-contamination of additives.
- **Patient Identifiers:** Specific information used to confirm a patient's identity (e.g., full name, date of birth, medical record number).

4.0 Responsibilities

- **Management/Supervisors** are responsible for providing necessary supplies, training, and ensuring compliance.
- **Collecting Staff** are responsible for adhering to all procedures, from patient identification to proper disposal of materials, and documenting all steps.
- **Laboratory Staff** are responsible for receiving, processing, and storing specimens according to established guidelines and reporting any issues.

5.0 Procedure

5.1 Patient Identification and Preparation

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- Greet the patient and confirm their identity using two identifiers (full name and date of birth are standard) which must match the requisition form.
- Verify that the patient has followed any necessary preparatory instructions (e.g., fasting status).
- Reassure the patient and obtain informed consent for the procedure.

5.2 Equipment Selection

- Inspect all supplies for defects and check expiration dates.
- Select the appropriate needle gauge and collection tubes based on the required tests and patient's vein characteristics.

5.3 Specimen Collection

- Perform hand hygiene (wash hands or use alcohol rub) and put on appropriate personal protective equipment (PPE), including gloves and a lab coat.
- Position the patient and select the venipuncture site.
- Follow the correct **order of draw** to prevent contamination of tubes.
- Do not attempt venipuncture more than twice; notify a supervisor or physician if unsuccessful.

5.4 Specimen Labeling

- Label all specimens immediately at the patient's bedside, in their presence.
- The label must be secure on the container (not the lid) and include the patient's full name, date of birth, date and time of collection, and the collector's initials.
- Ensure all information matches the request form.

5.5 Specimen Handling and Processing

- Gently mix anticoagulated tubes by inversion (4-5 times) immediately after collection.

- Allow serum tubes to clot in an upright position for a minimum of 30 minutes before centrifugation.
- Adhere to specific temperature requirements for transport and storage (e.g., refrigeration, room temperature).

5.6 Specimen Transport and Storage

- Package specimens in appropriate biohazard bags for transport.
- Ensure proper documentation, including the chain of custody for forensic specimens, if applicable.
- Store specimens according to laboratory guidelines until transport.

5.7 Safety and Waste Disposal

- Dispose of all used needles and hubs into a designated sharps container immediately after use; **never recap, bend, or break needles**.
- Dispose of all other contaminated materials (gloves, gauze) according to biohazardous waste disposal policies.
- In case of an accidental needle stick, immediately wash the area, express blood from the wound, and report the incident to a supervisor.

6. Principles of Specimen Collection and Management

Adherence to standard operating procedures (SOPs) is crucial for obtaining high-quality specimens and preventing contamination, which can lead to misdiagnosis or inappropriate treatment.

- **Patient Identification**: Use at least two unique identifiers (full name, date of birth, hospital/NHS number) to ensure the correct specimen is collected from the correct patient.

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- **Aseptic Technique**: Employ standard infection control precautions and appropriate personal protective equipment (PPE) to protect both the healthcare provider and the specimen from contamination.
- **Correct Containers and Labeling**: Use the appropriate, unexpired, and sterile container for each specific test, as different tests may require different additives or preservatives. Label the container immediately after collection, at the patient's side, and ensure the information on the label matches the request form.
- **Appropriate Quantity**: Collect the optimum amount of specimen needed for the examination.
- **Timeliness and Storage**: Transport specimens to the laboratory as soon as possible after collection. If a delay is unavoidable, store the specimen in a designated "specimen only" fridge at the specified temperature (typically 2-8°C) to maintain its quality.

Referral Policy and Regulation

Specimen referral policies establish a system for moving samples through the laboratory network, from collection points (spokes) to testing centers (hubs).

- **Roles and Responsibilities**: The policies define the responsibilities of all staff involved, including clinicians, nurses, laboratory personnel, and transport staff, in the collection, handling, and transportation process.
- **Documentation and Tracking**: A robust system for tracking samples is required, including a specimen referral log or a laboratory information system (LIS).
- **Packaging and Transport Regulations**:
  - **Triple Packaging**: Specimens must be packaged according to the International Air Transport Association (IATA) or national regulations, which typically require a triple-packaging system (primary leak-proof container, secondary leak-proof packaging with absorbent material, and rigid outer packaging).

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- **High-Risk Specimens**: Specimens from patients with known or suspected highly infectious conditions (e.g., HIV, Hepatitis B&C, Hazard Group 3 or 4 organisms) must be clearly marked as "high-risk" or "biohazard" to alert laboratory staff.
- **Trained Personnel**: Staff transporting infectious substances must be appropriately trained and certified in handling dangerous goods.

- **Specimen Acceptance/Rejection Criteria**: Laboratories have clear criteria for accepting or rejecting specimens (e.g., mismatched labels, inappropriate containers, external contamination). Rejected specimens must be managed and the requesting clinician notified.
- **Critical Value Reporting**: Policies dictate that critical or significantly abnormal results must be reported immediately to the physician or requesting laboratory.

These policies ensure a consistent and quality-controlled approach, from the patient bedside to the final test result and referral.

7.0 Quality Control and Assurance

- Regular training and competency assessments for all staff.
- Use of incident forms to report any errors in collection or handling that could affect patient safety or results.
- Adherence to internal and external audit requirements.

8.0 Physical facility requirements

Physical facility requirements for phlebotomy focus on maintaining a sterile, organized, and safe environment for both patients and staff. The following standards are the from KMLTTB guidelines:

8. 1. Core Area Design

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- **Space Allocation**: The facility must include a dedicated client waiting area, a triage/reception area, and a private blood collection permanent room with requisite security and accessible only to authorized personnel.
- **Work Surfaces**: Must be made of non-porous materials that can be easily decontaminated. Surfaces should be disinfected immediately after each patient procedure.
- **Lighting**: High-intensity examination lights or adjustable procedure lights are required to ensure clear visibility of veins.
- **Ventilation & Temperature**: Adequate climate control is necessary for both patient comfort and the stability of stored blood specimens.

8.2. Essential Station Equipment

- **Phlebotomy Chair**: Must provide comfortable seating with adjustable armrests to secure the patient's arm in a stable, downward position. It should be designed to prevent falls if a patient faints.
- **Procedures Trolley/Locker**: A mobile or fixed unit to hold organized supplies, including tubes, needles, and antiseptics.
- **Hand Hygiene Station**: A hand wash basin with running water, soap, and single-use towels must be immediately accessible.

8.3. Safety and Waste Management

- **Sharps Containers**: Puncture-resistant safety boxes must be placed no more than 4 feet (approx. 1.2 meters) from the phlebotomy chair to allow for immediate, one-handed disposal.
- **Waste Segregation**: The facility must have color-coded pedal bins for different waste streams (e.g., yellow for infectious waste, black for general waste, red for highly infectious materials).
- **Storage for Consumables**: Dedicated cabinets or shelves for clean supplies (gloves, gauze, bandages) to prevent cross-contamination.

8.4. Emergency Preparedness

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- **Resuscitation Area**: In larger clinical settings, a nearby resuscitation or acute treatment area must be available, equipped with oxygen sources and emergency trays.
- **Patient Recovery**: Space or couches for patients to remain in a recumbent position if they experience adverse reactions like syncope

9.0 References

- Medical laboratory technicians and technologists act, CAP 253A laws of Kenya.
- Clinical and Laboratory Standards Institute (CLSI) guidelines
- World Health Organization (WHO) Guidelines on Drawing Blood
- Best practices in phlebotomy - WHO Guidelines on Drawing Blood.

Specimen collection, management, and referral are governed by strict policies and regulations to ensure the integrity of the sample, the accuracy of the results, and the safety of personnel. This policy shall give road map to other protocols, guidelines and memorandum of understanding and/or agreements based on KMLTTB regulations which may also be aligned to national and international bodies like the Ministry of health Kenya, WHO, CDC, and IATA where applicable.

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

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