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Directorate General of Private Health Establishments

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Ministry of Health

National Guideline for Private Medical Laboratories

Directorate General of Private Health Establishments

Ministry of health

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CONTENTS

II. Acronyms

ALP	Alkaline Phosphatase
CBC	Complete Blood Count
CK	Creatine Kinase
CK-MB	Creatine Kinase isoenzyme form MB
CPD	Continuing Professional Development
CR	Commercial Registration
CT	Cytotechnologist
CV	Curriculum Vitae
DGDSC	Directorate General of Disease Surveillance and Control
DGPHE	Directorate General of Private Establishment
ESR	Erythrocyte Sedimentation Rate
E.N.T	Ear, Throat and Nose
EQA	External quality assurance
EQAS	External Quality Assessment Scheme
EQC	External Quality Control
LDH	Lactate Dehydrogenase
G6PD	Glucose- 6- Phosphate Dehydrogenase
HbA1c	Haemoglobin A1c
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HDL-C	High density lipoprotein-Cholesterol
HIV	Human Immunodeficiency Virus
HTL	Histo-technologist
ID	Identification Number
IQC	Internal quality control
LDL-C	Low density lipoprotein-Cholesterol
LJ chart	Levy–Jennings chart

MOH	Ministry of Health
LFPM	Linear Feet Per Minute
LFT	Liver Function Test
LIMS	Laboratory Information Management Systems
NCE	Nonconformity Event
NFPA	National Fire Protection Association Hazard
OSHA	Occupational Safety and Health Administration
RCPA	Royal College of pathologists of Austrasia
PPE	Personal Protective Equipment
PT	Proficiency Testing Program
QAP	Quality Assurance Program
RIQAS	Randox International Quality Assessment Scheme
SAA	Satellite Accumulation Area
SD	Standard Deviation
SDS	Safety Data Sheet
SOP	Standard Operating Procedure
TAT	Turnaround Time
TB	Tuberculosis
UE1	Urea and Electrolytes
UV	Ultraviolet

III. Definitions

4.1. **A policy** is a documented statement of overall intentions and direction defined by those in the organization and endorsed by management.

4.2. **An internal audit** is a process used to evaluate, amend and improve procedures in a systematic way to enhance quality. This kind of audit is organized and carried out by laboratory staff and management

4.3. **Authorization Matrix** is a list or table that sets out who can approve a change, subject to cost limits, or areas of responsibility.

4.4. **Continual improvement** is the ongoing effort to improve services, systems, processes or products to raise individual outcomes.

4.5. **Documents** provide written information about policies, processes, and procedures that require updating.

4.6. **External quality assurance (EQA)**, known as external quality assessment (EQA) and proficiency testing, allows for a comparison of a laboratory's testing procedures to other laboratories across the world. It assesses the quality of results obtained by laboratories, by means of an external agency.

4.7. **Internal quality control (IQC)** is a process of detecting analytical errors within the laboratory. This process is used to ensure the reliability and accuracy of test results to provide the best possible patient care. Unreliable performance can result in mismanagement of the patients.

4.8. **Medical laboratory** is an entity, which is established and equipped to perform medical diagnostic laboratory tests on an individual's body fluids or body tissues and to report the results back to the treating doctor. The Laboratory may be established separately without having to be part of a hospital or a clinic.

4.9. **Nonconformity event (NCE)** is defined as nonfulfillment of a requirement of existing policies, processes, and procedures, which could be minor, major or critical. This involves any occurrence that is not according to rules. NCE can affect the efficiency of work operation and has the potential to affect patient safety. Examples of nonconformity events may include but not limited to unlabeled/mislabeled specimens, missing specimens, specimen preparation errors, delay in turnaround times, incorrect delivery of reports and corrected reports.

4.10. **Phlebotomy** is the act of drawing or removing blood from the circulatory system through an incision or puncture to obtain a sample for analysis and diagnosis.

4.11. **Post-analytical phase** describes processes following the analytical phase including systematic review, formatting and interpretation, authorization for release, validating, reporting and transmission of the results, and storage of samples after the examinations.

4.12. **Pre-analytical phase** describes all actions and aspects of the medical laboratory diagnostic procedure that occur before the analytical phase. It represents the major source of inaccurate laboratory results and errors.

4.13. **Procedures** are the specific activities of a process. Procedures are very familiar to laboratorians–a procedure is easily described as the performance of a test.

4.14. **Process** is a set of interrelated or interacting activities that transform inputs into outputs.

4.15. **Records** are the collected information produced by the laboratory in the process of performing and reporting a laboratory test.

4.16. **Sampling plan** is a plan for implementation towards completing the test. It usually involves three steps: collecting the sample (primary sample) from the target/person/ population, preserving the sample as professionally required, and preparing the sample for the analysis/testing.

4.17. **Standard Operating Procedure (SOP)** is a document, and contains written step-by- step instructions that laboratory staff should meticulously follow when performing a procedure. A laboratory will have many SOPs, one for each procedure conducted in the laboratory.

4.18. **Analytic phase** involves the actual running of the test that initiates when the patient specimen is prepared for testing and ends when the test result is interpreted, verified and validated.

4.19. **The quality manual** is a document that describes the quality management system of an organization.

Chapter One

IV. Introduction

Laboratory medicine is a cornerstone in any healthcare system. Its role in diagnosis and management of patients can't be overlooked, from simple to complex tests, in hospitals and clinics, laboratory medicine is a major hub in the healthcare system. Clinical decision-making depends on reliable and timely laboratory test results. Approximately 60–70% of medical decisions are based on laboratory results[1]. Therefore, it is important that laboratory professionals give due importance to the management and quality of these laboratories. This will enable the laboratory to provide accurate and reliable results.

As the private laboratory medicine sector grows up to cover national needs, it deems essential to have guidelines that will provide owners with the essential requirements and agreed standards to provide the desired level of quality. The laboratory management should strive to ensure adherence to these requirements at all levels of the process. Compliance with the standard guidelines will be ensured through regular auditing by the Directorate General of Private Health Establishments (DGPHE), Ministry of Health.

V. Scope

This document applies to all private medical laboratory sectors.

VI. Purpose

This document is intended to standardize practices in different categories of the private medical laboratories in Oman. In addition, it sets out the specific requirements to be met by laboratories wishing to achieve the approval from the DGHPE for licensure of clinical laboratories and for the protection of the health, safety and welfare of the public. These requirements were developed taking into consideration the differences between each specialty. Therefore, adherence to the instructions and requirements in this document is required.

Chapter Two

VII. Legislation

All Rules and Regulations in Private Medical Laboratory Practice shall comply with the Sultanate of Oman Law system, refer to:

1.1. https://www.mjla.gov.om/legislation/laws/.

1.2. The Law on the Control of Communicable Diseases Promulgated by Royal Decree 73/92.

Note:

All laboratories shall comply with MOH notification on infectious disease policy and submit samples and organisms of public health concerns according to communicable disease manual. (MOH website)

VIII. General Rules And Regulation

6.1. It is prohibited to open a private medical laboratory of any type or publish any kind of advertising materials without prior approval from the MOH and obtaining a license from the Directorate General of Private Health Establishments (DGPHE).

6.2. The license is renewable every two years and must apply for renewal at least two months prior to its expiry date.

6.3. The laboratory must comply with all Ministry of Health (MOH) regulations. Failure to follow the regulations may result in withdrawal of the license.

6.4. It is prohibited to practice laboratory science without a license from the MOH.

6.5. The licenses shall be displayed in a visible place at the laboratory entrance (e.g., the laboratory reception), accreditation certificate, if any, and tests' prices.

6.6. Number of entitled staff members must be in accordance with the volume of work executed in that laboratory.

6.7. Laboratory should have a sampling plan (collection, handling and transportation) and procedures for testing. The sampling plans should be available at the location where sampling is undertaken (Standard Operating Procedures for sample collection) which will be located outside/away from the laboratory, the sampling test method must be approved by the MOH.

6.7.1. The laboratory shall be based according to approved plans and should **NOT** be located in the basement.

6.7.2. The laboratory shall have a barcode system for identifying samples. The identification shall be retained throughout the life of the sample in the laboratory.

6.8. The report of each test shall include the following:

6.8.1. Name of the issuing health institute and location.

6.8.2. Patient's full name, nationality, age and civil ID/ passport number.

6.8.3. Medical record number and sample ID number.

6.8.4. Name of sample collection site (Clinic/hospital).

6.8.5. Name and contact details of the requesting doctor.

6.8.6. Collecting, receiving and releasing date.

6.8.7. Type of sample and test requested.

6.8.8. Test results with units and reference ranges.

6.8.9. Signature of the authorized personnel.

6.9. In case of any technical, testing error or conflict of reports the laboratory should ask a second fresh sample to re-run the test, patients to be called back for new specimens and the new reports to be issued.

6.10. The laboratory shall implement internal quality control procedures.

6.11. The laboratory shall participate in External Quality Assessment Scheme (EQAS) e.g., interlaboratory sample comparison

6.12. The laboratory shall seek approval from the MOH and other governmental bodies to import any cells, organisms, genetic materials or live animals for laboratory testing or research purposes in the case of laboratory animals. Details of the intended use of these items must also be given and made clear.

6.13. The pathologist shall be responsible for supervision and/or management of the laboratory, in addition to reviewing, approving and signing of laboratory reports. Moreover, in-case of Clinics and polyclinics a laboratory personal with MSc holder will be responsible of supervising and managing the lab.

6.14. It is strictly prohibited to use any tests containing radioactive materials without prior approval from the MOH.

6.15. The MOH retains the right to acquire any information about the laboratory and the right to inspect the laboratory at any time without prior notification for the purpose of inspection and quality assessment.

6.16. Retention of Records shall be in concordance with the national laws and guidelines. (Refer to the Document: Retention and Disposition Schedules for Health Institutions)

7. Licensing

Pertaining to the Ministry of Health (MOH) Qarar number 25/2009 on private hospital organization bylaw, private health institutes shall receive applications to operate clinical laboratories in the Sultanate of Oman according to the applicable laws regarding this issue.

7.1. Laboratory License Requirements:

7.1.1. **First Step:** Requirements for initial general or specialized laboratory license from the directorate general of private health establishment (DGPHE):

7.1.1.1. Obtain a commercial registration from the Ministry of Commerce, Industry & Investment Promotion.

7.1.1.2. Write a letter to DGPHE general director and fill the application form of private health establishment license request evaluation form.

7.1.1.3. Submit required documents (commercial registration (CR) papers and a copy of the ID cards of registered investor(s) in the CR).

7.1.1.4. Upon request approval, proceed to the next step.

7.1.2. **Second Step:** General or Specialized Laboratory Sketch Approval Requirements

7.1.2.1. Written request to Department of licensing and Auditing of Private health establishment, along with the proposed sketch.

7.1.2.2. After sketch approval, submission of medical staff curriculum vitae (CV) and qualifications, analyzers and test lists is mandatory.

7.1.3. **Third Step:** General / Specialized Laboratory Final Inspection Requirements. Upon the completion of all medical and administrative requirements of the

general/specialized laboratory, the owner shall apply for request of final inspection, while ensuring the attachment of the following documents:

7.1.3.1. Submit Commercial registration papers after activating the activity.

7.1.3.2. A copy of the trade name or trademark reservation from the Ministry of Commerce, Industry & Investment Promotion.

7.1.3.3. A copy of municipal license.

7.1.3.4. A copy of security and safety license (Civil Defense License).

7.1.3.5. A copy of the approved sketch.

7.1.3.6. A copy of qualifications that have been verified through an approved organization to assist in mitigating potential risk by fraud for all laboratory personnel.

7.1.3.7. A copy of biohazard wastage disposal contract (e.g., Be'ah).

7.1.3.8. The license shall be issued once the facility site is inspected and all requirements, equipment and Laboratory personnel required to operate the facility are approved.

8. Categories of Medical Laboratories

8.1. **General Basic Laboratory** shall be supervised by a MSc holder Biomedical science and at least two general laboratory technologists. However, in rural areas general basic laboratory can be supervised by a qualified senior laboratory technologist with the following requirements:

8.1.1. Master degree in any medical laboratory specialty

8.1.2. Minimum 3 years' experience

8.1.3. No central or reference laboratory in the nearby area.

8.2. The following services could be provided by this laboratory category:

8.2.1. **Routine Haematology**

Complete Blood Count, Glucose- 6- Phosphate Dehydrogenase (G6PD), Malaria Parasite, Sickle solubility test (screening test), and Erythrocyte Sedimentation Rate, Reticulocyte count, peripheral smear (in case of any abnormalities found the slide should be referred to be revised by an pathologist)

8.2.2. **Core Biochemistry**

- Urea and Electrolyte, Liver Function Test, bone profile (Calcium, Adjusted calcium, phosphate, albumin, ALP), Uric acid, CK-MB, LDH, Magnesium, Osmolality, lipid profile (total cholesterol, triglyceride, LDH, LDL), Glucose, HbA1c, Microalbumin, Creatinine, CRP.
- Urine: Na^{+}, K^{+}, Mg^{+2}, and Ca^{+2}, Osmolality.

8.2.3. **Microbiology.**

Urine and stool routine microscopy, Urine Dip sticks, and Occult blood, Rapid pregnancy test, ASO titer, RA, VDRL.

8.3. **Specialized Laboratory (stand alone, hospital based or multispecialty polyclinic)** shall be supervised by general pathologist and specialized pathologist if needed

8.5.1. Core biochemistry, hormones and specialized biochemistry tests.

8.5.2. Hematology tests.

8.5.3. Blood Transfusion services. (Refer to detailed Transfusion services, Central Blood Bank Policy)

8.5.4. Serology and immunology tests.

8.5.5. Microbiology tests.

8.5.6. Histopathology and cytology.

8.5.7. Molecular Tests.

8. **Medical fitness Centers** Refer to detailed Criteria for Medical Centers Licensing for Expatriates Fitness Residency Requirement,

8. Organization and Management

9.1. The laboratory shall be directed by a competent person with delegated and clearly documented responsibilities. These should include administrative, advisory, organizational, financial, scientific and educational responsibilities which are relevant to the provided services. (Refer to Responsibilities section 5 for more details)

8.3. Responsibilities of all members in the laboratory shall be clearly defined.

8.4. The laboratory should have an Authorization Matrix, showing for each position in the laboratory the authorizations, responsibilities and tasks which should be signed and dated by the Laboratory Manager.

8.5. The staff members should know the Authorization Matrix which should be accessible to all staff members who should be able to explain how it works.

8.6. The laboratory shall have an appraisal system for all personnel at least annually. (Refer to task and responsibilities for details).

8.7. An SOP and a standardized form should be developed for the performance appraisal of the staff.

8.8. The performance appraisal shall be discussed with each staff, gaps to be identified and develop an approach to eliminate causes of poor performance. Appraisal forms should be kept in personnel files.

8.9. The laboratory management shall have regulations in place that ensure ethical conduct of the staff so that confidentiality of information is maintained, potential conflicts are appropriately declared and resolved, laboratory operational integrity is maintained with no commercial, financial or other pressure that influences quality of work.

8.10. The laboratory management shall have evidence of implementation and continual development of the quality management system in the laboratory at all its levels. (Refer to Quality Assurance section 16)

8.11. The laboratory management shall ensure optimal design, implementation and improvement of the quality management system.

8.12. The Hospital and standalone laboratories shall appoint a quality officer to monitor the implementation and function of the quality system in the laboratory and communicate this to the laboratory manager.

8.13. The laboratory management shall have an effective means of communication with staff with records of discussed items and meetings.

8.14. The laboratory management shall ensure appropriate communication with its stakeholders regarding effectiveness of the laboratory's pre-examination, examination and post examination processes and quality management system.

8.15. Laboratory shall support the smooth optimal workflow of samples from receipt to processing to minimize incidents and errors.

8.16. Laboratory shall ensure providing appropriate interpretation and advising services to meet needs of clinical staff and patients.

9. Laboratory Space (Module/ Bay Size)

9.1. Clinics laboratory: 5*5 square meters total of 25 square meters. (Routine Hematology and routine Biochemistry)

9.2. Polyclinics laboratories: two rooms each 5*5 square meters total of 50 meters. (Routine Hematology, routine Biochemistry, Immunoassay and Hormones). If Microbiology will be applicable with extra 4*4 square meter room space.

9.3. Hospitals laboratories / specialized diagnostic referral laboratories: each section 5*5 square meters. (Routine Hematology, routine Biochemistry, Immunoassay and Hormones). If Microbiology will be applicable with extra 4*4 square meter room space. This category depends on the service which is provided by the laboratory and final measurement and size can be determine at the time of sketch approval

9.4. Aisles should be maintained unobstructed and at least (90 cm) 36 in. wide throughout

9.5. Lab benches should be at least 60 cm wide.

10. Accommodation and Environment

10.1. Architectural Finishes and material

10.1.1. The laboratory area must be adequately sized to accommodate anticipated work including equipment and staff. The area and design must comply with international standards for laboratory.

10.1.2. Walls, floors, and surfaces shall be made of or covered with seamless appropriate material and can be easily decontaminated. All pits and floor openings shall be covered or guarded.

10.1.3. The work areas shall be sufficiently ventilated and illuminated.

10.1.4. Exit signs should be illuminated. Paths leading to all exits shall remain free from obstruction. Alternative emergency exits should be taken into consideration. Fire doors shall not be blocked or wedged open.

10.1.5. Water service should be available without disturbance for more than 99% of working hours.

10.1.6. All laboratory rooms shall be equipped with hand wash sinks. These sinks should not be used for other laboratory procedures.

10.1.7. Benches and furniture.

10.1.7.1. Due to the use of caustic reagents and complex instrumentation, choosing the right surface material for your laboratory workbenches is a crucial decision when outfitting a lab with furniture. The main factors that go into the decision-making process are:

- acid resistance
- microbial resistance
- scratch resistance
- ease of fabrication in the field
- hygiene, aesthetics
- static resistance
- stain resistance

10.2. **Access Control**

10.2.1. The Laboratory design shall take in consideration hazardous material flow.

10.2.2. Access to the laboratory area must be restricted to authorized personnel only.

10.3. **Allocation of Equipment.**

10.3.1. Laboratory equipment should be allocated in such a manner that their ability and efficiency is not affected or influenced.

10.3.2. International guidelines should be followed when placing biosafety cabinets and equipment affected by vibration.

10.4. **Hazard Communication Signage**

Biohazard sign should be posted at the entrance of the laboratory and the following signs should be clearly posted as described below:

10.4.1. The need for wearing laboratory coats and/or necessary PPE.

10.4.2. (Only authorized personnel)/ (Restricted entry) signs at the door of the laboratory.

10.4.3. (Food and drinks are prohibited) at the entrance of laboratory area.

10.4.4. (Not for storing food) on all laboratory fridges and freezers.

10.4.5. (Clean area) for areas where no samples or potentially contaminated materials are to be handled.

10.4.6. Emergency contact numbers in a visible location in the laboratory.

10.4.7. Signs indicating the location of the nearest safety shower/eyewash stations.

10.4.8. Fire safety symbols and signs near fire exits, fire alarm activators and fire extinguishers and reels.

10.4.9. Electricity hazards/high voltage where applicable.

10.4.10. All other hazard signs related to specific material or equipment used in the laboratory. This may include but is not limited to; UV light emitters, flammable materials, hot surfaces, strong magnetic fields, explosive materials, laser emitters…etc.

10.5. **Ventilation**

10.5.1. All laboratory rooms should have mechanically generated supply of air and exhaust air.

10.5.2. The temperature of the laboratory environment should be adjustable and should range between 18-26oC.

10.5.3. Laboratory furniture, cabinetry, equipment or other structures must not block or reduce effectiveness of supply or exhaust air.

10.5.4. Fume hoods and ducted biosafety cabinets should not be the only means of room air exhaust.

10.5.5. Openable windows should be prohibited in new laboratory buildings and should be forced closed or sealed in existing buildings.

10.5.6. Air exhausted from laboratory areas shall not pass unducted through other areas.

10.6. **Plumbing**

10.6.1. All piping and fittings should be made of appropriate chemical resistant materials.

10.6.2. The drainage system should be equipped with odor traps.

10.6.3. The plumping system should meet other requirements by the local municipality or any other national construction regulations and codes.

10.7. **Sink**

10.7.1. All laboratory rooms should be equipped with a hand washing sink (elbow operated).

10.7.2. Hand washing sinks should not be used to perform laboratory activities such as staining and washing of laboratory ware. A dedicated laboratory sink should be provided where applicable.

10.8. **Emergency Showers and Eyewash Stations**

10.8.1. The Hospitals and standalone laboratories should be equipped with an emergency shower and an eyewash station.

10.8.2. Both emergency shower and eye wash stations should be placed within 10 seconds of walking.

10.8.3. Emergency shower and eye wash stations should be inspected and flushed on regular basis (a least once every 3 months). Record logs are to be maintained.

10.9. **Illumination**

10.9.1. The laboratory should be sufficiently illuminated with about 500 lux lighting system.

10.9.2. Light sources should be of low glare and should provide a shadow-free good distribution of light within the room.

11. Equipment

11.1. **Selection of Equipment**

The Laboratory manager or senior laboratory technician staff shall select the equipment that best serves the needs of the laboratory. The following Criteria to be considered when selecting any laboratory equipment:

11.1.1. The equipment is registered at MoH Pharmaceutical Department

11.1.2. The equipment should match with the service the laboratory provides.

11.1.3. The performance characteristics of the equipment should be accurate and reproducible to suit the needs of the testing to be done.

11.1.4. Match the facility requirements, including the requirements for physical space.

11.1.5. The reagents should be readily available.

11.1.6. The equipment should be easy for staff to operate.

11.1.7. The health institution should ensure the availability of a service team within the country.

11.1.8. The laboratory should develop a contingency plan to ensure service continuity.

11.1.9. The equipment has a warranty and should include a trial period to verify that the equipment performs as expected.

11.1.10. To consider any safety issues regarding the equipment.

11.1.11. An operator's manual is provided, and the instructions are available in a language that is understood.

11.1.12. Wiring diagrams, computer software information and a list of parts needed shall be provided.

11.1.13. The manufacturer will install the equipment and train staff as part of the purchase price.

11.1.14. The manufacturer's maintenance can be included in the contract and, if so, whether maintenance is provided on a regular basis.

11.1.15. There must be adequate room to move the equipment into the laboratory; consider door openings and elevator access.

11.1.16. Verify that all physical requirements (electrical, space, doors, ventilation and water supply) have been met.

11.1.17. The vendor's responsibilities for installation should be confirmed in writing prior to beginning the installation process.

11.1.18. A checklist of the expected performance specifications should be developed, so that performance can be quickly verified as soon as the equipment is installed.

11.1.19. A copy of any software that is part of the system shall be available.

11.1.20. The equipment shall not be used before complete installation, performance verification and personnel training.

11.1.21. Assign responsibility for performing the maintenance and operation programs.

11.1.22. Provide training for all operators; only personnel who have been trained. specifically, to properly use the equipment should be authorized as operators.

11.1.23. Each equipment must have following records:

11.1.23.1. The identity /type of the equipment

11.1.23.2. The manufacturer's name, model and serial number or another unique identifier.

11.1.23.3. Contact information for the supplier or the manufacturer.

11.1.23.4. Date of receiving and date of entering the service.

11.1.23.5. Current location.

11.1.23.6. Condition when received.

11.1.23.7. A link or manual to manufacture instruction.

11.1.23.8. Validation records.

11.1.23.9. Maintenance carried out and the schedule for preventive maintenance.

11.1.23.10. A reference to the equipment performance records that confirm the equipment's on-going acceptability for use. This includes copies of all calibration and/ or verification including dates, times and

results, adjustments, the acceptance criteria and the due date of the next calibration.

11.1.23.11. Damage to or malfunction, modification or repair of the equipment.

11.1.23.12. Staff training on use and maintenance of the equipment.

11.2. **Validation and Calibration.**

11.2.1. A written plan shall be implemented for calibration, performance verification, and proper operation of the equipment.

11.2.2. The laboratory Supervisor shall continually make sure that equipment that is used for measurement activities is accurate and precise.

11.2.3. Prior to being used, calibration verification or performance check will be conducted to ensure it is in working condition.

11.2.4. When practicable, equipment requiring calibration will be labelled to indicate the status of calibration and the date when recalibration is due.

11.2.5. Calibration and measurement requirements are found in individual measurement procedures.

11.2.6. When equipment or reference standards are calibrated by an outside calibration service, the responsible staff will ensure the vendor demonstrates competency, measurement capability and traceability.

11.2.7. Reasonable measures should be taken to safeguard equipment from adjustments that may invalidate the measurements following calibration of the equipment.

11.2.8. Performance checks will be conducted by the contract personnel or the project leader prior to initial use and at intervals depending on the frequency of use.

11.2.9. For equipment maintained at the laboratory and sent off-site for calibration certificates or other records of calibration will be maintained in the lab where the equipment is stored.

11.2.10. Records of actions taken shall be maintained to verify the quality of equipment whose properties could affect the quality of sampling, measurement and related activities. Examples would be thermometer, calibration standard or buffer verification. Thermometers used during investigations should be verified.

11.2.11. Critical reference materials such as reagents and consumable materials that affect the quality of tests and/or calibrations will be verified.

11.2.12. The frequency of recalibrating the instrument needs to be determined, based on its stability and the manufacturer's recommendation.

11.2.13. The test methods using kits or laboratory instruments need to be evaluated by the laboratory for the ability to detect disease (sensitivity, specificity, positive and negative predictive value) and to determine normal and reportable ranges.

11.2.14. Samples with known values should be tested and comparing the results to the expected or certified value.

11.3. **Maintenance and Service.**

11.3.1. All laboratories shall maintain documents and records for equipment selection, preventive maintenance, and procedures for troubleshooting and repair.

11.3.2. A scheduled maintenance program shall be established to include daily, weekly and monthly maintenance tasks.

11.3.3. Equipment known or suspected to be defective will be taken out of service and clearly labelled, until it has been repaired and shown by calibration, verification or testing to function properly.

11.3.4. Records of all maintenance, service, repairs and histories of any damage, malfunction or modification of field measurement equipment will be maintained in the equipment logs. The record will describe hardware and software changes and/or updates and show the dates when these occurred.

11.3.5. The equipment maintenance shall be performed in-house or by an outside service.

11.3.6. When appropriate, adverse incidents relating to equipment should be reported to the manufacturer and documented on the equipment log.

11.3.7. Auditing and maintaining equipment maintenance, calibration and verification should be recorded in the equipment logs.

11.3.8. These records of the equipment logs shall include the following:

11.3.8.1. A copy of the Purchase Order, if available, or other record showing item received and date placed into service.

11.3.8.2. Acceptance inspection record of the equipment (copy of signed invoice).

11.3.8.3. Maintenance, calibration and verification logs.

11.3.8.4. Calibration certificates for manufacturers calibrations (if applicable).

11.3.8.5. Fundamental calibration or any other performance checks information.

11.3.8.6. Calibration verification record (showing standards/reference materials used).

11.3.8.7. Records of handling, transportation and storage of equipment.

11.3.8.8. A record of the most recent version of software for the equipment.

11.4. **Cleaning and Decontamination.**

14.4.1. Majority of decontamination of equipment is carried out by the service provider, a report is provided, and filed in the department.

14.4.2. Any decontamination carried out by the department prior to servicing is recorded using forms available.

14.4.3. Decontamination of equipment will be in accordance with procedures described in the SOP for Equipment Cleaning and Decontamination.

14.5. Equipment Safety

Refer to the Safety of Equipment in section 21.4 for details.

14.6. External Services and Supplies

14.6.1. Laboratory shall define and document its policies and procedure for selection and use of purchased external services, equipment, consumable supplies that affect the quality of its services. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials.

14.6.2. Laboratory shall have a list of manufacturer, supplier, and reagents.

14.6.3. Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as comply with standard specification or requirements defined for the procedure concerned.

14.6.4. Laboratory shall be responsible for selecting referral laboratories and shall ensure that the referral laboratory is competent to perform the requested examinations and shall maintain a register of all referral laboratories that it uses.

14.6.5. Laboratory shall verify the results from referral laboratories.

12. Inventory

12.1 General Recommendations

12.1.1 Laboratory shall have documented procedures for management of all laboratory reagents and consumables.

12.1.2 Laboratory items shall be listed in the Inventory Register.

12.1.3 The laboratory items should be organized in an accessible way.

12.1.4 The Inventory Register shall be up to date and maintained.

12.1.5 Laboratory staff should be aware of the inventory register and its procedure for item receiving and issuing.

12.1.6 Key specifications for each item in stock should be formulated e.g., minimum and maximum stock, expiry date and purity of some reagents.

12.1.7 Laboratory shall have a documented procedure for selection and evaluation of suppliers.

12.1.8 Laboratory shall have a documented procedure for receiving new items and products.

12.1.9 Laboratory should perform acceptance criteria on new delivered products prior to use.

12.1.10 Manufacturer's instructions / package inserts should be available.

12.1.11 Laboratory should have a documented procedure for maintaining the stock and inventory system.

12.1.12 Storage areas shall comply with Health and Safety requirements and labeled with hazard symbols.

12.1.13 Storage areas temperature and humidity shall be controlled, maintained and documented.

12.1.14 Storage areas shall be secured from unauthorized access.

12.2 Reagents and Consumables

12.2.1 Laboratory shall have clear selection and procurement criteria for reagents and consumables.

12.2.2 Reagent and test kits should be approved by the Directorate General of Private Health Establishment, MOH.

12.2.3 There should be a SOP for receiving and storage of reagents and consumables.

12.2.4 Laboratory shall ensure that storage of the reagents and consumables is as per the manufacturer's requirements.

12.2.5 Laboratory shall develop an SOP for acceptance testing of new reagents and consumables.

12.2.6 The laboratory should ensure that it has adequate and efficient capacity to store the reagents and consumables. In situations where a laboratory has a distant store or where it is not the receiving facility, it shall ensure purchased items are stored properly to prevent damage or deterioration.

12.2.7 The laboratory shall verify the performance of each new kit, a new lot of reagents or changes in reagents before use in examination. In addition, the laboratory shall also verify the performance of any consumables that can affect the test results before use in examination/testing.

12.2.8 Laboratory shall develop a system for inventory management.

12.2.9 The laboratory should ensure that instructions for use of each reagent and consumable are easily accessible.

12.2.10 The laboratory should develop a system to identify and report consumables and reagents' related adverse incidents to the manufacturer and Directorate General of Private Health Establishment, MOH when applicable.

12.2.11 The laboratory should keep the following record of each consumable and reagent contributes to the performance of examination:

15.2.11.1. Name of the reagent or consumable.

15.2.11.2. Manufacturer's name and batch code or lot number.

15.2.11.3. Supplier contact information.

15.2.11.4. Date of receiving, the expiry date, date of initial acceptance for use.

15.2.11.5. Manufacturer's instructions.

15.2.11.6. Performance records.

15.2.11.7. For in-house reagents, records should also include reference to the individuals preparing them and the date of preparation.

13 Quality Assurance

13.1 Internal Quality Control

13.1.1. An internal quality control program shall be established and implemented by the laboratory.

13.1.2. All types of laboratory test methods, quantitative, qualitative and semi quantitative, shall implement an interna l quality control system which varies according to the method used.

13.1.3. The laboratory shall use internal quality control (IQC) to monitor the examination (analytic) phase of testing in real time to detect the errors before releasing the results and to ensure the results' reliability and accuracy.

13.1.4. IQC policies and procedures, including corrective actions, should be established and all staff should be trained in how to properly follow policies and procedures.

13.1.5. Responsibility for overall monitoring and reviewing the internal quality control should be assigned, preferably to a quality officer.

13.1.6. The laboratory shall ensure that staff who process the quality material review and monitor the control values on a daily basis.

13.1.7. The laboratory shall use quality control materials similar to the patient's sample if feasible.

13.1.8. The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made.

13.1.9. The laboratory should consider using independent third-party quality control materials, either instead of, or in addition to, any control materials supplied by the vendor.

13.1.10. The laboratory shall use the appropriate statistical and non-statistical techniques for process control for continuous monitoring of the examination system (quantitative, qualitative and semi quantitative) performance.

13.1.11. It is the laboratory responsibility to identify the most appropriate statistical tool to establish the laboratory mean, standard deviation (SD), and control limits for each level of quality control materials. At least 20 data, preferably over a 20-to-30-day period, should be collected for each quality control level.

13.1.12. The laboratory should establish Levey–Jennings (LJ) charts to review and monitor daily QC results for the quantitative and semi quantitative assay.

13.1.13. The laboratory should create a troubleshooting record to document the violation and corrective actions. An immediate daily corrective action must be taken when the IQC is violating the multirules Levey–Jennings e.g., Westgard rules.

13.1.14. The laboratory shall have a procedure to prevent releasing patient results when quality control values fall outside the predetermined acceptable performance (IQC failure).

13.1.15. The laboratory shall have documented actions in case the quality control rules are violated, and the patient results are likely to contain clinically significant errors, the results shall be rejected, and relevant patient samples re-examined after the correction is implemented. The laboratory shall also evaluate the previously released results after the last successful quality control event.

13.2 External Quality Assurance.

13.2.1. The laboratory shall participate in inter laboratory comparison program(s) e.g., RIQAS, RCPA-QAP or proficiency testing program (PT) appropriate to the examination.

13.2.2. The laboratory should have an assigned staff who must be educated and trained on the inter laboratory comparison program(s) for better interpretation of the examination reports.

13.2.3. The laboratory shall have a document for inter laboratory comparison program(s) procedure that include the defined responsibilities and instructions for participation.

13.2.4. The laboratory shall choose an inter laboratory comparison program that provides clinically relevant challenges that mimic patient samples.

13.2.5. The laboratory shall handle and deal with inter laboratory comparison samples as patient samples by integrating these samples into the standard work process.

13.2.6. The laboratory should use the same examination process as used for patient samples whenever inter laboratory comparison samples are analyzed. These samples must be handled by staff who regularly handle patient samples.

13.2.7. The laboratory shall not contact other participants about inter-laboratory comparison sample data unless after the submission date.

13.2.8. The laboratory shall not refer inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

13.2.9. The laboratory performance of inter-laboratory comparison reports shall be reviewed and discussed with the assigned staff.

13.2.10. The laboratory quality officer shall monitor the results of the inter-laboratory comparison program(s) and corrective action should be implemented when the control values are not fulfilled the predetermined program criteria. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.

13.2.11. The laboratory shall provide evidence of corrective actions when results are out of control.

13.2.12. The EQA laboratory assigned staff should be aware of the pitfall of each inter laboratory program to its method when inter laboratory comparison is reviewed.

13.2.13. Whenever an inter laboratory comparison program for a test is not available, the laboratory shall use or develop other approaches e.g., national program, certified materials, samples previously examined, exchange of samples with other laboratories. In this program utilization of appropriate material is recommended.

14 Examination Process

All laboratories should consider implementing a process for using a set of indicators which cover pre-analytical, analytical, and post-analytical issues, as well as patient care systems.

14.1 Documentation

17.1.1. Examination procedures shall be documented and written in an understandable language.

17.1.2. These documents should be controlled and accessible to all concerned staff.

14.2 Pre-analytical

14.2.1 The laboratory should establish and maintain written documented procedures for pre-analytical phase comprising all activities that verify the fulfilment of the intended quality of results, the procedures should include but not limited to:

14.2.1.1 Test and sample requirements.

14.2.1.2 Request form including at least patient's details, requester details, date and time of collection, collection site, requested test(s) and sample type.

14.2.1.3 Instructions for urgent requesting.

14.2.1.4 Criteria for sample rejection.

14.2.1.5 Standards or protocols for patient preparation, samples collection, handling, and transportation.

14.2.1.6 Processing and storage until time of analysis.

14.2.2 The laboratory should monitor sample quality indicators in order to identify potential errors quickly for continuous improvement.

14.3 Analytical

14.3.1 The laboratory shall establish and verify test method performance specifications test accuracy, precision, sensitivity, specificity, and linearity.

14.3.2 The laboratory shall establish and maintain written policy, process, and procedure manuals including:

14.3.2.1 The turnaround time for each test

14.3.2.2 The reference intervals and, if applicable, the critical/alert values for specific tests.

14.3.2.3 A list of factors known to affect the performance of the examination or the interpretation of results of each examination.

14.3.2.4 Internal and external quality assurance programs appropriate for the test menu and specialties.

14.3.2.5 Instrument performance verification, calibration and maintenance.

14.3.2.6 Records of the laboratory environment (e.g., temperature, refrigeration and air quality when applicable).

14.4 Post-analytical

14.4.1 The laboratory shall ensure that the test results are correctly interpreted and applied in the client's best interest.

14.4.2 The laboratory shall establish and maintain written policy, process, and procedure manuals explaining the following:

14.4.2.1 The routine method of reporting.

14.4.2.2 The procedure for reporting urgent testing results.

14.4.2.3 A guideline to interpreting the result report.

14.4.2.4 Any additional/reflex testing to be requested, in the appropriate time-frame.

14.4.2.5 The client satisfaction/ complaint review.

14.4.2.6 The specimen retention after the examination and safe disposal in accordance with local regulations or recommendations for waste management.

14.5 Reporting

14.5.1 The reporting procedure shall be clearly established including methods of reporting e.g., telephone, computer network and reporting critical results.

14.5.2 The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results.

14.5.3 Reports shall include the information necessary for the interpretation of the examination results.

14.5.4 The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care.

14.5.5 The laboratory shall establish documented procedures for the release of validated results, including details of who may release results and to whom, alert or critical values.

14.5.6 The laboratory shall implement an electronic laboratory information management system (LIMS) for managing and reporting of data.

14.5.7 The laboratory shall establish and document policies and procedures for:

14.5.7.1 Regular backup and data protection.

14.5.7.2 Authorization for access.

14.5.7.3 Protocols for confidentiality.

14.6 Altering The Test Results

14.6.1 The laboratory shall not use an eraser or correcting fluid to correct wrong information.

14.6.2 A pen shall be used to cross out incorrect information and the new information shall be entered and signed by the concerned person, indicating the date of correction.

15 Documents and Records Control

15.1 Document Control

15.1.1 All documents that are produced by and/or used in the laboratory must be included in the document control system e.g., SOPs, policies,etc.

15.1.2 The laboratory shall control documents needed by the quality management system and shall guarantee that unintended utilization of any archived record is prevented.

15.1.3 The laboratory should have a standardized format and/or coding system that can be applied to all documents developed within the organization.

15.1.4 The laboratory document control system shall provide procedures for formatting and maintaining documents.

15.1.5 The laboratory document control system shall ensure that the most existing, updated, authorized version of any document is the one that is used.

15.1.6 The documents should be clear, easily understood and concise by all personnel including new ones.

15.1.7 The laboratory shall ensure the availability and ease access to the documents when needed.

15.1.8 The laboratory shall appropriately archive the documents when they need to be replaced.

15.1.9 The laboratory shall have a documented procedure to ensure that all documents, including those maintained in a computerized system, are reviewed and approved by authorized personnel before issuing.

15.1.10 The laboratory shall ensure that all documents are identified to include a title, the date of the current edition and /or edition number, page number to total number of pages, authority for issue and signature.

15.1.11 The laboratory shall have a documented procedure to ensure that:

15.1.11.1 The document control system shall allow for the amendment of documents by hand, pending the reissue of documents. The procedures of amendments shall be defined, clearly marked, initial, dated and a revised document is issued within a specified time period.

15.1.11.2 The documents shall be regularly reviewed and updated at a frequency that ensures that they remain fit for purpose.

15.1.11.3 The laboratory should date and mark old/archived controlled documents as obsolete.

15.1.11.4 The laboratory should retain at least one copy of an obsolete controlled document for a defined period of time or in accordance with relevant specified requirements.

15.2 Control of Records

15.2.1 A documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records.

15.2.2 The laboratory shall develop the records concurrently with performance of each activity that affects the quality of the examination.

15.2.3 Records shall be easily accessible but protected from unauthorized amendments.

15.2.4 The date and, where applicable, the time of amendments to records shall be documented along with the identity of personnel making the amendments.

15.2.5 The laboratory shall determine the retaining time period of various quality management system records, including pre-analytical, analytical and post-analytical processes. The length of time that the records are retained may vary; however, reported results shall be retrievable for as long as medically relevant or as required by regulation.

NOTE: *Legal liability concerns regarding certain types of procedures (e.g., histology examinations, genetic examinations, pediatric examinations) may require the retention of certain records for much longer periods than for other records.*

15.2.6 The laboratory management shall ensure providing a suitable environment for storage of records to avoid damage, deterioration, loss or unauthorized access.

NOTE: *For some records, especially those stored electronically, the safest storage may be on secure media and an offsite location.*

15.2.7 Records shall include, at least, the following:

15.2.7.1 Selection of supplier.

15.2.7.2 Personnel records (qualifications, training and competency).

15.2.7.3 Test request and sample receipt record.

15.2.7.4 Reagent details and materials used for examinations (e.g. lot number documentation, certificates of supplies, package inserts).

15.2.7.5 Laboratory work registry or worksheets.

15.3 Control of Nonconformities

15.3.1 The laboratory shall develop a standard operating procedure for handling and controlling nonconformities in any aspect of the quality management system.

15.3.2 The laboratory shall develop forms to record each nonconformity and its level with impact and corrective/preventive actions.

15.3.3 Non-conformity forms should not be archived until all action points have been completed.

15.3.4 Implemented actions should be studied for their effectiveness and discussed by the laboratory manager with the staff. This will help in the continuous improvement of the quality of provided services.

16 Internal Audits

16.1 The activities that are subject to regular auditing and frequency of auditing should be stated.

16.2 Activities shall cover pre-analytical, analytical and post analytical processes.

16.3 The frequency of auditing should be at least once every twelve months.

16.4 In general, the audit should be simple and focused on a specific activity.

16.5 The internal audit shall be conducted whenever problems encountered, examples are poor performance on proficiency testing, increased number of unexpected abnormal results for a particular test, increase in expected turnaround time, frequent laboratory incidents or customer complaints.

16.6 The audit checklist should be done against reference documents/regulations pertinent to the performance of the laboratory test (follow any established national policies and standards when available).

16.7 The audit can be horizontal or vertical. Horizontal audit looks at the process from beginning to end (e.g., a training program), while vertical audit provides a deep look into a specific process (e.g., sample rejection).

16.8 The laboratory director is responsible for setting overall policies for the internal audit program, assigning authority for the program (lead auditor), supporting the corrective action measures and following their implementation.

16.9 The lead auditor, usually a quality manager or any other qualified staff, is responsible for organizing and managing the laboratory internal audit program. This includes:

16.9.1 A time frame setting for the audits.

16.9.2 Choosing and training the auditors.

16.9.3 Coordinating the process.

16.9.4 Making sure that laboratory management and the laboratory staff are fully informed about outcomes of the audit and managing all corrective actions.

16.9.5 The auditors should be independent of the activity to be audited.

16.10 Audits must be documented and reports of findings (Nonconforming Activities/Actions) retained as a permanent laboratory record so as evidence of performing the audit and laboratory can learn from its activities.

16.11 Results must be reported to laboratory management for review.

16.12 Problems identified in the audit must be promptly addressed and appropriate actions taken, both corrective and preventive actions.

16.13 Continuous monitoring and follow up audits are key elements for success.

17 Continual Improvement

17.1 Process improvement is one of the quality system essentials that ensures continual improvement in laboratory quality over time.

17.2 The laboratory management shall perform a review to identify the problems and the potential sources of system weakness or error and put a plan and execute it according to the improvement needs.

17.3 The actions should be monitored to assess their effectiveness using focused review, quality indicators and audit processes. Finally, the action plan should be adjusted and modified in accordance with the review and audit results.

17.4 The management review is performed at least annually. Examples of quality elements reviewed include quality objectives of last year, quality indicators, nonconformities,

customer complaints, internal audit reports, proficiency testing reports, workload change, and quality objective for next year, actions of improvement, improvement of quality management system.

17.5 There are several tools used for process improvement, including internal/external audits, quality indicators, external quality assessment, quality controls and lean process. By using these tools, opportunities for improvement and the need for corrective actions will be identified.

18 Health, Safety and Security Plans

18.1 General Safety

18.1.1. Smoking, eating, and drinking must be prohibited in the laboratory.

18.1.2. Appropriate warning signs should be posted near the lab entrance.

18.1.3. Aisles should be maintained unobstructed and at least 36 inches (90cm) wide throughout.

18.1.4. Lab benches should be at least 24 inches (60cm) wide and must be kept free from clutter. Bench tops should be made of seamless chemical resistant material.

18.1.5. Shelves and cabinets should be made of appropriate materials and easy to clean or wipe. They must be secured to the walls and kept in good condition. Storage above eye level is minimized and items are restrained from falling.

18.1.6. Refrigerators and freezers should be clearly labeled "Not for Storage of Food for Human

18.2 Laboratory Safety Equipment

The laboratory should maintain the minimum following safety equipment:

18.2.1 First Aid kit.

18.2.2 Fire extinguisher.

18.2.3 Biological spill kit.

18.2.4 Chemical spill kit (when applicable).

18.2.5 A validated and certified Class II Biological safety cabinet when there are procedures of handling risk group 2 biological agents or higher.

18.2.6 A validated and certified fume hood whenever there are procedures of handling chemicals that generate hazardous fumes.

18.2.7 An emergency shower and eye wash station (please refer to the respective section).

18.2.8 Personal Protective Equipment (PPE)

18.2.8.1 Shoes that are flat and fully covering the feet and full-length clothing to protect legs shall be worn by personnel working in the laboratory. Long hair to be confined inside the laboratory coat. Similarly, jewelry, lanyards and other loose articles are to be confined or removed.

18.2.8.2 Laboratory coats shall be made of appropriate material and must be worn all the time in the laboratory.

18.2.8.3 Appropriate PPE such as gloves, goggles, face shields and aprons should be available and used.

18.2.8.4 When respirators (e.g., Automatic respirator, N95 masks, ...etc) are to be used in the laboratory, training for their use and fit testing to be completed along with medical evaluation for employees.

18.3 Safety Manual

The laboratory should develop a safety manual that is relevant to the activities performed. The manual should include but not limited to the following:

18.3.1 General laboratory safety rules.

18.3.2 Method specific precautions

18.3.3 Good laboratory practice.

18.3.4 Risk assessment and management.

18.3.5 Personal protective equipment.

18.3.6 Biological safety.

18.3.7 Emergency and incidents response.

18.3.8 Decontamination and Waste management.

18.3.9 Fire and electrical safety.

18.3.10 Chemical safety.

18.3.11 Occupational health

18.3.12 Specimen receipt, handling and storage.

18.3.13 The safety manual should be accessible to all staff and they all must read it. Records to be maintained.

18.4 Safety of Equipment

18.4.1 All users should be trained to operate the equipment.

18.4.2 Power cords, switches and connections should be kept undamaged and in good condition to avoid any electrical hazard.

18.4.3 Leaks of any chemicals from the equipment should be checked as it can cause slip hazards as well as possible exposure to harmful chemicals. Also, that leak can create a respiratory problem from vapors.

18.4.4 Appropriate PPE must be used to avoid hazards from equipment as indicated.

18.4.5 Equipment safety signs should be posted on/near the machines requiring such signs. These signs should demonstrate the risk associated with the equipment in clear language.

18.5 Training and Documentation

18.5.1. The laboratory should maintain an up-to-date inventory for all hazardous materials.

18.5.1. Chemical Safety Data Sheets (SDS) for all chemicals used in the laboratory must be available at all times. Employees should know the location of these SDS's.

18.5.2. A comprehensive workplace hazard assessment should be conducted. This should include but not limited to general safety, biosafety, biosecurity and any other risks that might present in the facility.

18.5.3. Employees must receive institutional and any other required supplemental laboratory-specific safety training for the hazards present in the laboratory. Employees should be able to describe how to detect the presence or release of hazardous materials or any other physical and health hazards in the work area. All employees should know how to protect themselves and others from the effects of hazardous materials.

18.5.4. Chemical hygiene plan (to add to definitions) (or equivalent) should be present, all employees should be familiar with this plan.

18.6. Fire Safety

18.6.1. The institute must comply with all local rules and regulations related to fire safety as per the Public Authority of Civil Defense & Ambulance.

18.6.2. An appropriate quantity and size of fire extinguishers should be available and mounted near the doorway. These extinguishers must be regularly inspected, fully charged and unobstructed. The tamper indicator must be in place.

18.6.3. The lab should be equipped with a fire alarm system. The fire alarm activators, strobes, speakers, and fire extinguishers must be kept unobstructed and visible Emergency lights must be present and are functional.

18.6.4. A fire blanket must be available.

18.6.5. Electricity circuit breaker panels should be kept unobstructed. When multiplug adapters are in use, they should be equipped with an overload protection feature.

18.7. Biological Safety

18.7.1. Biological materials should not be stored in hallways in unlocked freezers or refrigerators.

18.7.2. Biohazard signs should be posted in labs handling potentially infectious materials. These signs should be visible at the entrance of the lab area.

18.7.3. Appropriate disinfectants should be available for various lab decontamination procedures.

18.8. Physical Hazards

Compressed and Cryogenic Gas Safety

18.8.1. When applicable, cylinders must be stored upright and properly secured at all times unless otherwise advised by the manufacturer.

18.8.2. Caps must always be on when cylinders are not in use. Proper gas regulators and pressure gauges should always be used for working cylinders.

18.8.3. Cylinders should always be kept in good condition and clearly labeled.

18.8.4. Incompatible gases should be segregated from each other.

18.8.5. Oxygen monitors must be available in areas with increased likelihood of oxygen deficient atmospheres.

18.9. Chemical Safety

18.9.1. All hazardous chemical containers must be appropriately labeled.

18.9.2. Containers should be in good condition (e.g., labels intact, metal cans free of rust) and closed when not in use. Containers should be properly segregated by hazard class (e.g., flammables away from oxidizers, acids separate from bases, incompatible acids separated).

18.9.3. Storage of chemicals above eye level should be avoided. Flammable liquids should be stored in OSHA/NFPA approved cabinets and safety containers.

18.9.4. Large containers (4L or greater) should be stored near the floor.

18.9.5. Proper signs to delineate designated areas where high hazard chemicals should be used.

18.10. Hygiene Plans

Chemical and biological hygiene plans must be developed and posted in a visible location in the lab.

18.11. Spill and Emergency plans

18.11.1. Emergency procedures and phone numbers should be clearly posted. Employees must be familiar with the fire safety and building evacuation procedures including evacuation routes, nearest fire exits, fire alarm activators, and fire extinguishers.

18.11.2. First aid materials have to be readily available for staff.

18.11.3. The lab should be equipped with a safety shower and an eye wash station. These should be accessible within 10 seconds and must be kept unobstructed (e.g., no closed doors). Safety showers must be tested and documented at least annually. Eye wash stations must be tested, flushed, & documented at least monthly.

18.11.4. Spill cleanup materials shall be kept available and laboratory staff must be familiar with their use.

18.11.5. When chemical fume hoods are available, they should be kept free from clutter and inspected within the last 12 months and capable of drawing at least 100 Linear feet per minute (LFPM) or more. Hoods must be equipped with an air flow indicator.

18.11.6. When biosafety cabinets are available, they should be kept free from clutter and inspected within the last 12 months and capable of drawing at least 100 LFPM or more. Only Class II or Class III safety cabinets can be used.

18.11.7. Mechanical pipetting must be available and used. Mouth pipetting must be prohibited.

19. WASTE MANAGEMENT

19.1. The lab should have a signed agreement with the Waste Management Company (Be'ah) for handling biohazardous medical waste.

19.2. Wastes should not be discarded in trash or drain disposal unless specifically approved by the appropriate institutional authority (e.g., Environmental Health and Safety).

19.3. Generating chemical waste should be minimized by utilizing a chemical inventory management/ordering system and constant monitoring of stock before ordering new chemicals.

19.4. Waste containers should be kept closed unless actively adding or removing waste.

19.5. There should be a Satellite Accumulation Area (SAA) allocated for the building before dispatching to the waste company. The size of this area should be enough to handle the amount of the waste generated by this institution.

19.6. When instructed by MOH, certain biohazardous waste should be autoclaved within the building before dispatching. Such waste may include but not limited to waste material potentially contaminated with high pathogenic microorganisms.

19.7. Waste containers should be in good condition (not leaking, rusted, bulging or damaged). Each container must be marked with the words "Hazardous Waste". Containers used for chemical waste must be labeled with the full name of the chemical.

19.8. Sharps waste is to be immediately discarded into proper puncture resistant containers.

20. Client Management

20.1. Laboratory clients can be a health care establishment, another laboratory, or patients.

20.2. They should be provided with general information about the laboratory services including the testing menu.

20.3. This should detail how to order a test, collection procedure, type of samples, type of containers, transport, and storage of samples, expected turnaround time (TAT), and how the results are delivered.

20.4. The laboratory should provide routes of communication when errors occur.

20.5. The laboratory should give assurance to the client that the laboratory records are confidential and maintained properly so it can be easily retrieved.

20.6. Active quality management system ensures laboratory meets all client requirements.

20.7. The laboratory should have a system to ensure that the client's needs are being met.

20.8. The laboratory should have procedures to resolve complaints and feedback received from customers. The client has the right to know if the laboratory is accredited.

20.9. The laboratory shall establish and maintain procedures for review of contracts. The review should ensure that the laboratory possesses the physical, personnel and information resources needed to perform the examination.

20.10. Integration of laboratory information management systems (LIMS) with clients will enable transmission of data directly to the laboratory from the registration point. Results can be provided directly to computers accessible to the client.

20.11. The test result report should be carefully designed to meet the expectations of the clients.

20.12. The laboratory should carefully consider potential problems that may arise using LIMS and plan on how to avoid or fix them, e.g., data backup, etc.

20.13. Good customer service provides valuable information for best patient care and a professional image for the laboratory.

Chapter Three

21. Responsibilities

21.1. Laboratory Director

21.1.1. The director of a clinical laboratory is usually a board-certified medical doctor, PhD scientist, or in some cases, a medical laboratory scientist.

21.1.2. The director is responsible for managing overall operations within the laboratory, including maintaining the standards of agencies that inspect and accredit the laboratory and ensuring that all technical, clinical, and administrative functions of the laboratory are performed.

21.2. Pathologists

A pathologist is a qualified medical doctor who hold an approval from OMSB

21.2.1. Pathologist/Histopathologist

Histopathologists should be able to request -if needed- for both histochemical stains and immunohistochemical markers pertaining to each case in order to reach to a final diagnosis. When such resources are not available, the case should be directed to another laboratory.

21.2.2. Chemical Pathologist/Clinical Biochemist

Chemical pathologists have laboratory and clinical responsibilities:

21.2.2.1.1. They supervise the biochemistry laboratory where they contribute to the patient's management at all levels of treatment.

21.2.2.1.2. They oversee various outpatient clinics in hospitals, for example lipid clinics and metabolic bone clinics, if they have proper training.

21.2.2.2. The responsibilities of chemical pathologists extend far beyond the following list:

21.2.2.2.1. Administrative and scientific management of diagnostic clinical biochemistry laboratory.

21.2.2.2.2. Liaison with other medical professionals through advice and guidance on necessary further testing to support in diagnosis and appropriate management.

21.2.2.2.3. Provides consultancy and advice to internal and external clients.

21.2.2.2.4. Interpretation of abnormal results, medical advice on further investigations and treatment.

21.2.2.2.5. Participates in quality improvement activities within the department and organization including the responsibility of ensuring the quality of clinical biochemistry and diagnostic endocrinological investigations.

21.2.2.2.6. Contribute to the process of laboratory assessment and method validation e.g., when a new diagnostic assay is introduced or a new reagent lot number.

21.2.3. Genetic Pathologist

The scope of practice for a genetic pathologist includes the following*:

21.2.3.1. diagnostic detection and interpretation of genomic/ epigenomic variants in symptomatic patients (children, adults, fetuses).

21.2.3.2. diagnostic assessment of segregation in kindred of disease-causing mutations or genomic regions.

21.2.3.3. diagnostic detection, quantitative assessment, and interpretation of mosaic genomic variants.

21.2.3.4. determine the risk of inheritance of a familial disorder.

21.2.3.5. population-based screening for genetic abnormalities.

21.2.3.6. providing clinical interpretive and consultative services, with activities focused on delivering laboratory testing services that optimally address the clinical questions raised by the referring clinician.

*Adopted from Royal College of pathologists of Austrasia (RCPA).

21.2.4. Haematopathologist (laboratory haematologist)

There are three main areas to be handled by the haematopathologist:

21.2.4.1.1. Administrative and scientific management of diagnostic hematology laboratory.

21.2.4.1.2. Management of the benign Clinical Hematology conditions.

21.2.4.1.3. Consultation service to other specialties regarding hematological issues.

21.2.4.2. Responsibilities

Laboratory haematopathologist will perform most of the following functions:

21.2.4.2.1. Supervision of day-to-day hematological diagnostic tests such as peripheral smears, CBC, HPLC and serological tests.

21.2.4.2.2. Performs bone marrow aspiration and biopsy.

21.2.4.2.3. Supervise preparation and staining of blood and bone marrow aspirate smears.

21.2.4.2.4. Reporting of peripheral smears, bone marrow aspirates and biopsies, and touch preparations as well as interpretation of bone marrow biopsies.

21.2.4.2.5. Interpretation and ordering of general hematology and coagulation investigations.

21.2.4.2.6. Reporting of haemoglobinopathies investigations, flow cytometry, immunohistochemistry, and immunohematology.

21.2.4.2.7. Supervise and interpret special laboratory testing in suspected blood transfusion reactions.

21.2.4.2.8. Supervise therapeutic plasmapheresis and therapeutic phlebotomy.

21.2.4.2.9. Monitor internal and external quality control programs.

21.2.4.2.10. Diagnose and manage hematological disorders.

21.2.4.2.11. Interpretation and authorization of the results.

21.2.4.2.12. Assessment and validation of new diagnostic methods

21.2.5. Medical Microbiologist:

There are three main areas to be handled by the microbiologist:

21.2.5.1.1. Administrative and scientific management of diagnostic microbiology laboratory.

21.2.5.1.2. Provides advices on infection control measures related to diagnosed infectious diseases.

21.2.5.1.3. Public health management and notification of notifiable infectious diseases.

21.2.5.2. A microbiologist will perform most of the following functions:

21.2.5.2.1. Interpretation and authorization of the results.

21.2.5.2.2. Ensure quality assurance performance including internal and external quality controls.

21.2.5.2.3. Involvement in setting up and reviewing standard operating procedures and policies.

21.2.5.2.4. Assessment and validation of new diagnostic methods

21.2.5.2.5. Work as a key figure in the control of hospital infection and in antimicrobial policy.

21.2.5.2.6. Notification of communicable diseases of concern to Directorate General of Disease Surveillance and Control (DGDSC).

21.2.5.2.7. Provide teaching and guidance to laboratory technologists and other allied healthcare workers in the

institution in infectious disease and infection control related topics.

21.3. Technologists

21.3.1. General Laboratory technologist

Medical laboratory technologists are the backbone of a clinical laboratory. They are trained to perform and analyse various type of patient's samples in different laboratory's specialties.

21.3.2. Molecular Laboratory Technologist

Technologists who work in the molecular laboratory and are trained to prepare, perform, monitor, analyze, and interpret molecular tests.

21.3.3. Histo-technologist

Histopathogy Scientist is a qualified technologist that assist pathologists during gross examination. The scientists should be fully aware of all technical standard operation procedures of a particular laboratory with regard to solution preparation, staining, ...etc. Troubleshooting and frozen section skills will be required in some set ups. They should have some knowledge of inventory of suppliers, equipment, reagents and placing orders. They should have an adequate training in health and safety program.

21.3.4. Cytotechnologists

Cytotechnologists are specialized laboratory technologists whose job it is to prepare and examine samples of cells from body tissue and fluids under a microscope to look for signs of cancer or other diseases by recognizing changes in the cells, such as their color, size, or shape. They may assist in performing fine needle aspirations (using a needle to remove cells from a cyst, an enlarged lymph node, or abnormal tissue masses or fluids) and examine the sample removed during the procedure for abnormal cells. They assist pathologists in making a

diagnosis. Usually, CTs have a bachelor's degree and have completed an accredited CT program.

22. PERSONNEL

The laboratory shall have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements.

22.1. Qualification

22.1.1. Laboratory management shall document personnel qualifications for each position.

22.1.2. The qualifications shall reflect the appropriate education, training, experience and demonstrated skills needed, and be appropriate to the tasks performed.

22.1.3. The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience.

22.1.4. Professional judgements can be expressed as opinions, interpretations, predictions, simulations and models and values, and should be in accordance with national, regional and local regulations and professional guidelines.

22.2. Job Description

22.2.1. The laboratory shall have job descriptions for each position in the laboratory according to MOH policy.

22.2.2. A complete and clear impression of the tasks, responsibilities and authorities should be available for each position

22.2.3. Personal job descriptions should have been made for all the staff members.

22.2.4. All job descriptions (both Position Job Descriptions and Personal Job Descriptions) should be up to date and stored in the personnel files.

22.3. Training

22.3.1. The laboratory should provide an induction program for new staff that is documented as an SOP.

22.3.2. All staff members should participate in an introductory course in quality management for medical laboratories and the certificates should be stored in the personnel files.

22.3.3. Training in assigned work processes and procedures, laboratory information systems, health and safety, ethics and confidentiality should also be undertaken. The effectiveness of the training program is periodically reviewed.

22.3.4. A personnel replacement matrix in the laboratory should be present and the staff are aware of it as well as back up staff with training for the assigned task.

22.4. Competency

22.4.1. The laboratory shall implement a quality management system among laboratory staff.

22.4.2. Staff competencies should cover technical, practical skills and general knowledge.

22.4.3. Competency of each new employee is assessed and verified before permitting to perform testing and report results.

22.4.4. Competency assessment should be conducted using an SOP with standard format on an annual basis and a report that highlights points of improvement, training needs and strategy to do so should be prepared which then be stored in the personnel files.

22.4.5. The competency of the Laboratory Manager should be assessed annually.

22.4.6. Conflicts of interest among laboratory staff shall be investigated, identified then solved and documented.

22.5. Continuing Professional Development (CPD)

22.5.1. A continuing education program should be available for the professional development of staff and to be included in the yearly plan with allocated budget.

22.5.2. Expectations for staff participation are communicated for those education sessions that are deemed mandatory.

22.6. Staff Records

22.6.1. Records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel shall be structured in order and stored in a locked cabinet that is only accessible to the Laboratory Manager and the secretary.

22.6.2. The folder of the Personnel Files should be kept up to date, i.e., all certificates and diplomas have been collected for all staff members and been stored in the personnel files. Examples of some of the records, (for more details refer to ISO 15189:12):

22.6.2.1. Educational and professional qualifications.

22.6.2.2. Copy of certification or license.

22.6.2.3. Previous work experience.

22.6.2.4. Job descriptions.

22.6.2.5. Introduction of new staff to the laboratory environment.

22.6.2.6. Training in current job tasks.

22.6.2.7. Competency assessments.

22.6.2.8. Records of continuing education and achievements.

22.6.2.9. Reviews of staff performance.

22.6.2.10. Reports of accidents and exposure to occupational hazards.

22.6.2.11. Immunization status, when relevant to assigned duties.

22.7. Performance Appraisal

22.7.1. Performance appraisals shall be performed for all staff members at least once per year.

22.7.2. Findings of performance appraisals should be discussed with staff members and the root cause should be found and eliminated to improve the performance which should be recorded.

22.8. Immunization

22.8.1. Immunization should be up to date and cover special vaccination required for staff working in specialized areas e.g., meningococcal and polio vaccine for staff working in microbiology laboratory. (Refer to MOH policy for screening and immunization of Health care workers).

23. Document History and Version Control

Document History and Version Control			
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24. Related Documents: NIL.

25. References:

Sr No.	Title of book/ journal/ articles/ Website	Author	Year of publication	Page
1.	Science Translational Medicine. Vol. 6, Issue 226, DOI: 10.1126/scitranslmed.3008194	Mark Kessel	2014	226ed6
2.	ISO 9000 section 4.3.1			
3.	ISO - ISO 15189:2012 - Medical laboratories —Requirements for quality and competence		2012	
4.	Audit of internal quality control practice and processes in the south-east of England and suggested regional standards. Annals of Clinical Biochemistry;	David Housley, Edward Kearney, Emma English, Natalie Smith, Teresa Teal, Janina Mazurkiewicz, and Danielle B Freedman.	2008	Vol 45, 135-139
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