



**ACCREDITATION SCHEME FOR LABORATORIES**

**Technical Notes MED 001**  
**General Criteria for Medical Testing**  
**Laboratories**

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## 1. Introduction & Scope

- 1.1 This document describes the specific requirements for medical testing laboratories to be accredited.
- 1.2 The International Standard 'ISO 15189 Medical laboratories – Requirements for quality and competence', other MEDICAL Series Technical Notes published by SAC-SINGLAS shall be studied in conjunction with this document.
- 1.3 Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.
- 1.4 Whenever allowed, it is desirable that the medical laboratory services to include consultation services relating to the prevention and epidemiology of disease in addition to diagnosis and patient management.
- 1.5 Each laboratory ought to provide suitable educational and scientific opportunities for professional staff providing consultation services.

## 2. Personnel

### 2.1 Laboratory Director (LD)

- 2.1.1 The LD (however named) shall be
- \* SAB-registered pathologist or
  - \* registered medical practitioner with relevant laboratory experience of at least 5 years, or
  - \* scientist with appropriate qualification and experience

to direct the pathology or medical laboratory services. This individual shall be qualified and responsible for the professional, scientific, consultative, organizational, administrative and educational services provided. The LD shall have the authority to implement and maintain the quality standards of the services provided.

*\*Note: A person who has a degree in medicine or any other higher qualification in any disciplines specified below (a) to (j) that is acceptable to the Director of Medical Services (DMS), and who has at least 5 year's relevant working experience in a clinical laboratory acceptable to the Director.*

- a) *Anatomic pathology,*
- b) *Chemical pathology,*
- c) *Cytogenetic.*
- d) *Forensic pathology,*
- e) *Haematology,*
- f) *Histocompatibility,*
- g) *Immunology,*
- h) *Medical microbiology,*
- i) *Transfusion medicine, or*
- j) *Any other discipline acceptable to the Director of Medical Services.*

+ SAB : Specialist Accreditation Board, Ministry of Health

- 2.1.2 In all facilities where histopathology services are provided, a pathologist shall perform such services.
- 2.1.3 The LD shall delegate technical responsibility for each discipline within the laboratory or use the consultative services from a SAB-certified pathologist with relevant experience or qualification, or scientist with professional qualification or certification.
- 2.1.4 The supervising scientist and pathologist should be appropriately trained, qualified and experienced for the scope and complexity of the testing. Where pathologist is not available and on-site, access should be made available.

## 2.2 Consulting Pathologist

- 2.2.1 When the services of a qualified consulting pathologist are necessary, a close working relationship between the LD and the consulting pathologist shall be established.
- 2.2.2 The consulting pathologist shall play an active role in the programs established by the laboratory and the organization.
- 2.2.3 The services of the consulting pathologist shall be provided as often as required.
- 2.2.4 A written report shall be kept of each consultation.

## 2.3 Laboratory Supervisor (LS)

- 2.3.1 The laboratory supervisor (however named) assists the LD and his/her role is to ensure that the daily operations of the laboratory are met. He/She is required to hold one of the following:-
  - a) a Science Degree in a relevant discipline with a minimum of 3 years' medical laboratory experience,
  - b) a Polytechnic Diploma in Medical Technology Sciences, or relevant discipline or other recognised qualification by the Health Regulation Division of Ministry of Health with at least 5 years medical laboratory experience or equivalent.

## 2.4 Medical Laboratory Technologist (LT)

- 2.4.1
  - a) The MLT (however named) performs testing and assists the LS in the daily operations.
  - b) The MLT may hold a Bachelor of Science Degree, a Polytechnic Diploma in Medical Technology Sciences or a relevant discipline, or other recognised qualification by the Ministry of Health with at least 3 years working experience in a facility recognised by SAC-SINGLAS

# 3 **Accommodation and Environmental Conditions**

## 3.1 Physical Facilities

- 3.1.1 The laboratory shall have sufficient space for performance of work, storage of equipment, reagents, media and supplies. Ventilation, electrical supply, temperature and water shall be adequate as appropriate to the technical activities concerned. There shall be good housekeeping in the laboratory.

3.1.2 There shall be sufficient resources, including adequate space, instrumentation, furniture, communication systems, supplies, ventilation, piped gases, water, and public utilities security, to support the activities of the laboratory.

3.1.3 It shall be a safe working place for its personnel and for the patients it serves. It shall comply with the safety regulatory requirements. The laboratory shall ensure that patients, employees, and visitors are protected from laboratory hazards.

An appropriate Immunization programme for all laboratory personnel should be in place.

3.1.4 The environment within the laboratory shall be suitable for the effective performance of its scope of testing. It shall be able to demonstrate that the accommodation does not lead to contamination of the test samples. Work areas in which the analysis is done should preferably be separated from all other laboratory operations.

3.1.5 Separate work areas shall be available for the following operations:-

- a) cleaning of glassware, purification of reagents and solvents;
- b) media preparation
- c) analysis of highly infectious samples.
- d) analytical instruments must be housed in a separate area provided with adequate air-conditioning.
- e) adequate and appropriate storage facilities must be available for
  - i) the storage of sample before and following analysis;
  - ii) the storage of materials used in the course of analysis
  - iii) the safe storage of hazardous and non-hazardous wastes prior to disposal
- f) decontamination of persons and protective clothing.
- g) preparation or processing of specimens where cross-contamination from other analytical products can severely compromise assays and/or invalidate results, e.g. reagents for nucleic acid amplification

### 3.2 Laboratory Safety

3.2.1 There shall be written safety policies and procedures. Procedures on safety practices of the laboratory shall be part of new employees' orientation program. This shall be documented when completed.

3.2.2 The safety procedure manual shall be available on the workbench and a safety officer shall be appointed to ensure safety measures as contained in the manual and implemented.

3.2.3 The laboratory shall report serious accidents and laboratory acquired illnesses to the relevant authorities. Near-misses should also be documented, along with the preventive action taken.

3.2.4 All injuries that require medical treatment or time lost from work shall be reviewed as part of the laboratory's Quality Assurance program.

*Note: This includes every sharp injury requiring appropriate treatment according to the documented protocol.*

3.2.5 Injuries or occupational illnesses shall be documented and follow-up action recorded.

- 3.2.6 Laboratories shall ensure that its personnel wear protective clothing and safety equipment appropriate to the duties being performed.
- 3.2.7 There shall be a safety shower or other emergency source of water in all areas where quantities of concentrated caustics are handled. Piped eyewash fountains or the equivalent shall also be present. All of these and the protective equipment shall be easily accessible and shall not be obstructed by equipment, furniture, etc. Laboratories shall also provide fire extinguishers at appropriate places.
- 3.2.8 Chemical fume control devices such as hoods shall be checked annually and records shall be documented.

*Note: All workers are to be protected from dangerous levels of vapours and dusts. There are many such regulated substances and 29 CFR 1910; Subpart Z shall be consulted for the current listing.*

- 3.2.9 All laboratory instruments and appliances shall be grounded and checked for electrical leakage and in compliance with manufacturer's recommendation.

*Note: Exceptions can be made for instruments and appliances that are doubly insulated.*

- 3.2.10 All electrical receptacles in the laboratory technical work areas shall be checked annually for ground integrity and records of these shall be documented and maintained.

*Note: Such tasks shall be delegated to trained biomedical and electrical engineers.*

- 3.2.11 All dangerous and poisonous chemicals used in the laboratory must be contained, labelled and kept in a locked cabinet by a designated safety officer. The laboratory shall follow the guidelines from the relevant authorities.

- 3.2.12 Safety Data Sheets shall be documented for each hazardous chemical in the laboratory and be readily available at every point of use and storage. The designated safety officer shall maintain the location of such documentation.

- 3.2.13 A chemical hygiene plan (CHP) shall be developed and shall define storage requirements, handling procedures (including requirements for personal protective equipment), location and the medical procedures that are to be followed should accidental contact or over-exposure occur. Monitoring of vapour levels of potentially toxic substances is required at a defined interval. The indications for these monitoring activities shall be defined in the CHP and records of monitoring shall be documented. All testing staff shall be provided appropriate training in safe handling procedures.

- 3.2.14 CHP shall specify the clinical symptoms or the environmental condition (such as spills) that occur during over-exposure. When such conditions exist, the CHP shall have procedure for the appropriate medical attention to be provided.

- 3.2.15 The CHP shall be reviewed annually and all employees shall be trained.

*Note: Chemical carcinogens, reproductive toxins, and other severely toxic chemicals are special concerns. The laboratory shall be surveyed annually for the presence of carcinogenic and potentially carcinogenic chemicals. This includes any chemical, which has specific occupational regulations such as formaldehyde, ethylene oxide, and benzidine. The regulations also pertain to any other potentially carcinogenic chemicals. For practical purposes, this includes any substance so identified **and** because this list*

*encompasses hundreds of substances and is constantly changing, no attempt will be made to itemize those substances here.*

- 3.2.16 For Formaldehyde vapour the air contaminant shall not exceed the threshold of the regulatory requirement in the medical laboratory. The laboratory that handles formaldehyde shall have documented evidence, that formaldehyde vapour levels have been measured.
- 3.2.17 Personnel protection equipment e.g. gowns, gloves, masks, goggles shall be made available to staff who require such protection when at work, e.g. when working with known hazardous substances e.g. formaldehyde.
- 3.2.18 Proper signs shall be placed at significant hazard areas. Reagent vessels containing hazardous substances shall be labelled appropriately with warnings.
- 3.2.19 The laboratory safety manual shall have a section outlining policies and procedures to be followed in the event of disaster.

*Note: "Disasters" refer to events such as fire, flood, electrical outage or spillage of hazardous volatile substances, or any other mass casualty situation.*

### 3.3 Biological Hazards And Control Safety

- 3.3.1 The laboratory shall institute standard precautions against infectious hazards of blood and body fluids. Reference should be made to the following guidelines from the relevant regulatory bodies.

*Note: Staff, whose work is likely to involve contact with human tissues or fluids, or infectious material, shall use gloves and other appropriate personal protective devices. Gloves must fit properly; cleaning or disinfecting of disposable gloves for reuse is prohibited. Gloves, aprons, or laboratory coats and protective eyewear must be provided and are required for those activities likely to splash the skin. Powdered latex gloves are discouraged, and non-latex gloves are preferred (in accordance with occupational safety requirements from the Ministry of Manpower).*

- 3.3.2 Appropriate biohazard cabinet/s (BC) must be functioning in laboratories that handle infectious materials such as culture mycobacteria, fungi and viruses. Each BC shall be certified annually and records shall be documented.

*Note: This service is ordinarily performed by an outside vendor because of the specialized equipment required. Annual checks shall include filter checks, flow rate measurements and tests for seam integrity. Filters need not be replaced annually, only as needed but not exceeding every five years.*

### 3.4 Radioactive Safety

- 3.4.1 Laboratories that use radionuclides shall manage them according to the procedures set up in the safety manual. The laboratory shall function under the general license of the regulatory authority if the facility uses only small amounts of radioactive materials e.g., if the only contact with radionuclides is from commercially prepared kits for radioligand analysis. If larger amounts are used, the laboratory shall hold a specific license.

## 4. **Laboratory Equipment**

- 4.1 All equipment must be maintained and serviced regularly. Calibration of equipment shall be performed by SAC-SINGLAS accredited calibration laboratory wherever

possible. Records shall be kept for such calibration, maintenance and servicing.

4.2 **TABLE 1** in this document sets out the recommended frequencies for calibration and performance check of general equipment in the field of Medical Testing.

The frequencies of calibration stated in this documents are considered to be the minimum appropriate, provided that the other criteria specified below are met:

- a) the equipment must of good quality and proven stability and
- b) the laboratory has both the equipment required, competent staff and expertise to perform adequate internal checks, and
- c) if any suspicion or indication of overloading or mishandling arises, the equipment shall be checked immediately and thereafter at fairly frequent intervals until it can be shown that stability has not been impaired.

4.3 Where the above criteria cannot be met or the relevant registered methods have specified more stringent requirements, more appropriate frequencies shall be adopted.

4.4 Where the staffs of a laboratory has performed calibrations, a full record of these measurements shall be maintained, including details of the numerical results, date of calibration and other relevant observations.

4.5 Pipettes, micro diluters and automatic dispensers that are used for precise quantitative dispensing of material shall be checked at specified intervals for accuracy and reproducibility and results recorded. The intervals are to be determined by the laboratory, unless otherwise specified by SAC-SINGLAS.

4.6 All equipment that comes under the control of the laboratory which requires calibration or verification shall be labelled or coded to indicate the status of calibration or verification and the date when recalibration or re-verification is due.

4.7 The laboratory shall institute a preventive maintenance program (which, at a minimum, follows the manufacturer's recommendations) to prevent failure of equipment and ensure that the equipment is operating with the reliability required for quality results. The activities include specification checks, calibration, cleaning, lubricating, reconditioning and adjusting by competent personnel on a regular basis. Proper records shall be kept for such activities.

4.8 Corrective actions shall be documented when an unacceptable tolerance limit or instrument/equipment malfunction is detected.

## **5. Pre-Examination Procedures**

### **5.1 Sample Collection, Sample Transport & Sample Receipt**

5.1.1 Where primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimization of collection conditions. The environment shall not invalidate the results, or adversely affect the required quality, of any measurement.

5.1.2 The laboratory shall confirm with the patient their name and identification number prior to sample collection. In cases whereby special patient preparation is required, the laboratory shall ensure that the patient is aware of the preparation procedure before

sample collection.

- 5.1.3 The laboratory shall have procedures/policies for appropriate collection transport and rejection of samples including how to deal with samples submitted after office hours.

## **6 Examination Procedures (Quantitative)**

- 6.1 All analytical procedures from non-standard methods, laboratory developed methods, standard methods used outside intended scope and modified methods shall be validated against specified requirements and their limits defined.
- 6.2 Methods shall be validated by carrying out analyses of reference standards of known concentration, both in isolation and in the form of spiked samples to determine the recovery.
- 6.3 Where applicable, the method of quantification shall be evaluated using solutions of the analyte in a suitable solvent. An internal standard shall be included where possible.
- 6.4 Replicated analyses shall be carried out to ascertain the repeatability of analysis. Inclusion of a control sample in subsequent analyses will serve to check for deviations from the established method.
- 6.5 The stability of the analyte in the sample matrix during storage and throughout the analysis procedure shall be evaluated.
- 6.6 Method validation may also consist of analyzing the same sample material by different methods and comparing the recovery of known amount of reference standard.
- Note: Such validation should include determination of systematic bias against reference materials or otherwise stated values, limit of detection, limits of determination, within- and between-run reproducibility, interfering substances, and robustness.*
- 6.7 Method validation may also consist of analyzing the same sample material by different methods and comparing the recovery of known amount of reference standard.
- 6.8 Test procedures should include start-up instructions, precautions, pre-treatment, analysis, detection limit, lower and higher limit, disposal of waste, remarks and trouble shooting and safety of the personnel and environmental aspects. The laboratory director or designate shall be responsible for ensuring that the contents of examination procedures are complete and have been thoroughly reviewed.
- 6.9 The appropriate test procedure should also address the reporting of results, units, calculation, interfering substances, report values, critical limits, reference limits for the appropriate tests.
- 6.10 Outdated procedures should be archived for at least two years.

## **7. Assuring Quality of Examination Procedures – Quality Control and Proficiency Testing**

- 7.1 The effectiveness of the quality control programs shall be measured and be included in



the management review of the laboratory.

- 7.2 The quality control programs shall include tolerance limits and corrective action procedures to use when limits are exceeded.
- 7.3 Participation in Proficiency Testing (PT) programs shall cover the extent and complexity of analytical procedures, including consultative services in histopathology. Accredited laboratories shall have a minimum PT participation frequency of one analyte or test every year. Where such PT programs are not available, the laboratory should embark on alternative means of ensuring proficiency (e.g., by a process of inter-laboratory comparison with laboratories doing similar work or the development of a mechanism of internal quality control). PT programs shall be in accordance with *SAC-SINGLAS PROFICIENCY TECH NOTE 001*.

*Note: Please refer to MOH guidelines for the list of recommended proficiency testing organizers.*

- 7.4 The LD/LS or designate shall monitor the results of PT and participate in the documentation of corrective actions, where required.
- 7.5 The LD/LS or designate shall systematically monitor and evaluate the quality and appropriateness of the laboratory's contribution to patient care. When the program identifies systematic problems, the designated personnel shall take appropriate corrective actions.

7.6 Reagents

- 7.6.1 All laboratory personnel shall be made aware of their responsibilities on the use of suitable reagents, solvents, culture media, reference materials and laboratory ware in terms of the types of analysis they conduct.
- 7.6.2 Proper storage of all reagents and culture media shall be observed according to the requirements set up by the manufacturers.
- 7.6.3 Chemical reagents, solvents and gases shall be available in various grades and purity. The appropriate grade of materials as specified in the methods or procedures shall be used.
- 7.6.4 All reagent containers shall be labelled and tightly closed. They shall bear the original label or as minimum: reagent name, date of receipt, strength, solvent (if not water), any special precautions or hazards and date of expiry. The person responsible for the preparation of the reagent shall be identifiable either from the label or from records.
- 7.6.5 Laboratories shall establish written procedures for preparation of reagent solutions and culture media. Records of such preparations shall be maintained for later reference in case of doubtful test result. Records for reagent solutions shall include measured weights and volume, burette readings, pH readings, calculation of standardization factor and solution concentration. For culture media, they shall include medium name, batch number, amount prepared, pH before and after autoclaving, autoclave time and pressure.
- 7.6.6 For substances that are classified as scheduled poisons under the Poisons Act and its rules, they shall be kept separately from other reagents and held in locked cabinets. These substances shall be handled in accordance to the rules and guidelines set out in the Poisons Act. Stock flammable materials shall be kept in flammable cabinets.

## 7.7 Certified Reference Materials

- 7.7.1 A certified reference material can be defined as a homogenous material with specific properties such as identified purity and potency that has been measured and certified by a qualified and recognized organization.
- 7.7.2 Certified reference materials are used to help calibrate instruments and measurement systems to ensure the long-term reliability and integrity of the measurement process.
- 7.7.3 Regardless of the source of certified reference materials, care shall be exercised to see that they are packaged, stored, and handled to prevent deterioration. This means that efforts shall be made to minimize exposure to moisture, air, heat, and light. They shall be kept under secure and appropriate storage conditions, and records shall be maintained of receipt and use.
- 7.7.4 It is preferable that records are kept in sign-in; sign-out logbooks located near the storage areas. Each analyst using a certified reference material shall be required to enter the name of the reference material in the log book, the date and time it is taken and returned, and his or her initials.
- 7.7.5 All analysts shall be instructed in the care of certified reference materials and procedures for handling them.

## 7.8 Working Reference Material

- 7.8.1 A working reference material can be defined as a substance other than a certified reference material that is used as a reference material in day-to-day analyses.
- 7.8.2 Laboratories may develop and perform tests and assays on a substance to establish it as suitable reference for an intended analysis especially when a certified reference material is not available. This substance is considered to be the laboratory's working reference material.
- 7.8.3 Working reference materials purchased shall be checked for integrity on receipt. For in-house prepared reference materials, the laboratory shall verify quality of materials used for the preparations.
- 7.8.4 A working reference material shall be assayed by the best method available, and the results shall be entered in a notebook for that purpose. The report shall include the analyst's name, date of analysis, source, lot number, all raw data, charts, and calculations.
- 7.8.5 A working reference material shall be handled in essentially the same manner as a certified reference material, and a record shall be made each time the standard is withdrawn for use. When the working reference material is used in the assay of a sample, a reference to it shall be made so that there can be no mistake as to the identity and purity of the material.

## 8. **Post-examination Procedures**

### 8.1 Retained Samples

- 8.1.1 A retained sample refers to the tested sample or part of the original sample, which is preserved at the laboratory for future use in case of dispute over the findings.

8.1.2 Where applicable, a representative sample with sufficient quantity shall be retained for a specified period. It shall be properly sealed, appropriately identified and stored under appropriate conditions.

## 8.2 Waste Disposal

8.2.1 The laboratory shall have policies and procedures for waste management for the disposal of all solid and liquid and gaseous waste. These methods shall be in compliance with applicable local regulations and reviewed annually.

8.2.2 Waste shall be disposed of at regular intervals not exceeding a week.

8.2.3 Mechanical pipette tips, sample cups, etc. should not be washed and reused.

8.2.4 All sharps needles and razor blades should be placed into puncture-resistant containers.

8.2.5 Infectious waste shall be placed into biohazard disposal bags for appropriate disposal in a government-approved incinerator by licensed waste contractors.

8.2.6 Safe disposal of samples no longer required by the examination shall be carried out in accordance with local regulations or recommendations for waste management.

## 9. **Reporting of Results**

9.1 There shall be a policy and procedure governing the reporting of results, such as by hardcopy, telephone, fax, text messaging and/or any other electronic means. Reporting of results should include an authorization procedure. The policy shall also ensure that confidentiality, integrity and security are maintained.

9.2 Stat results, results obtained in out of hours service and results outside alarm limits should be reported as soon as possible and only after verification by a competent technologist as approved by the laboratory.

9.3 A record of result transmitted by telephone, fax, text messaging and/or any other electronic means (other than the laboratory information system) shall be documented. Such record shall be controlled and limited to authorized or defined recipients and it should be followed up by the verified results. A read back procedure should be instituted to ensure complete communication.

9.4 Results should be archived and retained as determined by the laboratory complying with regulatory requirements.

9.5 Reported results should only be corrected by authorized technical / professional staff of the accredited laboratory. Correction of the results should be reported as soon as possible to the requesting physicians.

9.6 The turn-around-time of all tests must be made known to all requesting physicians and they should be familiar with the normal reporting time for assays.

9.7 The laboratory should regularly audit the turn-around time for stat and routine tests. The turnaround time for assays sent to other laboratories should be known and checked.

- 9.8 Reference values should be available for all assays, where relevant.
- 9.9 Consultation concerning interpretation of results and advice on further investigation should be available at all times.
- 9.10 There should be regular meetings of laboratory staff with the clinical staff regarding use of the laboratory and interpretation of results.
- 9.11 The laboratory should provide additional interpretative or qualifying comments on reported results where applicable, e.g. warnings should be added to the report when pathological pitfalls or interfering substances are suspected.

**References :**

- 1. Merrick, T Et al. Laboratory Accreditation Manual, Commission on Laboratory Accreditation, College of American Pathologists (1998 Edition).
- 2. Standards for Laboratory Accreditation (1998 Edition), Laboratory Accreditation Program, College of American pathologists.
- 3. National Association of Testing Authorities, Australia (NATA), NATA/RCAP Medical Testing Requirements 1996.
- 4. SAC 01, Terms and Conditions for Accreditation
- 5. SAC-SINGLAS MED 001, Accreditation Process for Medical Testing Laboratories
- 6. EAL - G25 (ECLM-1), Accreditation for Medical Laboratories (1997).
- 7. OSHA Requirements (refer to Reference No.1).
- 8. ISO 15189:2012 Medical laboratories – Requirements for quality and competence

**TABLE 1: RECOMMENDED CALIBRATION AND PERFORMANCE CHECK OF EQUIPMENT COMMONLY USED IN THE MEDICAL TESTING LABORATORIES**

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
1.	Anaerobic jars and cabinets	Each use: Check using indicators, vacuum gauge or control cultures.
2.	Analyzers <ul style="list-style-type: none"> <li>• Automated</li> <li>• blood gas</li> <li>• electrolyte</li> <li>• glucose</li> <li>• oxygen</li> <li>• protein</li> </ul>	Check using appropriate controls and standard materials with frequency depending on the particular use of the equipment and manufacturer's recommendation.
3.	Atomic absorption spectrophotometers	6 monthly: Check for sensitivity, baseline variation, background correction, and optimization parameters.
4.	Autoclaves	(a) When used: Check for temperature and pressure on display. (b) Use autoclave tape to check performance; use biological indicator where appropriate. (c) Every 2 years: Calibrate gauges. (d) Register with the Ministry of Manpower.

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
5.	Balances and scales	(a) When used: Zero point check.  (b) Yearly: Calibration by accredited calibration laboratory for repeatability, linearity and accuracy. Use ten weighing of a mass having a value close to the maximum load of balance.
6.	Biological Safety Cabinet & Laminar flow	Yearly: Certified to ensure filters are functioning properly and that airflow rate meet specifications.
7.	Centrifuges	Yearly: (a) Check temperature using a calibrated thermistor, or more frequently if required,  (b) Check speed using a calibrated tachometer and/or  (c) Check frequency (for ultracentrifuge) using calibrated multi-meter/ universal counter, in accordance to manufacturer's recommendation.
8.	Chromatography, Gas	Instrument must be routinely monitored during use with standard reference materials. System components (e.g. integrators, ovens, electronic amplifiers and detectors) must also be checked periodically, and records kept.
9.	Chromatography, Liquid & (HPLC)	Liquid chromatography, including high performance (or high pressure) liquid chromatography (HPLC) and ion chromatography :  The total system must be monitored during use with reference standards. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (e.g. pumping system and detectors) must be subject to periodic checks and details must be recorded.
10.	Counter <ul style="list-style-type: none"> <li>• beta</li> <li>• cell</li> <li>• gamma</li> <li>• particle size</li> </ul>	Each use: Check using appropriate controls and standard materials.

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S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
11.	Deionizers	(a) Daily or when used: Check for conductivity using conductivity meter. (b) 6 monthly: Check for sterility
12.	Densitometers	6 monthly: Check for linearity.
13.	DNA-sizing equipment	Instrument performance must be routinely monitored during use with control samples.
14.	Electrophoresis	Instrument performance must be routinely monitored using the appropriate controls. System components (e.g. electrodes, tank and power supply), must be checked periodically.
15.	Flame photometers	Each use: Check using appropriate controls and standard materials.
16.	Freezers	(a) Daily: Check temperature using a thermometer. (b) Yearly: Check temperature with a reference thermometer.
17.	Glassware	(a) Volumetric glassware (burettes, pipettes, and volumetric flasks). Once – before first use. (b) Volumetric glassware for general use. Need and extent of calibration to be appropriate for intended use.
18.	Haematocrits	Yearly: Check speed using a calibrated tachometer.
19.	Haemoglobinometers	Twice weekly: Check using the appropriate controls and standard materials.
20.	Heating Baths	Daily or When used: Check temperature with a thermometer.

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S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
21.	Heating Blocks	For use analytical measurement or critical procedure: each day of use - by thermometer.
22.	Incubators	(a) Daily: check for temperature, using a calibrated thermometer. To maintain temperature to accuracy of $\pm 2^{\circ}\text{C}$ or within a given range as stipulated in methods.  (b) Yearly: temperature checks, using a reference thermometer.  (c) Carbon dioxide incubator (microbiology): check carbon dioxide content daily using built-in gauge; 6 monthly using fyrite device or equivalent device.
23.	Manometers	(a) Reference: Ten years (complete) and check fluid every three years.  (b) Working : Three years (Check against reference)
24.	Masses	Reference: Three years initial, six years subsequent.
25.	Microscopes	(a) Regular cleaning and maintenance. Clean stage and lenses after use.  (b) Yearly: Service maintenance.
26.	Microscopes, Fluorescent	(a) Check for the used time of UV bulb. Bulb should be changed when time reaches 200-300 hours or depending on life-span of bulb.  (b) Yearly: Service maintenance.
27.	Ovens	(a) Drying oven. By thermometer – frequency appropriate to use.  (b) Sterilizing oven (Hot air oven). Daily using thermometer.
28.	pH Meters	Daily or When used: Check for accuracy. Bracket pH value expected as closely as possible with buffers.



S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
29.	Piston-operated volumetric apparatus <ul style="list-style-type: none"> <li>Pipettes and Dispensers</li> </ul>	Every 6 months: For gravimetric checks, volume delivery and weighing under specified conditions must be repeated at least ten (10) times. For adjustable devices check volume delivered at several settings. Delivery of volumes less than 100uL may be verified by spectrometry using a dye solution.
30.	Refrigerators	(a) Daily: Temperature checks, using calibrated thermometer. (b) Yearly: Temperature checks, using reference thermometer.
31.	Spectrophotometers <ul style="list-style-type: none"> <li>UV-visible Spectrophotometer / colorimeter</li> </ul>	6 monthly: (a) Wavelength accuracy and reproducibility. Run two spectra. (b) Photometric accuracy and reproducibility.
32.	Sterilizers, gas	Each use: Using biological indicators.
33.	Stop Watches	Yearly: Calibration by accredited calibration organization.
34.	Tachometers	(a) Reference: Five years (b) Working : Once a year
35.	Thermocouples	Yearly: calibration by accredited calibration organization.
36.	Thermometers	(a) Reference : <ul style="list-style-type: none"> <li>2 Yearly: Specific points check by accredited calibration organization.</li> </ul> (b) Working : <ul style="list-style-type: none"> <li>Yearly: Temperature is checked at specific point using reference thermometer.</li> </ul>

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
37.	Timing Devices	Yearly: Verification.
38.	Temperature-controlled equipment	<p>The performance of water baths, incubators, ovens and refrigerators must be monitored continuously to ensure compliance with the temperature requirements of test methods.</p> <p>Accordingly, daily-recorded checks of the temperature within the load space of these items of equipment must be maintained.</p> <p>The thermometers used to monitor the performance of temperature-controlled equipment must be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods.</p> <p>The spatial distribution of temperature throughout the load space of temperature-controlled equipment may be checked following installation of equipment and at appropriate intervals thereafter.</p> <p>Temperature recording devices must be checked at yearly intervals against a reference thermometer and the results recorded.</p>
39.	Water Bath	<p>Daily or when used: Check the temperature using a calibrated thermometer contained in water bath.</p> <p>Maintain the accuracy of <math>\pm 1^{\circ}\text{C}</math> of the requirement. Record water bath thermometer correction factor and attach to water bath.</p>
40.	Water purifiers	<p>(a) Daily or When used: In-line check for conductivity. For instruments without in-line checks: weekly off-line check for conductivity.</p> <p>(b) 6 monthly: Check for sterility.</p>