ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MED 001

General Criteria for Medical Testing Laboratories

Technical Notes MED 001, 30 June 2025
The SAC Accreditation Programme is managed by Enterprise Singapore

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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 document shall be read in conjunction with ISO 15189 Medical laboratories – Requirements for quality and competence', SAC-SINGLAS documents, Proficiency Testing Technical Note 001, and other MEDICAL Series Technical Notes published by SAC-SINGLAS.

1.3 Medical laboratory services are essential to patient care and should 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.

2. Personnel

2.1 There shall be adequate and competent staff with the required education, training and experience to perform the procedures and tests. A comprehensive competency assessment programme should be in place with provisions made for all personnel to further their knowledge and skills.

2.2 For all medical laboratory services (e.g. microbiology, haematology, biochemistry) there should be access to the relevant medical specialist (e.g. medical microbiologist, haematologist or chemical pathologist) or a scientist with the relevant professional qualifications and experience to provide advice and make decisions on the following:

- Choose test methods to meet the clinical objectives'
- Evaluate, choose and apply testing and reporting guidelines, as published by scientific and professional bodies, modifying as necessary according to local clinical and laboratory context;
- Advise users on further laboratory investigations where needed, including need for confirmatory or supplemental tests
- Interpret and report results in a clinically relevant manner
- Provide further advice in the case of unexpected or difficult-to-interpret results

2.2 <u>Laboratory Director (LD)</u>

2.2.1 The LD (however named) shall be

- [+] SAB-registered pathologist or
- * registered medical practitioner with relevant clinical 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 (i) that is acceptable to the Director-General of Health (DGH), and who has at least 5 year's relevant working experience in a clinical laboratory acceptable to the DGH.*

a) Anatomic pathology,
b) Chemical pathology,
c) Cytogenetic.
d) Forensic pathology,
e) Haematology,
f) Immunology,
g) Medical microbiology,
h) Transfusion medicine, or
i) Any other discipline acceptable to the DGH.

[+] SAB : Specialist Accreditation Board, Ministry of Health

2.2.2 The LD shall delegate technical responsibility for each discipline within the laboratory or use external consultative services from a pathologist with relevant experience or qualification, or scientist with professional qualification or certification.

2.2.3 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.

2.3 Consulting Pathologist (Visiting Consultants)

2.3.1 When the services of an external consulting pathologist are necessary, an effective working relationship between the LD and the consulting pathologist shall be established.

2.3.2 The consulting pathologist shall play an active role in the programmes established by the laboratory and the organisation.

2.3.3 The services of the consulting pathologist shall be provided at a frequency and manner to meet the laboratory's quality requirements. The scope of duties and responsibilities shall be stated, and a written report kept of each consultation.

2.4 Laboratory Supervisor (LS) / Section Leader

2.4.1 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 the following:-

a) a Science Degree in a relevant discipline OR a Polytechnic Diploma in a field relevant to medical laboratory science

b) at least 5 years of clinical laboratory working experience

2.5 Medical Laboratory Scientist / Technologist

2.5.1 a) The Laboratory Personnel (however named) performs testing and assists the LS in the daily operations.

b) Laboratory Personnel shall hold a Degree, a Diploma, or other qualification in a field relevant to medical laboratory science,

3 Facilities and Environmental Conditions

3.1 Physical Facilities

3.1.1 There shall be sufficient resources, including adequate space, instrumentation, furniture, communication systems, supplies, ventilation, piped gases, water, and public utilities security, proper waste disposal / collection, to support the activities of the laboratory. There shall be good housekeeping in the laboratory.

3.1.2 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. Appropriate license from regulators (e.g. National Environment Agency, Singapore Civil Defence Force) must be obtained and regular check on the environment shall be conducted to ensure the accommodation is safe for staff to work in.

3.1.3 An appropriate immunization programme for all laboratory personnel should be in place. Policies and procedures shall be developed to minimize the occupational risk of exposure to infectious agents handled in the microbiology laboratory, in accordance with current recommendations regarding the biosafety levels (or Risk Groups, RG) for working with different organisms.

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 environment 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 or 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 programme. This shall be documented when completed.

3.2.2 The Laboratory Safety Manual shall be available on the workbench and a safety officer shall be appointed to ensure safety measures as contained in the manual are 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 programme.

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 personnel protective equipment (e.g. gowns, gloves, masks, goggles etc) and safety equipment are appropriate to the duties being performed.

Laboratory shall also provide fire extinguisher, safety shower and eye wash in close proximity to the laboratory working area. Safety shower and eyes wash shall be activated weekly for a period long enough to verify operation and ensure that flushing fluid is available. Self-contained units shall be visually checked weekly to verify that adequate flushing fluid is available. Such inspection shall be conducted in accordance with manufacturer's instructions [ANSI Z358.1-2014])

3.2.7 All of these and the protective equipment shall be easily accessible and shall not be obstructed by equipment, furniture, etc.

3.2.8 Chemical fume control devices such as hoods shall be checked by the user before each use and recertified annually and records shall be documented. Refer to Table 1 on the minimum maintenance criteria.

3.2.9 All laboratory instruments and appliances shall be grounded and checked for electrical leakage and time of implementation, following manufacturers' recommendation and after any ad hoc repairs when appropriate. All related chemicals and gas cylinders are safely stored and secured.

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

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

3.2.11 Safety Data Sheets (SDS) shall be documented for each hazardous chemical in the laboratory and be readily available at every point of use and storage. The designated staff shall maintain the location of such documentation.

3.2.12 A chemical hygiene plan (CHP) may be developed and should 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.

3.2.13 The CHP should be reviewed annually and all employees should 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.*

3.2.14 If the laboratory uses hazardous chemicals such as formalin, xylene or ether, appropriate precautions shall be taken to protect staff and the environment. Such precautions may include storing only the minimum feasible volume of reagent on the bench (e.g. ether) and setting up an environmental monitoring programme (e.g formaldehyde and xylene). The laboratory that handles hazardous chemicals shall have documented evidence, that formaldehyde vapour levels have been measured.

3.2.15 Appropriate extraction systems shall be in place to minimize the levels of noxious vapours.

3.2.16 Proper signs shall be placed at significant hazard areas.

3.2.17 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. Non-latex gloves should be provided to all staff (in accordance with occupational safety requirements from the Ministry of Manpower).

3.3.2 Biological Safety Cabinet and Personal Protection Equipment

a) A biological safety cabinet (BSC) and appropriate personal protection equipment (PPE) should be provided based on the laboratory's risk assessment.
b) BSC must be functioning in laboratories that handle infectious materials such as blood, fluids, culture mycobacteria, fungi and viruses.
c) BSC shall be certified annually to assure that the filters are functioning properly and the airflow rates meet expected specifications. The records shall be documented.
d) When high filtration masks are used, annual fitting test should be performed if applicable. This is to ensure the selected model and size adequately accommodate an individual's facial characteristics.
e) Training and annual competency check should be performed to ensure the users can operate BSC and don PPE properly in order to achieve the anticipated protection during use.

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 Autoclave: All personnel using autoclave should have been trained and demonstrate competency in its operations. There should be written procedures to verify autoclave effectiveness based on risk assessment.

3.5 Radioactive Safety

3.5.1 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

3.5.2 Laboratories shall have documented procedures to collect and dispose radioactive waste, in accordance to local regulatory requirements.

4. 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.

4.2 Written and documented policies and procedures shall be available for all equipment before they can be used for patient testing. Preventive maintenance and instrument function checks shall be put in place.

4.3 For Multiple Analysis Automated Instruments and Systems, written standard procedures shall be available for calibration set up, operation and control of the systems.

4.4 **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 document is 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) 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.

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

4.6 Where the laboratory personnel 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.

4.7 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.

4.8 The laboratory shall institute a preventive maintenance programme (which, as 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.

4.9 Documentation of all maintenance and service activities shall be retained for the life of the instrument at appropriate rendition times in accordance to local regulations. Corrective actions shall be documented when an unacceptable tolerance limit or instrument/equipment malfunction is detected.

5 Reagents

5.1 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.

5.2 Proper storage of all reagents and culture media shall be observed according to the requirements set up by the manufacturers.

5.3 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.

5.4 All reagent containers shall be labelled according to the GHS label standards and tightly closed. They shall bear at least the following information: Product Identifier (the chemical name) & its concentration, GHS pictogram, Signal Word, Hazard/Precautionary statement, Supplier & Supplementary information (such as Expiry dates). For small containers such as calibrators and cellular controls, the label should contain sufficient information which can identify what is stored in the container. This should also include the date opened, and date of expiry.

The person responsible for the preparation of the reagent shall be identifiable either from the label or from records.

5.5 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.

5.6 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.

5.7 The Laboratory shall maintain the quantity of flammable and dangerous chemicals within the allowable limit, as stipulated in its SCDF license and NEA license.

5.8 Certified Reference Materials

5.8.1 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.

For traceability provided by reference material producers, refer to SAC-SINGLAS 006 Clause 5.2.

5.8.2 Certified reference materials are used to help calibrate instruments and measurement systems to ensure the long-term reliability and integrity of the measurement process.

5.8.3 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.

5.8.4 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.

5.8.5 All analysts shall be instructed in the care of certified reference materials and procedures for handling them.

5.9 Working Reference Material

5.9.1 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.

5.9.2 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.

5.9.3 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.

5.9.4 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.

5.9.5 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.

6. Pre-Examination Procedures

6.1 Sample Collection

6.1.1 The laboratory must have sample collection instructions for all available tests. Sample stability post-collection must be available in the sample collection instructions.

6.1.2 Tests requiring patient preparation should be included in detail in the sample collection instructions.

6.1.3 The laboratory shall have regular consultations with clinical staff on the use of the laboratory and laboratory tests, including the efficacy of tests, repeat frequency and required specimen types.

6.1.4 There shall be documentation or evidence of assessment for the verification of sample containers for interferences before use.

6.1.5 The laboratory shall confirm the patient's identify by checking at least two identifiers such as name, unique identification number / hospital number and birth date 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.

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

6.1.7 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.

6.2 Sample Transport

6.2.1 The laboratory shall have documented procedures for appropriate transport of samples to testing laboratory. A monitoring system should be in place to ensure appropriate temperature control is maintained for the samples at all times. A robust tracking process for sample movement across labs should be in place.

6.2.2 The laboratory should ensure a protocol is in place with evidence of competency in the event of a sample or formalin leakage during specimen transport.

6.2.3 High speed automated transport system for samples i.e. pneumatic tube transport, if available, requires the laboratory to verify the impact on sample quality before implementation.

6.3 Sample Receipt

6.3.1 The procedure for verification of sample receipt should be available.

6.3.2 The laboratory shall have a procedure for sample rejection on receipt. All rejected samples should be documented with reason and communicated to the requesting physician. There shall be criteria for defining the rejection of sample including any exception (i.e. precious samples).

6.3.3 The collection documentation should include the time the sample is collected from the patient and the arrival in the laboratory.

6.3.4 There shall be documented procedures for both urgent (STAT) and routine requests. There shall be a documented list of the laboratory tests available on a STAT and 24-hour basis.

6.5 Centrifugation

6.5.1 The centrifugation of blood samples should be documented for speed and duration. Manufacturer's guidelines should be followed for brand and anticoagulant. Centrifuge may be a stand-alone unit or a component of a laboratory automation system.

6.5.2 Urine/fluid centrifugation should follow the test requirements when necessary.

6.5.3 Sealed buckets shall be used in centrifuges when infectious organisms are present or are likely to be present. Where infection may be acquired by aerosolisation, the bucket shall be unloaded in a BSC after waiting for a suitable time before opening the sealed buckets.

7 Examination Procedures (Quantitative)

7.1 In the event a laboratory procures a new methodology for a test, or a new test to their test menu, verification or validation processes must be carried out before this test can be put into routine service.

7.2 Verification process is required for all new automated tests that are not modified from the manufacturer's information sheet. All documentation of the test verification is required to be retained for the life of the test in service.

7.3 Validation of a new test is required if it is a new test or it is a laboratory developed test (LDT). The extent of the validation required should be aligned with the tests intended use. Test results obtained should be correlated clinically with the patients' diagnosis. All documentation of the validation is required to be retained for the life of the test/analyser in service.

7.4 The verification process should include:

a) Within day and between day precision at clinical decision levels
b) Comparison with previous methodology
c) Limit of quantitation, limit of detection, for all tests.
d) Functional sensitivity for the relevant tests
e) Linearity of measuring range, reportable range

f) Dilution to extend reportable range, verification of dilution
g) Carry-over where relevant
h) Interference study on the effects of haemolysis, icterus and lipaemia
i) Clinical concordance for qualitative tests
j) Reference range validation or establishment
k) Measurement of uncertainty at clinical decision levels
l) Summary report for all tests

8. Ensuring Validity of Examination Results –

Quality Control and External Quality Assessment (EQA)

8.1 Quality control programmes shall be put into place for all tests. This includes levels of quality control materials run each day, frequency of performing QC, types of QC material and the QC acceptable criteria to be observed by the laboratory staff. The selection of QC levels should be appropriate for the clinical objectives of the intended tests. Clearly understood information should be available for action to be taken in the case of QC result falling out of the acceptable limits. Documentation of all action should be available. The quality control programmes shall include tolerance limits and corrective action procedures to use when limits are exceeded.

8.2 Quality control and proficiency testing samples shall be tested in the same manner as patient samples and shall be integrated within the routine laboratory workflow and performed by personnel who routinely perform tests patient samples.

8.3 Participation in EQA programmes shall cover the extent and complexity of analytical procedures, including consultative services in histopathology. Accredited laboratories shall have a minimum EQA participation frequency of one analyte or test every year. Where such PT programmes 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 programmes shall be in accordance with *SAC-SINGLAS Technical Note PROF-001 Policies on Proficiency Testing.*

8.4 The LD/LS or designate shall monitor the results of EQA and participate in the documentation of corrective actions, where required.

8.5 Satisfactory verification of the performance of unmodified commercial tests, validation of modified commercial tests and lab developed tests must be in place before introducing a new test or replacing an existing test.

8.6 The LD/LS or designate shall systematically monitor and evaluate the quality and appropriateness of the laboratory's contribution to patient care. When the programme identifies systematic problems, the designated personnel shall take appropriate corrective actions.

9. Post-examination Procedures

9.1 Waste Disposal

9.1.1 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.

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

9.1.3 Disposable pipette tips, sample cups, etc. should not be washed and reused.

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

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

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

10. Reporting of Results

10.1 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.

10.2 A list of critical results shall be available and critical values should be reported as soon as possible and only after verification by a competent technologist as approved by the laboratory.

10.3 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.

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

10.5 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.

10.6 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. There should

be a procedure for review and informing users should the turnaround time exceed reasonable limits.

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

10.8 Reference values should be available for all assays, where relevant.

10.9 Consultation concerning interpretation of results and advice on further investigation should be available at all times.

10.10 There should be regular meetings of laboratory staff with the clinical staff regarding use of the laboratory and interpretation of results.

10.11 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.

10.12 There should be timely reporting of test results based on testing priorities and a system should be in place to document problems in communication of laboratory results.

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 02, Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement Marks

6. SAC-SINGLAS 001, Accreditation Process

7. EAL - G25 (ECLM-1), Accreditation for Medical Laboratories (1997).

8. OSHA Requirements (refer to Reference No.1).

9. ISO 15189:2022 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 (e.g. methylene blue strips, fastidious anaerobes etc.).
2.	Analyzers • Automated • electrolyte • glucose • oxygen • protein	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.
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.

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
6.	Bilirubinometer	When used: Calibration according to manufacturer's or laboratories specifications and at least two levels of matrix appropriate QC
7.	Blood gas analyser	Calibration according to manufacturer's recommendation. QC should be performed every eight hours for benchtop analysers.
8.	Biological Safety Cabinet & Laminar flow	Yearly: Certified to ensure filters are functioning properly and that airflow rate meet specifications.
9.	Chemistry Analysers, Automated	Calibration should be performed according to manufacturer's or laboratories specifications for all sample types required. At least two levels of QC material should be assayed at least every 24 hours for all sample types being tested. Therapeutic drugs may require three levels of QC to be performed to cover all critical areas of the measuring range.
10.	Centrifuges	Yearly: (a) Check temperature using a calibrated thermistor, or more frequently if required, and (b) Check speed using a calibrated tachometer.
11.	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. Calibration and QC performed following manufacturer's specifications and for the sample types being tested. All related chemicals and gas cylinders are safely stored and secured.

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
12.	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. Calibration and QC performed following manufacturer's specifications and for the sample types being tested. All related chemicals and gas cylinders are safely stored and secured.
13.	Counter • beta • cell • gamma • particle size	Each use: Check using appropriate controls and standard materials.
14.	Deionizers	(a) Daily or when used: Check for conductivity using conductivity meter. (b) 6 monthly: Check for sterility
15.	Densitometers	6 monthly: Check for linearity and optics checks.
16.	DNA-sizing equipment	Instrument performance must be routinely monitored during use with control samples.
17.	Electrophoresis	Instrument performance must be routinely monitored using the appropriate controls. Appropriate control material should be used in parallel with patient samples. System components (e.g. electrodes, tank and power supply), must be checked periodically.
18.	Flame photometers	Each use: Check using appropriate controls and standard materials.

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
19.	Freezers	(a) Daily: Check temperature using a thermometer. (b) Yearly: Check temperature with a reference thermometer.
20.	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.
21.	Haematocrits	Yearly: Check speed using a calibrated tachometer.
22.	Haemoglobinometers	Twice weekly: Check using the appropriate controls and standard materials.
23.	Heating Baths	Daily or When used: Check temperature with a thermometer.
24.	Heating Blocks	For use analytical measurement or critical procedure: each day of use - by thermometer.
25.	Incubators	(a) Daily: check for temperature, using a calibrated thermometer. To maintain temperature to accuracy of ± 2^{o}C or within a given range as stipulated in methods. (b) Yearly: temperature checks, using a reference thermometer. (c) Carbon dioxide incubator: check carbon dioxide content daily using built-in gauge; 6 monthly using fyrite device or equivalent device.
26.	Immunoanalysers, Automated ((including nephlometers and turbidimeters)	Calibration should be performed according to manufacturer's or laboratories specifications. At least two levels of QC material tested for each analyte. For tests with very low concentrations being reported e.g. troponin, QC should be performed with a suitably low concentration to ensure robust performance at low concentrations. Auto-dilution should be available when required.

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
27.	Manometers	(a) Reference: Ten years (complete) and check fluid every three years. (b) Working : Three years (Check against reference)
28.	Masses	Reference: Three years initial, six years subsequent.
29.	Mass Spectrophometry (MS-MS)	Calibration and QC performed following manufacturer's specifications and for the sample types being tested. All related chemicals and gas cylinders are safely stored and secured.
30.	Microscopes	(a) Regular cleaning and maintenance. Clean stage and lenses after use. (b) Yearly: Service maintenance.
31.	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. The microscope should contain the appropriate filter(s) recommended by the manufacturer. (b) Yearly: Service maintenance.
32.	Ovens	(a) Drying oven. By thermometer – frequency appropriate to use. (b) Sterilizing oven (Hot air oven). Daily using thermometer.
33.	Osmometer	Daily or when used: Calibration according to manufacturer's specifications and at least two levels of appropriate QC for the sample matrices being tested.
34.	pH Meters	Daily or When used: Check for accuracy. Bracket pH value expected as closely as possible with buffers.
35.	Piston-operated volumetric apparatus • Pipettes and Dispensers	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.

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
36.	Refractometer	When use: To be tested with appropriate QC materials
37.	Refrigerators	(a) Daily: Temperature checks, using calibrated thermometer. (b) Yearly: Temperature checks, using reference thermometer.
38.	Spectrophotometers • UV–visible Spectrophotometer / colorimeter	6 monthly: (a) Wavelength accuracy and reproducibility. Run two spectra. (b) Photometric accuracy and reproducibility.
39.	Sterilizers, gas	Each use: Using biological indicators.
40.	Stop Watches	Yearly: Calibration by accredited calibration organization.
41.	Tachometers	(a) Reference: Five years (b) Working : Once a year
42.	Thermocouples	Yearly: calibration by accredited calibration organization.
43.	Thermometers	(a) Reference : • 2 Yearly: Specific points check by accredited calibration organization. (b) Working : • Yearly: Temperature is checked at specific point using reference thermometer.
44.	Urinalysis – Automated or Manual Dipsticks	Daily QC: To be performed using matrix appropriate material. Calibration should be performed according to manufacturer's or laboratories specifications for an automated analyser. If the analyser is used for fluid analysis a suitable QC should also be used.

S/N	TYPE OF INSTRUMENT OR EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS OR PERFORMANCE CHECKS
45.	Timing Devices	Yearly: Verification.
46.	Temperature-controlled equipment	The performance of water baths, incubators, ovens and refrigerators must be monitored according to testing needs to ensure compliance with the temperature requirements of test methods. Accordingly, daily-recorded checks of the temperature within the load space of these items of equipment must be maintained. 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. The spatial distribution of temperature throughout the load space of temperature-controlled equipment may be checked following installation of equipment at an appropriate interval thereafter. Temperature recording devices must be checked at yearly intervals against at reference thermometer and the results recorded.
47.	Water Bath	Daily or when used: Check the temperature using a calibrated thermometer contained in water bath. Maintain the accuracy of ±1^{o}C of the requirement. Record water bath thermometer correction factor and attach to water bath.
48.	Water purifiers	(a) Daily or When used: In-line check for conductivity. For instruments without in-line checks: weekly off-line check for conductivity. (b) 6 monthly: Check for sterility.