



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

STANDARD OPERATING PROCEDURES FOR THE MOBILE MEDICAL LABORATORY SERVICES AND SHIPMENT OF MEDICAL LABORATORY SPECIMENS USING VARIOUS METHODS INCLUDING UNMANNED AERIAL VEHICLE (DRONES), 2024

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

	STANDARD OPERATING PROCEDURES FOR THE MOBILE MEDICAL LABORATORY SERVICES AND SHIPMENT OF MEDICAL LABORATORY SPECIMENS USING VARIOUS METHODS INCLUDING UNMANNED AERIAL VEHICLE (DRONES), 2024		DOCUMENT CONTROL Serial: KMLTTB/SOP/SP/SHP/01 Revision No. 001 Revision Date: 2 ND MAY 2024
	OWNER OF THE FORM	REGISTRAR	

IN EXERCISE of the powers conferred by section 25 (1) of the Medical Laboratory Technicians and Technologists Act, Cap. 253A, the Registrar of the Kenya Medical Laboratory Technicians and Technologists Board, makes the following Standard operating procedures—

STANDARD OPERATING PROCEDURES FOR THE MOBILE MEDICAL LABORATORY SERVICES AND SHIPMENT OF MEDICAL LABORATORY SPECIMENS USING VARIOUS METHODS INCLUDING UNMANNED AERIAL VEHICLE (DRONES), 2024

PART I —PRELIMINARY

- Citation. 1. These Standard operating procedures may be cited as the Medical Laboratory Technicians and Technologists (mobile Medical Laboratory services and shipment of Medical Laboratory specimens using various methods including unmanned aerial vehicle (drones) Standard operating procedures, 2024.
- Interpretation. 2. In these Standard operating procedures, unless the context otherwise requires—
- Cap. 253A. “Act” means the Medical Laboratory Technicians and Technologists Act;
- “Board” means the Kenya Medical Laboratory Technicians and Technologists Board established under section 3 of the Act;
- “hospital Medical Laboratory” means a facility in a health institution in which Medical Laboratory analysis and investigations are carried out;
- “mobile Medical Laboratory” means a Medical Laboratory that is either fully housed within or transported by a vehicle such as converted bus, rail vehicle or tractor or even trailer;

“immediate supervision” means being Medical Laboratory to give help and guidance when required;

“Medical Laboratory” has a meaning assigned by the act;

“The act” means Medical Laboratory technicians and technologist act

“Medical Laboratory specimen” means a biological specimen in any material derived from a human such as blood, urine, tissue organs, saliva, DNA/RNA, hair nail, clippings or other cells or fluids whether

Collected for research purposes or residual specimens from diagnostic or therapeutic purposes.

“Medical Laboratory technologist” has the meaning assigned by the act.

“Medical Laboratory technician” has the meaning assigned by the act.

“Specimen collection site” means an area set site in a Medical Laboratory or in any health Institution for collection of human specimens and has the same means with a phlebotomy area or section.

“Health institution” has the meaning assigned by the act.

“Drone” means unmanned aircraft and has the same meaning as unmanned aerial vehicle (UAV) or unmanned aircraft system. “Phases of Medical Laboratory testing” means pre-analytical (pretesting phase), analytical (testing phase) and post-analytical (post testing or reporting phase).

“Triple package” means leak-proof primary receptacles, leak proof secondary receptacles and rigid outer packaging

4. These Standard operating procedures shall apply to

the—

- (a) terms and conditions of the business and practice of Medical Laboratory technicians and Medical Laboratory technologists engaged in practice;
- (b) services to be rendered by Medical Laboratory technicians and Medical Laboratory technologists in practice; and
- (c) employment of Medical Laboratory technicians and Medical Laboratory technologists in Medical Laboratory.

PART I – SHIPMENT OF MEDICAL LABORATORY SPECIMENS USING VARIOUS METHODS INCLUDING UNMANNED AERIAL VEHICLE (DRONES).

Application for certificate to engage in Medical Laboratory specimen shipment

1. (1) A person who wishes to engage in shipment of *Medical Laboratory* specimens shall apply to the Board for a license to engage in shipment of Medical Laboratory specimens using various methods including unmanned aerial vehicles (UAVs or Drones)

(2) An application for shipment of Medical Laboratory specimens shall be made in KMLTTB/HSP/01 set out in the First Schedule.

(3) An application for shipment of Medical Laboratory specimen using UAVs under Standard operating procedures(2) shall be accompanied by a—

(a) non-refundable application fee as set out in the Medical Laboratory Technicians and Technologists (Fees) Standard operating procedures, 2024, equivalent to Medical Laboratory equipment validation in the appropriate class;

(b) a certificate of good conduct; and

(c) detailed inspection report of where the applicant intends to carry out the shipment of *Medical Laboratory* specimens containing information including the—

(i) description of the premises;

physical address of the specimen collection site and recipient

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Medical Laboratory including their KMLTTB/MEDICAL
LABORATORY/06, A

- (ii) registrations and license; and
- (iii) Contacts information including a telephone number and an e-mail address of the persons in charge of specimen collection site and the recipient Medical Laboratory.

(4) Where a health institution intends to engage in shipment of Medical Laboratory specimens under a business name or a limited liability company, the application under this Standard operating procedures shall be accompanied by—

- (a) a certified copy of the search of the business name;
- (b) a certified copy of the certificate of incorporation; and
- (c) Documents clearly specifying the controlling interest which the applicant has in such a firm or company.

2. (1) Where an applicant fails to submit all documents or information required under these Standard operating procedures, the Board shall reject the application and inform the applicant, in writing, of the rejection and the reasons for the rejection using Form KMLTTB/MLSP/02 set out in the First Schedule within twenty-one days from the date of receipt of the application.

(2) Where the Board rejects an application due to incomplete or

Insufficient information, the rejection shall not bar the applicant from re-submitting the application.

(3) The Board shall treat the re-submitted application as a new application.

Grant of
Medical
Laboratory
specimen
shipping
certificate.

3. (1) The Board shall, if it is satisfied that the applicant has complied with the requirements under the Act and these Standard operating procedures and is in good standing, issue a *Medical Laboratory* specimen shipping certificate to the applicant in accordance with section 21 of the Act within sixty days from the date of the receipt of the application.

(2) A *Medical Laboratory* specimen shipping certificate issued under these Standard operating procedures shall be in Form KMLTTB/HMLSP/03 set out in the Schedule and shall contain information including—

(a) the start date of the Medical Laboratory specimens shipping certificate;

(b) the expiry date of the *Medical Laboratory* specimens shipping certificate;

(c) consequences of removal from the register; and

(d) the name of the Medical Laboratory or laboratories for which the *Medical Laboratory specimens shipping certificate has been granted*.

(3) A *Medical Laboratory specimens shipping* certificate issued under Standard operating procedures (1) shall expire on the 31st December of the year in which it was issued, and may thereafter be renewed annually on payment of the renewal fee set out in the Medical Laboratory Technicians and Technologists (Fees) Standard operating procedures, 2024.

(4) A *Medical Laboratory* specimens shipping certificate issued under the Act and these Standard operating procedures shall not be transferable.

Refusal to issue
Medical
Laboratory
specimen
shipping
certificate.

4. (1) Where an applicant in Standard operating procedures 1 does not comply with these Standard operating procedures, the Board may refuse to grant a Medical Laboratory specimens shipping certificate to the applicant.

(2) Where the Board refuses to grant a Medical Laboratory specimens shipping certificate, the Board shall inform the applicant, in writing, of the refusal and the reasons for the refusal using Form KMLTTB/MLSP/04 set out in the First Schedule within twenty one days from the date of receipt of the application.

Renewal of
Medical
Laboratory
specimen
certificate.

5. (1) An application for renewal of a Medical Laboratory specimens shipping certificate shall be made in Form

KMLTTB/MLSS/05 set out in the First Schedule, and shall be

accompanied by the proof of payment of the renewal of the *Medical*

Medical Laboratory specimens shipping certificate fee set out in the

Medical Laboratory Technicians and Technologists (Fees) Standard operating procedures, 2024, equivalent to renewal of license for Medical Laboratory equipment validation license or the relevant class.

(2) The application in Standard operating procedures (1) shall be made thirty days before the date of expiry of the *Medical Laboratory specimens shipping* certificate.

(3) The Board may charge a late application fee of fifty per cent of the application for Medical Laboratory specimen shipping certificate fee set out in the Medical Laboratory Technicians and Technologists (Fees) Standard operating procedures, 2024 equivalent to renewal of license for Medical Laboratory equipment validation license or the relevant class.

(4) The Board shall communicate its decision on the application made in Standard operating procedures (1) using Form KMLTTB/MLSS/06 set out in the First Schedule.

Conditions of a
*Medical
Laboratory
specimens
shipping
Certificate.*

6. (1) The Board may impose any conditions on a Medical Laboratory practitioner under these Standard operating procedures and in particular may impose a condition that the *Medical Laboratory specimens shipping* practice of the practitioner shall not conflict with the terms and conditions of his or her employment.

(2) A *Medical Laboratory specimens shipping* certificate shall be issued in respect only of the premises named therein and may not apply to any other premises unless the authority of the Board for it to do so has been obtained.

(3) A practitioner shall display a *Medical Laboratory specimens shipping* certificate in a conspicuous position at the premises to which it relates and any practitioner who fails to do so shall be guilty of an offence.

(4) The Board may cancel a *Medical Laboratory specimens shipping* certificate if any of the conditions imposed under the *Medical Laboratory specimens shipping* certificate are contravened.

Where a practitioner ceases his or her *Medical Laboratory specimens shipping* practice he or she shall surrender his or her *Medical Laboratory specimens shipping* certificate to the Board within thirty days of the cessation.

Notice of refusal
to grant a *Medical
Laboratory
specimens
shipping
Certificate.*

7. (1) The Board shall, before—

- (a) refusing to grant or renew a Medical Medical Laboratory specimens shipping certificate;
 - (b) refusing to allow a change of premises to which the Medical Laboratory specimens shipping r certificate relates; or
 - (c) cancelling or withdrawing the Medical Medical Laboratory specimens shipping certificate, give to the applicant or practitioner not less than twenty-eight days' notice in writing stating its intention; and such notice shall inform the applicant or the practitioner that he or she may within twenty-one days of receipt of the notice inform the Board in writing whether he or she wishes to be heard on the intended refusal, cancellation or withdrawal.
- (2) Where the applicant or private practitioner informs the Board in writing under Standard operating procedures (1) that he or she wishes to be heard the Board shall not effect such refusal, cancellation or withdrawal before it has given the applicant or private practitioner an opportunity to show cause why the application or Medical Laboratory shipping certificate should not be refused, cancelled or withdrawn.
- (3) Where the Board, after complying with this Standard operating procedures, refuses to grant or renew a license, or cancels a certificate, it shall inform the applicant or private practitioner of its decision within fourteen days of the expiry of the period of twenty-eight days referred to in Standard operating procedures (1) or, where the applicant or the

KMLTTB/SOP/SP/SHP/01

practitioner has been heard, within fourteen days of the hearing; and the Board shall inform the applicant or the practitioner the reason for its decision.

(4) A person dissatisfied with decision of the Board under this Standard operating procedures may lodge an appeal to the High Court within thirty days from the Date of the decision.

Duties of owners or operators of *Medical Laboratory specimens shipping services* 8. The operator of a *Medical Laboratory specimens shipping services* shall—

(a) submit to the Board once in every six months a list of all Medical Laboratory technicians and Medical Laboratory technologists —
(i) in their employment; and
(ii) who are authorized to use their premises, indicating in each case the authorized place for use as a *Medical Laboratory specimens shipping facility*;

(b) acquaint themselves fully with the qualifications and professional conduct of all Medical Laboratory technicians and Medical Laboratory technologists working at the *Medical Laboratory specimens shipping facility*
(c) Be responsible for any instance of professional misconduct occurring within the premises about which they know or ought reasonably to have known.

Requirements for *Medical Laboratory specimens shipping services* 9. (1) A *Medical Laboratory specimens shipping practitioner* shall—

a. conform to the standards issued by the Board;
b. be approved by the Board before starting to function;
c. be at all times supervised by a registered and licensed Medical Laboratory technician or

technologist; and

- d. Keep an accurate record of all Medical Laboratory analysis and investigations undertaken by their licensed Medical Laboratory facilities.

(2) The Board may inspect any premises used as a *Medical Laboratory specimens shipping service* at any reasonable time.

(3) Any person who hinders or obstructs an officer of the Board acting in the course of his or her duty under Standard operating procedures(2) shall be guilty of an offence.

PART II – MOBILE MEDICAL LABORATORY SERVICES (MML)

Mobile Medical
Laboratory as a mode
of health services
delivery

1. mobile Medical Laboratory shall be a recognized as mode of Medical Laboratory services
2. Mobile Medical Laboratory services shall be complementary to existing Medical Laboratory services
3. mobile Medical Laboratory shall be a recognized as mode of Medical Laboratory services
4. Mobile Medical Laboratory services shall be complementary to existing Medical Laboratory services

Provision of mobile
Medical Laboratory

Mobile Medical Laboratory services will be provided by l
Medical Laboratory professionals in line with the provision of

Standard operating procedures of “inspection of Medical Laboratory” under section 40(g) of the act.

An entity providing mobile Medical Laboratory services shall be;

- A mobile Medical Laboratory services provider holding a valid license issued by a Kenya Medical Laboratory Technicians and Technologist Board.
- A health institution licensed to offer mobile Medical Laboratory services by the Kenya Medical Laboratory Technicians & Technologist Board
- Kenya Medical Laboratory Technicians & Technologist Board shall develop standards and guidelines for the mobile Medical Laboratory services

Principles and objectives of mobile Medical Laboratory services

1The mobile Medical Laboratory services shall be an integral part of health service delivery to benefit people in a manner that is ethical, safe, secure, equitable and sustainable.

2.The objectives of mobile Medical Laboratory shall be;

- To promote patient-centered health care services;
- To ensure equitable access to quality health care services to benefit the Kenyan population;
- To promote the integration of mobile medical Laboratory into the healthcare system
- To facilitate the integration of mobile Medical Laboratory solutions; and
- To promote the use of mobile Medical Laboratory solutions

Mobile Medical Laboratory services

1. In the provision of mobile Medical Laboratory services to client, a health care provider shall;

- Provide the client with all the information for the mobile Medical Laboratory’ analysis and investigations for his or

her health

- Ensure the client can access their own medical Laboratory analysis and investigations
- Ensure the clients data is managed as prescribed in the law
- Ensure the highest possible quality of care is delivered
- Ensure that medical Laboratory services providers adhere to the provisions of this Act.
- Ensure that platform used is interoperable with the system
- Ensure that mobile medical Laboratory service delivery invoices a minor, the consent of the parent or an appointed guardian is obtained; and
- Ensure that when mobile Medical Laboratory services delivery involves a mentally ill person, the consent of an appointed guardian of the patient is obtained.
- The use of mobile Medical Laboratory service platforms to share the information of a patient including Medical Laboratory result for consultation and training shall adhere to the standards prescribed by the law

Reporting

In the delivery of mobile Medical Laboratory services, it shall be the responsibility of the medical Laboratory director to meet their reporting obligation in accordance with the provisions of this Act and applicable regulator.



MR. PATRICK KISABEL,

A.g Registrar,

*Kenya Medical Laboratory Technicians and Technologists
Board.*

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