



III. LEGAL NOTICE.....

THE MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS ACT
(Cap. 253A)

IN EXERCISE of the powers conferred by section 40(g) of the Medical Laboratory Technicians and Technologists Act, the Medical Laboratory Technicians and Technologists Board, with the approval of the Cabinet Secretary, makes the following Regulations—

THE MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS (INSPECTION OF MEDICAL LABORATORIES) REGULATIONS, 2024

PART I -- PRELIMINARY

Citation.	1. These Regulations may be cited as the Medical Laboratory Technicians and Technologists (Inspection of Laboratories) Regulations, 2024.
Interpretation. Cap. 253A.	2. In these Regulations, unless the context otherwise requires— “Act” means the Medical Laboratory Technicians and Technologists Act; “Inspector” means a person appointed by the Board to conduct inspection of medical laboratories; “Cabinet Secretary” means the Cabinet Secretary for the time being responsible for matters relating to health; “Board” has the meaning assigned to it under the Act; and “medical laboratory” has the meaning assigned to it under the Act;
Objective.	3. The objective of these Regulations shall be to provide a framework for the inspection of medical laboratories.
Application.	4. These Regulations shall apply to the inspection of medical laboratories.

PART II –REGISTRATION AND INSPECTION OF LABORATORIES

Establishment of laboratories.	5. (1) A person or entity seeking to establish a medical laboratory shall apply to the Board for registration in the Form KMLTTB/LAB/06A set out in the First Schedule. (2) An application under sub-regulation (1) shall be accompanied by the following—
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	<p>(a) a registration certificate in respect of a company or business name;</p> <p>(b) a copy of the KRA pin;</p> <p>(c) the list of medical equipment;</p> <p>(d) prescribed fee;</p> <p>(e) evidence of physical resources; and</p> <p>(f) any other requirement as may be determined by the Board.</p> <p>(3) The Board shall review the application within seven days of receipt and notify the applicant of the status of the application.</p> <p>(4) Where the application under sub-regulation (1) meets the minimum requirements, the Board shall notify the applicant of the date for inspection of the proposed medical laboratory upon payment of the prescribed fee.</p> <p>(5) The Board shall cause the inspection of the medical laboratories for applicants who have paid the inspection fee.</p> <p>(6) Where the information submitted under sub-regulation (2) is incomplete, the Board shall notify the applicant to avail additional information within fourteen days.</p> <p>(7) Where an applicant, without good cause, fails provide the additional information required by the Board under sub-regulation (6), within the fourteen days, the Board shall reject the application.</p> <p>(8) An applicant whose application has been rejected in accordance with sub-regulation (5), may reapply in accordance with sub-regulation (1).</p>
Inspectors.	<p>6. (1) There shall be Inspectors appointed by the Board after competitive recruitment process.</p> <p>(2) The Inspectors shall hold office on such terms and conditions as the Board shall determine from time to time.</p> <p>(3) The Inspectors shall conduct inspection of medical laboratories as the Board shall determine from time to time.</p>
Classification of medical laboratories.	<p>(1) Medical laboratories shall be classified in accordance with the Checklist set out in form KMLTTB/LABS/01 of the Schedule.</p> <p>(2) The Inspectors shall conduct the inspection and share with the medical laboratory a preliminary report with recommendations within thirty days. Set out in form KMLTTB/LAB/05 on schedule</p>

	<p>(3) The Inspectors shall submit a final report with recommendations to the Board, within seven days.</p> <p>(4) The recommendations referred to in sub-regulation (3) may either be for—</p> <ul style="list-style-type: none">(a) the issuance of a medical laboratory registration certificate; or(b) the rejection of the application. <p>(5) Where the Board approves the recommendation of the Inspectors report, it shall issue the registration certificate within seven days of receipt of the Inspectors’ final report.</p> <p>(6) Where the Board rejects the application in accordance with sub-regulation 4(b), it shall notify the medical laboratory of the rejection within seven days of receipt of the Inspectors’ final report in form KMLTTB/LAB/?? Set out on the schedule</p> <p>(7) An applicant whose application has been rejected in accordance with sub-regulation (6), may appeal to the Board within ninety days for review or re-inspection, as the case maybe, upon payment of the prescribed fee.</p> <p>(8) The Board may issue a closure notice to a medical laboratory that has not complied with the provisions of the Act or these Regulations. Set out in KMLTTB/LAB/04 on the schedule.</p> <p>(9) A medical laboratory that operates without the medical laboratory registration certificate shall be guilty of an offence and shall, on conviction, be liable to the penalties provided under section 18(2) of the Act.</p>
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Made on the....., 2024.

Titus Mutwiri,
Chairman,
Kenya Medical Laboratory Technicians
and Technologists Board.