REPUBLIC OF KENYA

MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD (KMLTTB

MEDICAL LABORATORY (EQUIPMENT AND REAGENTS VALIDATION) STANDARD OPERATING PROCEDURES

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

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD *Make Testing a Safe Reality*	MEDICAL LABORATORY (EQUIPMENT AND REAGENTS VALIDATION) STANDARD OPERATING PROCEDURES		DOCUMENT CONTROL Serial: KMLTTB/SOP. VALID/01 Revision No. 001 Revision Date: 6th TH 19TH MAY, 2024
	OWNER OF THE FORM	REGISTRAR	

IN EXERCISE of the powers conferred by section 25 of the Medical Laboratory Technicians and Technologists Act, the Medical Laboratory Technicians and Technologists Board makes the following Procedures—

MEDICAL LABORATORY (EQUIPMENT AND REAGENTS VALIDATION) STANDARD OPERATING PROCEDURES

1. Citation	1.1. These Procedures may be cited as the Medical Laboratory (Equipment and Reagents Validation) Procedures, 2024.
2. Interpretation	2.1. In these Procedures, unless the context otherwise requires— "equipment" means all machines, instruments, and apparatus and their accessories that are used in medical laboratory diagnosis including manual, semi-automated or fully automated medical analyzers for clinical chemistry, Hematology, immunology, histology, bacteriology, parasitology, serology and related disciplines, incubators, refrigerators, water-baths, autoclave instrument, pH meter, balance, spectrophotometers, air sampler (viable, none-viable)and any other instruments that fall within this class; 2.1.1. "person" includes a company, association or other body of persons whether incorporated or unincorporated; 2.1.2. "reagents" means all chemicals either as simple strips or as finished kits, solutions or powders that are used in medical laboratory diagnosis including discs for bacterial sensitivity testing; 2.1.3. "samples" means representative parts of equipment, devices and reagents that is submitted for validation; 2.2. "validation" means the process of authentication undertaken by Board or its appointed agents for the purposes of confirming the quality of medical laboratory reagents and equipment by performing tests to confirm the information provided by the manufacturers relating to their precision, linearity, specificity, sensitivity and accuracy in the description of the equipment, reagents and chemicals for use within medical laboratories in Kenya

3. Regulation of business	3.1. No laboratory technician or technologist engaged in private practice shall, whether solely, or through any business arrangement with other persons, stock, use, handle, distribute or procure the supply of any equipment or reagents for use within medical laboratories in Kenya unless the equipment or reagents have been validated in accordance with these Procedures. 3.2. No medical laboratory shall stock, use, handle, distribute or procure the supply of any equipment or reagents for use within medical laboratories in Kenya unless the equipment or reagents have been validated in accordance with these Procedures. 3.3. No medical laboratory, laboratory technician or technologist engaged in private practice shall use donated equipment and reagents from donor agencies, partners and other stakeholders in the health service industry within their laboratories, unless the equipment or reagents have been validated in accordance with these Procedures. 3.4. Nothing in these Procedures prohibits any vendors, suppliers, distributors, dealers and retailers engaged in bulk supply of laboratory reagents and equipment directly to medical laboratories in Kenya from sending samples for validation in accordance with these Procedures. 3.5. A medical laboratory, laboratory technician or technologist engaged in private practice shall maintain a record, in their premises, of certificates of validation issued by the Board after the validation of any equipment and reagents used in their medical laboratories.
4. Application for validation	4.1. An application for validation shall be in Form A set out in the Schedule and shall be accompanied by a sample from every batch of reagents or equipment. 4.2. In addition to the information required in Form A, an applicant shall, on request, furnish such additional information and samples as may be required by the Board for the validation of the equipment and reagents in respect of which the application is made.

5. Fees	5.1. An application for validation shall be accompanied by such fees as may be prescribed by the Board from time to time.
6. Issue of certificate of validation	6.1. The Board shall consider the applications made under rule 4 and carry out the necessary validation processes, and if satisfied of the safety, efficacy, quality and environmental aspects of the equipment or reagents, it shall issue a certificate of validation in Form B set out in the Schedule and submit a report on any adverse effects associated with the use or disposal of equipment and reagents in accordance with the Environmental Management and Co-ordination Act. 6.2. The Board shall keep a record of all the applications made for validation and all the batches of equipment and reagents that it has validated. 6.3. Where the Board has requested for additional information or is querying the information provided by an applicant, the processing of the application shall be suspended until the information is provided or query responded to and the application will stand rejected if the additional information is not provided or the queries are not responded to after three months. 6.4. The Board shall while undertaking the necessary validation processes on the equipment and reagents under sub-regulation (1), verify the specifications supplied by the applicant, and validate the reagents and equipment in respect of any the following particulars— 6.4.1. the name under which the equipment or reagents may be sold; 6.4.2. the labeling; 6.4.3. the statement of the representations to be made for the promotion of the equipment and reagents in respect of— (i) package, size, weight, dimensions and volume; (ii) technical information including specification, methods, formulation or composition and standard operating procedures; (iii) concentration, potency, avidity, confluence or constitution; (iv) wavelength, resolution, linearity, voltage requirements, workload capacity and environmental stability;

	(v) storage requirements, expiry date, environmental complicity; and (vi) batch numbers or bar codes. 6.5. If the Board is not satisfied of the safety, efficacy, quality or economic value of the equipment or reagents, it may, after providing an opportunity to the applicant to be heard, reject the application for the validation of the equipment and reagents and inform the applicant the reasons for rejection, in writing.
7. Duration of Certificate of Validation.	7.1. A certificate of validation issued under these Rules shall, unless earlier suspended or revoked, remain valid for every batch of reagents in relation to which it was issued or for the duration of the technological relevance of the equipment in relation to which it was issued. 7.2. Where an original validation certificate is defaced, damaged or lost the Board, may, upon payment of such fees as it may determine, issue a duplicate copy of the certificate that bears the words "DUPLICATE COPY".
8. Suspension or revocation of the certificate of validation	8.1. The Board may suspend or revoke a certificate of validation issued under these Procedures, or amend the conditions of such validation for such a period as it may determine. 8.2. The Registrar may upon giving a thirty days' notice and reasons, in writing revoke a certificate of validation. 8.3. The power conferred by sub-regulation (1) shall not be exercised in respect of any certificate of validation except in one or more of the following grounds— 8.3.1. the matters stated in the application on which the certificate of validation was granted was false or incomplete in a material particular (sample particulars); 8.3.2. a provision of the certificate of validation has to a material extent (sample extent) been contravened by the holder of the certificate;

	8.3.3. the premises on which or on part of which the equipment or reagents are manufactured, assembled or stored by or on behalf of the holder of the certificate of validation are unsuitable for the manufacturer, assembling or storage of the equipment or reagent; or 8.3.4. new information has been discovered by the Board which renders the equipment or reagents unsafe, dangerous or scientifically and technologically obsolete.
9. Appeals	9.1. A person aggrieved by a decision of the Board in relation to any application for validation of medical equipment or reagents may appeal, in writing to the Board, and pay the prescribed fee. 9.2. The Board may after considering an appeal, allow or dismiss the appeal and give reasons for any rejection, in writing.
10. Conditions of validation of reagents or equipment	10.1. The Board shall before registering any reagent or equipment for which the research has been conducted in another country, whose efficacy, safety and quality, has been established in that country, require an investigation, on any aspect of the reagent or equipment which are necessary to establish its quality and where applicable the standard component viability and its environmental safety and efficacy to be established under local conditions to be conducted and any modification of the equipment or reagent after validation shall require the approval of the Board. 10.2. Notwithstanding paragraph (1) the Board may validate a new reagent or equipment and require the investigation and chemical trials specified in rule (1) to be conducted after validation.
11. Inspection of premises	11.1. The Board may, before issuing a certificate of validation under these Procedures, cause the premises in which the manufacturing of the equipment or reagent is being conducted, to be inspected by inspectors appointed for that purpose, and the inspectors shall have powers to enter the premises and inspect the plant and the process of

	manufacture employed in the manufacturing and submit a report to the Board.
12. Offences	12.1. A person who contravenes any of the provisions of these Procedures commits an offence and shall be liable on conviction to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or to both.
13. Compliance	13.1. It is the duty of the proprietor of a medical laboratory in which equipment and reagents are procured for diagnostic purposes to take all reasonable steps to ensure that validation is undertaken in order to comply with regulation 3. 13.2. It is also the duty of each of following persons to take reasonable steps to ensure that validation is undertaken in order to comply with regulation 3 — 13.2.1. the Laboratory Manager; 13.2.2. laboratory Quality Assurance Officer; 13.2.3. the laboratory in-charge; and 13.2.4. any other person who is responsible for the management a medical laboratory. 13.3. All medical laboratories shall use validated equipment and reagents. 13.4. No medical laboratory in Kenya shall conduct any validation or verification excise for any medical laboratory of use in the country unless such a laboratory for a registered under this act and specifically authorized by the Board to conduct the specific validation or verification. 13.5. A medical laboratory that contravene this requirement shall be guilty of an offence of contradiction of medical laboratory code of ethics and shall be barred from operating as a medical laboratory 13.6. A medical laboratory professional involved in an authorized validation or verification of medical laboratory reagents, equipment's or shall be referred to the disciplinary committee of the Board to

	answer to charges of contradiction of medical laboratory code of ethics and the applicable oath for medical laboratory professionals pursuant to section 26 of MLTT Act and technologies act, CAP 253 A laws of Kenya. 13.7. Medical laboratory professionals referred to the disciplinary committee for conducting illegal validation and verification of medical laboratory reagents, equipment or chemicals shall be disciplined in accordance with the provisions of section 26 and 39 of the medical laboratory technicians and Technologies Act. 13.8. Medical laboratory facilities used for unethical validation and verification of medical laboratory reagents equipment's and reagents also known as Invitro diagnostics (IVDs) shall be removed from the register of deceased medical laboratories until such a time a committee of the board specifically constituted to investigate the laboratory and give it a clean bill of health and payment of any charged applicable as if the laboratory was the vender of the reagent equipment of chemical under investigation.

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