Ministry of Health

Document Title	Policy & Procedure of Laboratory Quality Manual
Document Type	Policy & Procedure
Directorate/Institution	Directorate General of Specialized Medical Care
Targeted Group	All Medical Laboratories
Document Author	Quality manual policies & procedures development team
Designation	Quality manual policies & procedures development team
Document Reviewer	Dr. Fausta Mosha
Designation	Reginal advisor—PPHL DCD EMRO WHO
Release Date	December 2022
Review Frequency	Three years

Validated by		**Approved by**	
Name	Dr. Qamra Al Sariri	Name	Dr. Said Al Lamki
Designation	Director General, Quality Assurance Center	Designation	DG of DGSMC
Signature		Signature	
Date	December2022	Date	December2022

Acknowledgment

The diagnostic laboratories services at the Directorate General of Specialized Medical Care (DGSMC) at Ministry of Health (MOH) would like to thank and appreciate the great effort of the Omani quality manual development team. Participated and contributed personnel are:

Member name	**Institution**	**Designation**	**Written section**
Dr.Buthaina Al-Bahri	Nizwa Hospital	Team Leader Specialist Chemical pathologist	All & 5.1
Zainab Al Hadhrami	Directorate General of Specialized Medical Care	Team Coordinator Head of Quality unit in Diagnostic laboratories services	All & 5.4, 5.5, 5.10, 5.11, 5.14 & related procedures
Ms. Huda Al-Saadi	Sultan Qaboos University Hospital	Specialist A Medical Lab	5.13, 5.21 & related procedure
Dr.Moza Al-Nabhani	Armed Forces Hospital	Chemical Pathologist	5.2, 5.22, 5.23, 5.24 & related procedure
Ms.Munira Al-Kindi	Nizwa extended health center(polyclinic)	Senior laboratory technologist A	5.17, 5.19, 5.25 & related procedure
Mr.Abdullah Al-Ghazi	Ibra Hospital	Consultant-Laboratory	5.12, 5.15, 5.16, 5.18 & related procedure
Dr. Elham Al-Reesi	Suhar Hospital	Senior Specialist Chemical Pathology	5.6, 5.7, 5.20 & related procedure
Atika Al Lawati	Directorate General of quality assurance center (DGQAC)	Head of the document development section	5.3, 5.8, 5.9 & related procedure

Contributors:

- Mr. Salam AlRashdi, DGSMC
- Abdullah Al Abri, Quality assurance section - Royal Hospital
- Sabah al Habsi, Quality assurance section -Royal Hospital
- Abullrahman Al Bilushi, Quality Assurance Section -Royal Hospital
- Haidar Al Lawati, Medical Biochemistry Laboratory-SQUH
- Shital Paraj Shah, Medical Laboratory-Ibra Hospital
- Dr .Samia Al Rabhi, DGQAC
- Asma Al Headify, DGQAC
- Dr. Al Warith Al Kharousi, Medical Laboratory-Nizwa Hospital
- Aisha Al Sibani, Quality Assurance - Nizwa Hospital
- Rajaa Al Bulushi, Coordination and Follow up-Nizwa Hospital

Contents

Linkage roadmap

This roadmap supports the reader to understand the linkage between each policy and its related sections in the documen

Policy number & name	Procedure number& name	Responsibilities number	Charts &Forms number	Checklist number
5.1. Organization and management responsibility	6.1. Organization and management responsibility	7.1.	10.1.1.	10.3.1.
5.2.quality management system	6.2 Quality management system	7.2.	10.1.2.	10.3.2.
5.3. Document Control	6.3 Document Control	7.3	NA	10.3.3.
5.4. Service agreement	6.4.Service agreement	7.4.	10.2.1	10.3.4.
5.5. Examination by referral laboratories	6.5.Selection of referral laboratories	7.5.	10.2.2	10.3.5
5.6. External services and supplies	6.6. Services and supplies management	7.6	NA	10.3.6
5.7. Advisory Services	6.7 Advisory Services	7.7	NA	10.3.7
5.8.Resolution of complaints	6.8.1 Resolution of complaints	7.8.1 resolution of complaints	NA	10.3.8
	6.8.2. Incident reporting	7.8.2. incident reporting	10.2.3	
5.9. Identification and control of nonconformities	6.9 Nonconformities identification and control	7.9	10.2.4	10.3.9
5.10. Corrective action	6.10 Corrective Action	7.10	10.2.5	10.3.10
5.11.Preventive Action	6.11 Preventive Action	7.11	NA	10.3.11
5.12. Continual improvement	6.12 Continual improvement	7.12	NA	10.3.12
5.13. Control of records	6.13 Control of records	7.13	NA	10.3.13

5.14.Evaluation of audits	6.14.1 Internal audit	7.14.1 internal audit	10.2.6	10.3.14
	6.14.2. Quality indicators	7.14.2. Quality indicators	NA	
5.15. Management review	NA	7.15	NA	10.3.15
5.16.Personnel	6.16. Technical competency assessment	7.16	10.2.7.1.	10.3.16
			10.2.7.2	
			10.2.7.3	
			10.2.7.4	
5.17. Accommodation and Environmental Conditions	NA	7.17.	NA	10.3.17
5.18.Laboratory Equipment, Reagents and Consumables	6.18.1 Equipment management	7.18.1	NA	10.3.18
	6.18.2. Equipment calibration	7.18.2.	NA	
	6.18.3. Equipment Validation	7.18.3.	NA	
	6.18.4. Equipment maintenance/ servicing and repair	7.18.4.	NA	

	6.18.5 Laboratory Reagents and Consumables contingency plan	7.18.5	NA	
	6.18.6. Laboratory new reagent batch validation	7.18.6	10.2.8	
	6.18.7 Temperature Sensitive Equipment validation	7.18.7	NA	
5.19.Pre-examination processes	6.19. Pre-examination processes	7.19.	10.2.9	10.3.19
5.20.Examination processes	6.20. Method verification	7.20.	10.2.10	10.3.20
5.21.Ensuring quality of Examination results	6.21.1 Internal Quality control management	7.21.1	10.2.11.1 10.2.11.2	10.3.21
	6.21.2. External Quality Assurance management	7.21.2	10.2.12	
5.22. Post-Examination process	NA	7.22	NA	10.3.22
5.23. Reporting of Results	6.23.Notification of critical results	7.23	NA	10.3.23
5.24. Release of Results	6.24.1 Delayed laboratory report	7.24.1	NA	10.3.24
	6.24.2. amended laboratory report	7.24.2	NA	

5.25. Laboratory Information Management	6.25.1 Hospital Information system validation	7.25.1	10.2.13.1 10.2.13.2	10.3.25
	6.25.2. Information system failure	7.25.2.	NA	

Acronyms:

AMR	Analytical Measuring Range
AST	Antibiotic Susceptibility Testing
ATCC	American Type Culture Collection
BHcG	Beta Human Chorionic Gonadotropin (hCG)
C.V	Curriculum Vitae
CA	Corrective Action
CAP	Correction Action Plan
CE	Conformite Europeenne
CLIA	Clinical Laboratory Improvement Amendments
CME	Continues Medical Education
CMV	Cytomegalovirus
CRE	Carbapenem-Resistant Enterobacteriaceae (CRE)
CSF	Cerebral Spinal Fluid
CV	Coefficient of Variation
DGPDC	Directorate General of Pharmacy &Drug Control
EQA	External Quality Assurance
FDA	Food and Drug Administration
FNA	Fine Needle Aspiration
FOC	Free of Cost
H&S	Health and Safety
HBV	Hepatitis B virus
HIS	Hospital Information System
HIV	Human Immunodeficiency Virus

HOD	Head of Department
ID	Culture Identification
INR	International Normalized Ratio
IQC	Internal Quality Control
IRLS	Incident Reporting & Learning System
IT	Information Technology
KPI	Key Performance Indicator
LG	Levey-Jennings Chart
LIS	Laboratory Information System
LPO	Local Purchase Order
LQM	Laboratory Quality Management
MDRO	Multidrug Resistant Organism
MOH	Ministry of Health
MRSA	Methicilin Resistant Staph. Aureus
MSDS	Material Safety Data Sheets
NC	Non – Conformities
NCEP	National Cholesterol Education Program
NCF	Non – Conformities Form
NICE	National Institute of Clinical Excellence
PA	Preventive Action
PCR	Polymerase Chain Reaction
PDCA	Plan, Do, Check, and Analyze
PICK-Chart	Possible, Implement, Challenge and Kill (thus the name PICK).
PPM	Planned Preventive Maintenance

QC	Quality Control
QMS	Quality Management System
QP	Quality Procedure
RCA	Root Cause Analysis
SARS CoV2	Severe Acute Respiratory Syndrome Coronavirus 2
SD	Standard Deviation
SE	Sentinel Event
SMART	Specific, Measurable, Achievable, Relevant, and Time-Bound
SOP	Standard operating procedure
SWOT	Strength, Weakness, Opportunities, Threats,
TAT	Turnaround time
TAE	Total Allowable error
TTP	Total Testing Process
WHO	World Health Organization

1. **Introduction:**

   The diagnostic laboratories services of the Directorate General of Specialized Medical Care (DGSMC), Ministry of Health(MOH), provides quality policies and procedures as national guidance towards the establishment of laboratory quality manuals at different health institutions. In fact, the quality manual is a document that states the laboratory intentions for operating the processes within the quality management system. In this document, there are two types of quality policies: management (**5.1. to 5.15**) and technical (**5.16 to 5.25**) with related quality procedures. Importantly, each locally developed laboratory quality manual has to have the department's vision, mission, values and scope of services at their introduction section.

2. **Scope:**

   This document is applicable for all medical laboratories under MOH and other collaborative governmental and non-governmental health institutions.

3. **Purpose:**

   3.1. To unify the approach towards well-grounded laboratory quality management system.

   3.2. To adapt the most applicable recommendation from the international guidelines.

   3.3. To make reference to all laboratory quality documents including quality policies, quality procedures, auditing checklists and forms.

   3.4. To define the roles and responsibilities of laboratory staff in order to prepare the medical laboratories for accreditation.

4. **Definitions**

   4.1 **Accreditation:** the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks.

   4.2 A**ccuracy:** is how close or far off a given set of measurements (observations or readings) are to their true value.

   4.3 **Action Plan**: the product of the root cause analysis which identifies the strategies that an organization (or department) intends to implement to prevent/ reduce the risk of similar events occurring in the future.

   4.4 **Incident Reporting & Learning system** (IRLS): is a computerized information database used as a mechanism for monitoring and improving quality of healthcare in a non-punitive approach.

4.5 Analytical validation: the process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended application.

4.6 Analytical verification: the process by which a laboratory determines that an unmodified FDA- cleared/approved test performs according to the specifications set forth by the manufacturer when used as directed.

4.7 Assayed control: control materials with specific assigned values and ranges. Assayed controls are more expensive than un-assayed controls, used to evaluate accuracy and precision and may only be suitable for specific method systems.

4.8 Automated selection and reporting of results: a process where patient examination results are sent to the laboratory information system and compared with laboratory-defined acceptance criteria, subsequently results that fall within the defined criteria are automatically included in patient report formats without any additional intervention.

4.9 Biological reference interval: specified interval of the distribution of values taken from a biological reference population. A reference interval can depend upon the type of primary samples and the examination procedure used. Other terms such as: 'normal range', 'normal values' and 'clinical range' are also used to express this.

4.10 Built-in controls: are those that are integrated into the design of a test system such as a test kit device.

4.11 Calibration:. The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material measure, and the corresponding known values of a reference standard.

4.12 Competency: the capability to apply or use the set of related knowledge, skills, and abilities required to successfully perform tasks in a defined work setting.

4.13 Complainant: a person (or a representative of a person, such as: next of kin or first degree relative) who initiate a complaint due to dissatisfaction.

4.14 Complaint: any dissatisfaction about services or product.

4.15 Corrective action: Action taken to eliminate the causes of non-conformities or other undesirable situations, to prevent recurrence.

4.16 Critical result: is a result/value suggesting that the patient is in imminent danger unless appropriate therapy is initiated promptly and in which a pathophysiologic state might lead to a life threatening event necessitating an immediate action.

4.17 Dependent quality control material: quality control material provided by the analyzer manufacturer.

4.18 Documentation: All the written or electronic instructions and records, quality procedures and recorded test results involved in the manufacture of a product.

4.19 Event Manager: the person responsible for the management of adverse events/incidents in the quality management department. Event Manager takes the lead in reviewing all reported adverse events, commenting and forwarding the feedback in the system to the concerned department.

4.20 Events: Any adverse event/incident that is not consistent with routine patient care or hospital procedure which may give rise to claim against the institution, or the employees.

4.21 Examination: set of operations having the object of determining the value (quantitative) or characteristics (qualitative) of a property. Laboratory examinations that yield an approximate quantity or quality value of a property are called semi-quantitative, semi-qualitative examinations respectively. Laboratory examinations are also often called assays or tests. The qualitative is expressed in terms such as "positive", "negative", "reactive", "nonreactive", "normal" or "abnormal".

4.22 External Quality Control: It is a retrospective analysis of internal quality control results by an external agency whereby samples provided by the agency are analyzed and the results sent back by each participant, which are evaluated by the agency and calculated, showing the participant's performance in comparison with the other laboratories in the worldwide scheme.

4.23 General incidents: is an adverse event or occurrences that may cause an interruption in patient or staff safety or physical facility or routine health care operation.

4.24 Adverse Event: any unintended injury or complication which results in disability death or prolonged hospital stay and is caused by health care management (not by the underlying disease process.)

4.25 Health and Safety: Regulations and procedures intended to prevent accident or injury in workplaces or public environments

4.26 Health information system: Computerized databases that are designed to manage healthcare operational data including patient data, administrative, financial, and legal issues of health organizations.

4.27 Immediate action: intervention that must take place immediately in order to respond to an emergency and lead to stabilization. This usually occurs directly after the impact phase of an emergency.

4.28 Independent Quality Control material: quality control materials that is provided by a different company from that of the used analyzer. It is also called a third-party control.

4.29 Interface validation: Confirmation process by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.

4.30 Internal audits: a systematic independent examination and review to determine whether actual activities and results comply with planned arrangements.

4.31 Investigation Team: team members assemble for the purpose of conducting a timely to investigate the incidents/sentinel and near miss events, thorough and credible root cause analysis.

4.32 Key of Performance Indicator: is measure on how well an organization meets the needs and requirements of users and the quality of all operational processes progress toward an intended result.

4.33 Laboratory information system: is a healthcare software designed to process, store and manage patient data that are related to laboratory activities

4.34 Laboratory management: person(s) who direct the activities of a lab and maintain the quality management system. The term is could be referred as laboratory director / manager / HOD.

4.35 Medical laboratory /clinical laboratory: is a laboratory where varieties of examination are carried out on clinical specimens to obtain information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health. It can also offer consultant advisory service covering all aspects of total testing process.

4.36 Metrological Traceability: the property of the result of a measurement or the value of a measurement standard that relates it to a stated reference via continuous chain.

4.37 Near Miss: an incident that did not reach the patient**.**

4.38 Nonconformity: non-fulfillment of a specified requirement.

4.39 Planned Preventive Maintenance: A scheduled maintenance routine, set out to ensure machinery, services and equipment are all maintained at regular intervals

4.40 Post examination /post analytical phase: processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results.

4.41 Pre examination / pre analytical phase: processes that are initiated by the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins.

4.42 Precious / Irreplaceable/ Unrepeatable sample: A biological sample that cannot be re-collected because of their sensitive collection process and complex requirements. The medical team and/or pathologist deem whether the specimen is irreplaceable on a case-by-case basis.

4.43 Precision: is how close or dispersed the measurements are to each other

4.44 Preventative action: Action taken to prevent the occurrence of such non-conformities, generally as a result of a risk analysis.

4.45 Preventive action: is a proactive activity performed to eliminate potential event that can create nonconformity.

4.46 Primary sample: discrete portion of a body fluid, breathe, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole.

4.47 Proficiency Testing: external provider sends unknown samples for testing to a set of laboratories, and the results of all laboratories are analyzed, compared, and reported to the laboratories.

4.48 Quality: The totality of features and characteristics of a product, service or test method that bear on its ability to satisfy stated or implied needs.

4.49 Quality assessments: is the data collection and analysis through which the degree of conformity to predetermined standards and criteria are exemplified

4.50 Quality Assurance: is a continuous process based on identifying quality problems for a given health delivery, and determining criteria and standards in relation to this.

4.51 Quality audit: A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are appropriate to achieve objectives.

4.52 Quality control: The operational techniques and activities that are used to fulfill requirements for quality.

4.53 Quality control product: a patient-like material ideally made from human serum, urine or spinal fluid. It can be liquid or lyophilized and it is composed of one or more constituents (analytes) of known concentrations.

4.54 Quality management: Aspect of the overall management function that determines and implements the quality policy

4.55 Quality Management System: Coordinated activities to direct and control an organization with regard to quality.

4.56 Quality objective: is an objective that is related to quality commonly based on the laboratory's quality policy and specified for relevant functions and levels in the organization.

4.57 Quality policy: overall goals and path of a laboratory related to quality as formally expressed by laboratory management. It is consistent with the overall policy of an organization and provides a framework for setting quality objectives.

4.58 Random Error: Statistical fluctuations (in either direction) in the measured data due to the precision limitations of the measurement device.

4.59 Rechecking or retesting in inter-laboratory comparison: samples that have been analyzed are retested by a reference laboratory.

4.60 Referral laboratory: external laboratory to which a sample is submitted for supplementary or confirmatory examination procedure and report.

4.61 Root Cause Analysis: An evidenced based, structured investigation process which utilizes tools and techniques to identify the influencing and underlying factors that led to

an incident or problem, by understanding what, why and how a system failed. It focuses primarily on systems and processes, not individual performance.

4.62 Sentinel event: an adverse event that should never be allowed to happen, is usually unexpected and involving a patient death or serious physical or psychological injury to a patient.

4.63 Service agreements: is a written contract used to state out the work and responsibilities between the referring laboratory and the referral laboratory**.**

4.64 Specification: Document that states the requirements to which the product, service, or test method has to conform

4.65 Systematic Error: Reproducible inaccuracies that are consistently in the same direction. Systematic errors are often due to a problem which persists throughout the entire experiment.

4.66 Tolerance value: a total allowable error within an item or a range of values that is acceptable or permitted by the user from the result of the process or product measurement

4.67 Traceability: Ability to trace the history, application or location of an item, activity or result by means of documented records. e.g. sample and metrological traceability

4.68 Traditional control materials: materials made to mimic patient samples tested with the patient samples to evaluate the examination component.

4.69 Un-assayed control: control materials that do not have assigned values and ranges provided by the manufacturer and the control values for these materials must be determined by the individual laboratory. Un-assayed controls are less expensive and not linked to specific method system.

4.70 Validation: The act of confirming a product, service, or test method that it meets the requirements for which it was intended.

5. Policy

5.1. Organization and management responsibility

5.1.1. General

Medical laboratory depending on their identity, shall mention in its quality manual the following management elements:

- **Organizational chart(s)**

Each medical laboratory internal organization chart(s) shall be clear for all professional levels depending on their authority levels, licensures, and regulations in place. It should be defined clearly in the quality manual and displayed in the lab with assignments and responsibilities. The following example in appendix **10.1.1** might be applicable for governmental institutions medical laboratories according to institution structure and laboratory workload. Other non-governmental medical laboratories shall formulate their organization charts as appropriate to their line of management and licensure ensuring that.

- **Legal Entity**

  The lab shall state its known legal identity and if applicable their licensure information.

- **Ethical conduct**

  Laboratory management shall have agreements in action to ensure the following:

  - Compliance with the policies, laws and regulations of MOH-Oman, other Governing bodies, and international laws as long it does not conflict with the profession's ethical guidelines
  - Confidentiality & privacy of information are maintained.
  - Respect shall be assured to human rights, colleagues, and patients.
  - Medical Laboratory personnel are accountable for their actions, records, and documents
  - Clinical research ethics in medical laboratory practices are applied through approved bodies.
  - Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work.

- **Lab director/ HOD/ Manager:**

  - Shall be named with his/ her known documented trainings, qualification, and accountability in relation to line of command in the parent institution/organization.

- Have clear roles and responsibilities in various aspects e.g. administrative, professional, advisory, organizational, scientific, educational and proper utilization of resources
- Shall assign delegations to staff in focused areas e.g. Deputy Lab management, quality management, health and safety, professional development etc.
- Have to ensure the implementation of the quality policy
- Shall ensure the provision of clinical advice if applicable to the examination provided including use of the service and interpretation of examination results;
- Have to design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;

5.1.2.Management responsibility

- **Management commitment**

  There shall be evidence proving laboratory management obligation towards application and improvement in quality management system aiming better effectiveness via the following:

  - Communicating to laboratory staff the significance of meeting their needs and requirements of users
  - Founding the quality policy
  - Ensuring that lab quality objectives and planning are established
  - Describing the responsibilities, authorities, and interrelationships of all personnel
  - Forming communication processes
  - Assigning a quality manager / officer
  - Leading management reviews
  - Ensuring that all staff are competent to perform their assigned activities
  - Confirming availability of adequate resources to permit the proper performance of pre-examination, examination, and post-examination activities.

- **Needs of users**

  Laboratory management shall state its commitment at providing quality and timely service to meet the needs of patient and other users through appropriate means. These means should be documented covering customer focus (i.e. complaints, and incident reports), advisory and interpretative services, service agreement and assessment of user satisfaction.

- **Quality policy**

  Laboratory management shall define the intent of its quality management system in a quality policy and ensure that the quality policy is as following:

  - Appropriate to the purpose of the organization;
  - Includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services.
  - Provides a framework for establishing and reviewing quality objectives.
  - Communicated and understood within the organization.
  - Reviewed for continuing suitability.

- **Quality objectives and planning:**

  Laboratory management shall launch quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and at different levels within the organization. These quality objectives have to be measurable and consistent with the quality policy. The Quality objectives shall be reviewed at defined time as per the Quality manual

  If there has been any planned and maintained change in the quality management system, the integrity has to be ensured.

- **Responsibilities, authority, and interrelationships**

  Laboratory management shall define, document, and communicate importantly organizational chart, personnel policies and job descriptions that define qualifications and duties for all personnel. There could be variation in the assigned responsibilities and function according to the institution.

- **Communication**

Laboratory management shall communicate effectively with their staff through appropriate means. The management should conduct regular meetings to monitor the performance in laboratory quality system and testing processes e.g. management review, departmental meetings, quality management and health safety. All meeting minutes should be recorded and stored.

The communication externally shall include importantly communications with patients, healthcare providers, suppliers and referral laboratories

- **Quality Manager / Officer:**

  There shall be a statement notifying all laboratory personnel that Ms/Mr/Mrs is a Quality Manager/ officer as authorized by the laboratory. Any change in this position requires the reissue of related the Quality Manual. The quality Manager / officer responsibilities include but are not limited to:

  - Ensures that the Quality System is established, implemented and maintained in accordance with international guidelines. For example, ISO15189.
  - Ensures the maintenance and distribution of the Quality Manual and associated documents
  - Maintains a master list of current versions of quality documentation
  - Establishes laboratory quality team as needed with defined responsibilities.
  - Manages the continuous improvement programs including internal audit.
  - Coordinates laboratory accreditation activities
  - Trains personnel on Quality System activities
  - Monitors the Quality System via monitoring of quality objectives and plans
  - Reports on the performance of the Quality System to management for review and as a basis for improvement of the Quality System
  - Monitor the internal and external quality control programs.
  - Manage incidents, complaints, and non-conformances to ensure the appropriate closure.
  - To interact with the accreditation bodies on behalf of the organization
  - Scheduling of organizing management review meetings
  - Compilation and distribution performance reports for management review

- **Safety Officer:**

- Trains staff in safety.
- Implements and maintains a safe work environment for laboratory staff.
- Monitor safety events and report to management
- Ensures safe and appropriate disposal of laboratory waste on a daily basis.
- Compile a list of all hazardous materials, chemicals and reagents
- Plan and conduct regular safety audit.

5.2. Quality Management System

5.2.1 General Requirements

Clinical laboratories shall design, document, implement and maintain a quality management system to ensure the integration in all laboratory operations as per the process model in **appendix 10.1.2**approach in alliance to ISO 9001:2008. The system shall comply with Quality manual requirement and achieve the laboratory quality policy objectives to meet the needs of the users.

5.2.2 Documentation requirements

5.2.2.1 General

The quality management system documentation shall contain the following:

- Statements of quality policy and quality objectives
- The Quality Manual
- Plans
- Quality processes
- Quality procedures
- Technical procedures
- Forms, Logs, registers
- Minutes
- Checklists
- Charts
- Reports
- Audits
- Non-conformances

- Notifications
- Job description
- Health and safety document
- Other applicable regulations and guidelines documents.

5.2.2.2 The Quality Manual

The laboratory shall establish and maintain its quality manual considering the following tasks:

- Contains the needed policies for establishing quality management system.
- Outlines the structure and scope of laboratory Quality management system.
- States the quality policy, quality objectives, and other supporting managerial and technical procedures.
- Defines the roles and responsibilities of managerial, technical, and quality personnel.

When the term documented procedure appears within a quality manual, the procedure is established, documented, implemented, and maintained.

The laboratory shall maintain its documents electronically or as a hard copy.

Note: All laboratory staff shall have access to and be instructed on the use and application of the quality manual and the referenced documents.

5.3. Document Control

Laboratory Documents provide a framework for the whole quality management system. All laboratory Documents should be preferably under the Ministry of Health document control process. Laboratory shall ensure that the following conditions are met.:

- Document code: a title, a unique identifier on each page, the date of the latest version and/or version number, page number to total number of pages (e.g. “Page 1 of 5,” “Page 2 of 5,”), template elements and an authority for issue.
- All documents shall be issued as part of the quality management system and are reviewed and approved by authorized personnel before issue, including those maintained in a computerized system,

- Only latest, authorized versions of applicable documents are available at points of use.
- Documents periodically reviewed, revised, when necessary, to ensure that they remain fit for purpose. and approved by authorized personnel,
- Updated amendments are clearly marked, initialled and dated and maintained to ensure that latest versions and their distribution are available.
- Active controlled documents shall be maintained on any appropriate medium including soft or hard copy.
- Inactive or obsolete documents shall be marked, removed, and archived. All quality documents are retained for a minimum period as defined in the documents and sample retention schedule.
- A backup of all laboratory documents shall be maintained
- Master list for all documents maintaining current and authorized access
- All documents issued to personnel should be approved prior to issue

5.4. Service agreement

5.4.1. Establishment of service agreements

Each lab has to have a documented procedure for the establishment and review of agreements with medical laboratories in all hospitals and health care centers to provide lab services and integrity of the lab services between the health sectors. Each request accepted by laboratories under Ministry of Health for examination(s) shall be considered an agreement. The agreement shall specify needed details by the requester to ensure appropriate examination and result interpretation. The agreement ensures the following conditions:

- The laboratory has the facility and resources to meet the requirements (this includes infrastructure, personnel, information resources, skills, and expertise).
- The end user's requirements to be met by defining, specifying, and documenting the used examination method.
- The performance of the laboratory personnel are supported by essential skills and expertise.

- The suitable examinations are selected on basis of the end user's requirements and clinical needs.
- Any deflection from the service agreement that has an effect upon the examination results are notified to the end user in adequate time duration.
- Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.

5.4.2. Review of service agreements

Each laboratory has to periodically or as needed review the service agreements, considering all testing aspects and importantly test workload. Statistics and minutes of reviews, which include any significant consideration and relevant discussions, are recorded, and maintained.

5.5. Examination by referral laboratories

5.5.1 Selecting and evaluating referral laboratories and consultants:

- MOH medical laboratories: there are assigned labs which have such authority. Hence, the focus of this edition is on non-governmental labs.
- The non – MOH laboratory shall have a documented procedure for selecting and evaluating referral laboratories performance, consultant's competency and qualification that provide opinions and analysis for complex testing in any discipline. The procedure shall ensure that the conditions listed below are fulfilled:
    - Evaluation of referral laboratories and referral consultants' qualification, as well as controlling service consistency.
    - Agreement / contract with referral labs and consultants are checked and evaluated on a regular basis to ensure consistence compliance with the quality standard.
    - Periodic reports are recorded and kept on file.
    - Both referral laboratories and experts whose inputs are obtained are clearly listed.
    - Details of requests and results of all referred samples are stored for a predetermined time.

- Agreement / contract with the referral laboratories shall be reviewed periodically as stated in the Quality manual

5.5.2 Provision of examination results

- The laboratory shall ensure that the referral laboratory examination results and findings are provided to the test requester.
- When the laboratory prepares the report, it shall include all important elements of the referral laboratory's findings without making any changes that could impair clinical interpretation.
- The test report shall include the referral laboratory and the Lab specialist names.
- The author of any additional remarks shall be clearly identified.
- Laboratories shall use the most suitable method of reporting referral laboratory findings, considering report language, processing times, measurement accuracy, transcription procedures, and interpretative skill criteria.

5.6. External services & supplies

- Purchased items and **supplier's** selection shall meet the laboratory's quality requirements.
- The laboratory shall have a documented procedure for the selection and purchasing of external services, equipment, reagents, and consumable supplies that affect the quality of its service.
- The laboratory in collaboration with concerned departments shall select, approve and evaluate suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements.
- Records of evaluations shall be maintained.
- Appropriate quality records of external services, supplies and purchased products shall be established and maintained by purchase Section and Medical store.

5.7. Advisory Services

Each lab shall have a test manual or a website and shall offer advisory services for the users on the following:

- Advising on choice of examinations and use of the services, including required type of sample (clinical indications and limitations of examination procedures and the frequency of requesting the examination)
- Advising on individual clinical cases
- Professional judgments on the interpretation of the results of examinations
- Promoting the effective utilization of laboratory services;
- Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.

Only pathologist with appropriate training shall provide clinical advice and interpretive comments.

In case of no pathologist, Laboratory shall collaborate with the nearest higher hierarchy institutions to offer clinical advice.

5.8. Resolution of complaints

The laboratory shall have a documented procedure for handling and dealing with complaints. Feedbacks and claims from staff, clinicians, patients, suppliers, or other parties shall be documented along with their investigations, corrective actions, preventive actions, and archiving. All complaint records should be collected and analysed in management review meetings.

The laboratory shall conduct client satisfaction survey of its service users

5.9. Identification and control of nonconformities

The laboratory shall have a documented procedure to Identify, handle, control and monitor non-conformities (NC) which covers the quality management system ensuring the following:

- The designation of responsibilities and authorities for handling and resumption of non-conformities
- The identification of potential sources of NC
- Defining immediate taken actions and if reoccurrence is possible then decision for corrective action is necessary
- Considering the significance of non-conformance and determine the extent.
- Holding nonconforming examination results or recalling already released results as necessary.

- Defining and eliminating the root cause(s) after investigation where appropriate.
- Review of records at regular intervals to detect trends and initiate corrective action.

5.10 Corrective action

The laboratory shall have a documented procedure that illustrates the process of eliminating non-conformances or errors via investigating and implementing corrective action or tracing trends. It shall involve the following aspects:

- Reviewing the detected non-conformities.
- Determining the root cause of non-conformities, when needed.
- Determining and implementing corrective action needed.
- Recording the results of corrective action taken, evaluate effectiveness of corrective action taken.
- Monitor and observe any recurrence of the original problem.
- Take the necessary action (remedial and corrective). Otherwise, if the problem is detected before the error occurs, take preventive action.
- Keeping and maintaining all non-conformities records as a reference.
- Communicate the changes made to all staff members as a results of implementation of corrective actions
- The result of corrective actions shall be forwarded to management review meeting

5.11 Preventive action

The laboratory shall have a documented procedure to eliminate the potential causes of nonconformities and to reduce the likelihood of the re-occurrence in technical and quality management system. In order to activate the proactive Preventive action process, the Laboratory shall:

- Review and analyse laboratory data (trends, risk analysis and external quality assurance) to identify where potential non-conformities exist.
- Determine root cause(s) of impending nonconformities.
- Evaluate need for a preventive action
- Implement needed preventive action
- Record results of preventive action taken
- Review the effectiveness of the preventive action taken

5.12 Continual Improvement

Laboratory quality management system and its effectiveness shall continually be monitored to identify more opportunities for improvement. Continual improvement program requires commitment, planning, structure, leadership, participation, and engagement. The Laboratory shall regularly:

- Ensure that the medical laboratory contributes to quality improvement process that deals with related areas and outcomes of patient care.
- The quality system shall be reviewed for redundancies and inherent weaknesses especially in areas that have frequent nonconformance's or client complaints
- Promote planning, developing, and implementing of the documented actions for continual improvement.
- Review the effectiveness of the action via piloting of focused review followed by auditing to adjust the action plan and modify the system in accordance.
- Approval of needed change in quality management system before implementation by laboratory management.
- Provide quality indicators for systematic monitoring and assessment of the contribution of the laboratory to patient care.
- Systematic monitoring of quality indicators

5.13 Control of records

The laboratory shall have a well-established procedure for identification, collection, indexing, access, storage, maintenance, amendment, and safe disposal of quality and technical records.

Records shall be created concomitantly for all laboratory activities that affects quality of examination.

Records amendment time and date shall be documented along with the assigned laboratory personnel identity.

The laboratory shall define the retention time of all records according to the guidelines and records can be stored in any format that suits the institution.

The institution shall provide a safe and a suitable environment for records storage to prevent their damage and deterioration.

Records shall include, at least, the following:

- Supplier selection and performance.
- Staff portfolio and competency.
- Examination request forms
- Reagents and materials information, e.g. lot documentation, certificates of supplies, package inserts.
- Examination results
- Instrument maintenance records.
- Calibration records
- Quality control records
- Incident reports and action taken.
- Risk management records
- Nonconformities, corrective, and preventive actions taken.
- Internal and external audit records.
- Interlaboratory comparison sample examination result.
- Records of quality improvement activities.
- Meeting minutes and records of decisions made about the laboratory quality management activities.
- Management review records.

All records shall be accessible and available for quality management review.

5.14 Evaluation of audits

5.14.1 General

The laboratory shall plan and activate the processes of quality assessments, evaluation, and internal audits of all quality management system elements to demonstrate that laboratory operations continue to meet the needs and requirements of the system. The results of evaluation and improvement activities shall be discussed in the management reviews to ensure the continuous effectiveness.

5.14.2 Periodic review of requests, and suitability of procedures and sample

To ensure that samples are collected properly and in the correct volume needed for the best performance of the test, the Laboratory shall systematically review

samples requests and evaluate the appropriateness of the volume and methods used for the test required. The laboratory shall maintain updated information about sample general requirements periodically by an authorized reviewer.

5.14.3 Assessment of user feedback

The laboratory shall collect, analyze, and review Customer feedback on a regular basis to demonstrate that the service has met the needs of users. The method used is by conducting end user's satisfaction surveys. Results of the survey shall be used to design the quality objectives yearly to improve end-user's satisfaction. Records of collected information shall be kept and actions taken.

5.14.4 Staff suggestions

Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be discussed, evaluated, during departmental meetings. Minutes records to be maintained.

5.14.5 Internal audit

The laboratory shall have a documented procedure to define the responsibilities and requirements for planning and conducting types of audits, frequencies, and for reporting results and maintaining records. Laboratory management shall ensure appropriate organized and formal auditing process carried out by a well-trained auditor that initiates the auditing and action is promptly undertaken. Personnel shall not audit their own activities. The cycle for internal auditing should normally be completed in one year. When nonconformities are identified, Corrective action shall be taken without delay to eliminate the root causes of the detected nonconformities. The results of internal audits shall be submitted to laboratory management for review.

5.14.6 Risk management

The laboratory shall:

- Assess the impact of critical work processes and potential failures on examination results that are likely to affect patient safety,
- Identify the possible risk to preserve staff safety.
- Modify the processes to reduce or eliminate the detected risks.

5.14.7 Quality indicators

The laboratory shall monitor quality indicators to evaluate performance throughout critical aspects of total testing processes (TTP). The indicators are periodically reviewed, to ensure their continued appropriateness. When outliers are identified, the laboratory shall undertake the appropriate corrective actions and document them.

5.14.8 Reviews by External auditors:

Audits are performed periodically by external auditors. When non-conformities are identified, the laboratory shall undertake the appropriate corrective actions and document them.

5.15 Management review

5.15.1. General

Laboratory management review of LQM system, examination and advisory activities shall be carried out at regular intervals as indicated in the Quality Manual. Thus, continuous, suitable, adequate, appropriate, and effective services are offered for patient care. The outcome of the review shall be placed into a plan that includes goals, objectives, and action plans.

5.15.2. Review input

Management review input shall include following information as an outcome of the evaluation of the laboratory quality system.

- Periodic review of pre-examination requirements and suitability of procedures
- Assessment of user feedback
- Staff suggestions
- Internal audits
- Risk management and H&S audit
- Reviews by external organizations
- Implementation of quality indicators
- External quality assurance schemes Comparability of examination results with peer group in inter-laboratory comparison programs (EQA)
- Analysis and resolution of complaints

- Performance of supplier
- Identification and control of nonconformities
- Outcome of continual improvement with corrective actions and preventive actions
- Action taken from the feedback of the previous management reviews
- Changes that could affect the quality management system like change in type of work, workload, personnel, and premises.
- Suggestions for improvement along with technical requirements.

5.15.3. Review activities

The management review activities shall analyze all the information which is responsible for causing nonconformities, trends and patterns that shows the problem occurrence. This review shall analyze the scope of improvement and the requirements for the update in the quality management system including quality policy and quality objectives. The contribution of the laboratory to patient's care shall be adequate, appropriate and be evaluated objectively.

5.15.4. Review output

The management review output shall be documented for any decisions and actions taken related to:

- Improvement of the quality management system and its procedures.
- Improvement of the laboratory services to patient care.
- New quality indicators to be established with new quality objectives
- Requirements of the resources.

Feedback from the management reviews and required actions for the correction shall be recorded and reported to the laboratory staff.

Laboratory management shall make sure that action to be taken according to the management review and completed within defined time.

5.16 Personnel

5.16.1 General

The laboratory shall have a documented procedure for personnel management including maintaining and updating staff records, management of policies and procedures, positions, job description of personnel etc.

5.16.2 Personnel qualifications

All the qualification requirements meet the institutional regulations & guidelines.

The Laboratory management shall keep demographic information about all laboratory personnel that include educational details and academic/professional qualifications.

The educational qualifications, training, experience, and further skills shall be related to test performed.

Note: the personnel department keeps records for the personnel relevant educational and professional qualifications.

5.16.3 Job description

The laboratory personnel designations shall follow health system regulations for medical and biomedical. Moreover, the laboratory management shall provide job descriptions that describe the actual responsibilities and authorities for all personnel.

5.16.4 Personnel Induction program

All new employees should go through the Induction program within early stage of employment according to local regulations. The orientation to be completed before the employee is assigned to any duties. The following are the most important aspects that included during induction:

- Institution's roles and regulations (for example: punctuality, leave types and application procedure, finance affairs), Work schedules
- Infection control and prevention program orientation
- Occupational health and safety program orientation
- Fire safety program orientation
- Information technology (IT) system orientation
- Library facility orientation
- Quality manual orientation, Personnel policies, ethics, confidentiality,

5.16.5 Training

Laboratory shall prepare plan for training laboratory staff. Training in different specialty is selected according to work requirement and job description to ensure that the quality of the provided service is improving. Each staff shall have an

individual training plan covering the assigned tasks. The training should meet the requirements and fill the gaps in specific topic by development of knowledge, skills, and behaviors of the staff. The following are examples of some aspects that shall be included in training plan:

- Training on the quality management system
- Assigned work processes and procedures
- Available laboratory information system
- Health and safety, including the prevention or containment of the effects of adverse incidents
- Confidentiality of patient information
- Ethics

The individual training plan once needed should be flexible in shifting or reassigning staff in situations where the staff can cover outside their own discipline during the crisis or staff shortage. Supervision all the times is required for all personnel that are undergoing training. All training activities should be documented, and the effectiveness of the training plan is reviewed and evaluated regularly.

5.16.6 Competency assessment

Competency assessment shall be conducted following the training at regular basis or when needed. The content of competency or the criteria should be performed or designed based on tasks and responsibilities that fits the purpose. The competency assessment performance evidence should be recorded and saved. Re-Training shall be performed and recorded when the result of competency assessment is not within the expectation.

5.16.7 Review of staff performance

The formal appraisal of the overall performance shall be done periodically for all staff. The assessment should cover work needs, individual skills & plans and achieving work objectives towards improving productivity.

5.16.8 Continuing education and professional development

Each lab staff shall take part in continuing education program. The laboratory shall establish continuing education program for laboratory personnel who

participate in the examination processes. The effectiveness of the continuing education program shall be periodically reviewed by responsible staff.

5.16.9 Personnel records

The following list of records for each staff shall be maintained securely and confidentiality in individual file that remains accessible as needed and relevant staff

- Employment details including National identity card, CV, and emergency contact information
- Copy of certification, educational, work experience and professional qualifications
- Health information, including records of work injury or exposure to occupational hazards, vaccination history
- Job descriptions document with staff signature indicates that staff is agreed about all contents
- Introduction and orientation of new staff to the laboratory environment
- Records of continuing education attended, training and achievements
- Individual Training program with date and signature of trainee and trainer.
- Competency assessments performance

5.17 Accommodation and environmental conditions

5.17.1 General

Each laboratory shall have the basic facilities that are well maintained to ensure performing laboratory work under quality and safety measures. Among those is the laboratory space which shall be designed to ensure quality and efficiency of laboratory services provided to the users and at same time ensure the health and safety of laboratory personnel, patients, and visitors. The personnel shall be trained in the basics of patient health and safety and bio risk management issues. The laboratory shall collaborate with the concerned departments to maintain the same regulations at sample collection and examination sites.

5.17.2 Laboratory and office facilities

Laboratory working area and office facilities shall provide an environment appropriate for the work to be carried out. The followings shall be considered when providing these facilities:

- Entrance to laboratory areas affecting the quality of lab examination should be regulated. This should be regulated in a way that ensures safety, confidentiality, quality and prevailing practices.
- Ensure authorized access to the medical information, patient samples and laboratory resources.
- Provided facilities for examination permit proper performance of laboratory examinations. These include: energy resources (uninterruptable power supply), lighting, heating, ventilation, noise, water supply and disposal and other environmental conditions like dust and humidity.
- Provided communication systems within laboratory are compatible with the size and complexity of the facility to ensure efficient transfer of information.
- Safety facility and devices are provided and regularly maintained. This includes operational of emergency release, intercom and alarm system for cold rooms, fridges and walk in freezers, accessibility of emergency shower and eyewash, etc..
- All hazardous/biomedical waste is discarded into appropriate biohazard waste containers that are handled and disposed off in accordance with the laboratory safety manual

5.17.3 Storage facilities

Sufficient storage space and conditions shall be made available which ensure continuing integrity of sample materials, documents, equipment, reagents, consumables, recodes, results and other items that may affect the quality of laboratory results.

Cross-contamination shall be prevented during storage of clinical samples and any other materials used in examination process. In addition, there shall be a proper storage and disposal facilities for dangerous materials according to the hazardous of the materials and as specified by applicable requirements.

5.17.4 Staff facilities

Laboratories shall be set with sufficient access to washrooms, safe supply of drinking water, and facilities for storing personal protective equipment, clothing and belongings. It shall also provide areas for staff activities including meeting rooms, quit study area and rest area if possible. All rooms shall be with adequate ventilation and lightings.

5.17.5 Patient sample collection facilities

The patient sample collection facilities shall be made appropriate to staff, patients and their accompanying person (e.g., guardian or interpreter). The reception/waiting and collection areas shall be allocated separately with consideration of patient privacy, comfort and needs (e.g., disabled access and toilet facilities). First aid materials and any other equipment that may be needed for resuscitation at these areas shall be made available, maintained and under local regulations.

The collection shall be done with appropriate facilities and procedures to ensure valid results and good quality of the examination.

5.17.6 Facility maintenance and environmental conditions

The laboratory shall monitor, control, and record environmental conditions according to the relevant specifications requirements or where quality of samples, results and/or staff health could be affected. The laboratory working area shall be kept clean and maintained. Consideration shall be given to any factors that may invalidate the results or adversely affect the required quality of the examination. These factors include light, sterility, dust, noxious, hazardous fumes, electromagnetic interferences, radiation, humidity, electrical supply, temperature, sound, vibration levels, and workflow logistics.

Different laboratory procedures can negatively affect each other's. Therefore, there shall be an effective separation between laboratory sections in which there are incompatible activities. Measures shall be kept in place to avoid cross-contamination where examination procedures pose a hazard or at places where the work need segregation. There shall be allocated locations for work that require a quit and uninterrupted work environment such as cytopathology

screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing and review of molecular mutation results.

5.18 Laboratory equipment, reagents, and consumables

5.18.1 Equipment:

5.18.1.1 General:

Laboratory shall be equipped with needed instrumentation that covers for the service provided. There shall be documented procedures for equipment management including selection, purchasing, installation and post installation. In addition, equipment's replacement shall be according to the need and results reliability. There shall be access to equipment contract that includes the agreements and responsibilities.

5.18.1.2 Equipment acceptance testing:

Equipment acceptance testing shall be performed according to validation/verification procedure to achieve defined acceptance criteria of the concerned laboratory.

Laboratory equipment validation/verification shall be carried out for all new or upgraded or majorly repaired or relocated. For further details, refer to related procedures of equipment validation/verification and temperature sensitive equipment validation procedure.The laboratory shall label each item of equipment properly using unique identifier number or name.

5.18.1.3 Equipment instructions for use:

There should be a clear and up to date guidance on how to handle the laboratory equipment. This guidance should be accessible to all staff. All authorized staff shall be trained on equipment safety, maintenance, and any special requirement for reagent or sample preparation.

The laboratory shall collaborate with supplier to provide training of the laboratory staff on newly installed equipment or any change in test performance.

5.18.1.4 Equipment calibration and metrological traceability:

There shall be documented procedure for the equipment calibration which directly or indirectly affects the laboratory results.

The lab shall have procedures for thermal and mechanical equipment calibration separately.

5.18.1.5 Equipment maintenance and repair:

The Laboratory shall have a documented procedure of equipment maintenance repair and decontamination for all the laboratory equipment according to manufacturers' recommendation and in collaboration with Biomedical Engineers.

Equipment maintenance shall be carried out for all laboratory equipment as per the manufacturer's recommendation.

The environment where equipment maintenance and repair carried, shall have importantly the following facilities: emergency stop devices, electrical safety instruction and safe handling and disposal of potentially hazardous material according to local method safety data sheet by authorized staff.

All laboratory equipment which needs to be repair shall be performed by authorized staff.

Whenever laboratory equipment is found to be defective, then clearly labelled as out of order and shall hold testing until get repaired. Once the equipment is repaired, the laboratory shall ensure the equipment performance.

All equipment maintenance, repair and defects shall be documented formally and monitored.

5.18.1.6 Equipment adverse incident:

Error or fault detected in the laboratory equipment shall be investigated by the concerned staff and the manufacturer. Any faulty result released during equipment breakdown, the lab staff shall recall and inform the change. During the breakdown, the lab should activate the contingency plan to maintain the needed services.

5.18.1.7 Equipment records:

Laboratory shall maintain documents and records of all the equipment and its items according to local guidelines. These records might include:

- Equipment identification (serial number, model number, name of manufacturer, or other unique identification)
- Date of equipment installation.
- Equipment location.
- Equipment condition (new, used, or reconditioned).
- Equipment validation/ verification record.
- Equipment preventive maintenance (PPM) records.
- Equipment failures, malfunctioning and repairs.
- Other equipment related records e.g. (equipment calibrators, controls, temperature records and reagent)
- Equipment important contacts (Manufacture, supplier and biomedical)
-

5.18.2 Reagents and consumables:

5.18.2.1. General:

Each laboratory shall have a documented procedure for purchasing, reception, storage, acceptance testing and inventory management of reagent and consumables which allow uninterrupted availability of reagents, supplies and laboratory service. Where the reagents and consumables interrupted, the lab shall follow the related contingency plan.

5.18.2.2. Reagent and consumables reception and storage:

The lab shall verify that the receiving location has adequate storage and proper handling conditions to maintain the purchased items according to manufacturer's specifications.

5.18.2.3. Reagents and consumables acceptance testing:

The laboratory shall have documented procedures for reagent and consumables batch validation for new reagent lot or new shipment or any

change in reagent and procedure prior to use. Each batch validation or any reagent defect should be recorded and raised to the responsible person as per reagent batch validation procedure.

5.18.2.4. Inventory management for laboratory reagents and consumables:

The laboratory shall follow the inventory control system. This system shall allow timely follow up of stock for the continuous workflow of the laboratory. It should separate uninspected, expired or unacceptable reagents and consumables. The rejected items shall be recorded and reported to the concerned department. Follow laboratory reagents and consumables contingency plan procedure.

5.18.2.5. Instruction for the use of the laboratory reagent and consumables:

Instructions including manufacturer recommendation shall be available and accessible in examination technical procedures.

5.18.2.6. Adverse incident for reagents and consumables:

Where laboratory reagents or consumables are not accepted, adverse incident shall be investigated and reported according to the institutional policy.Any fault or defect causing erroneous result release, the lab shall recall and inform the change. In case of service interruption, the lab should activate the contingency plan to maintain the needed services.

5.18.2.7. Records for reagents and consumables:

Appropriate record keeping system shall be developed for all reagents and consumables. The records should contain at least the following:

- Reagent or consumable item code
- Item manufacturer’s name and batch or lot number
- Quantity requested / issued
- Price of item
- Supplier or manufacturer contacts
- Dates of receiving, expiry, and usage (starting & ending)
- In-house prepared reagent traceability record with the person initial and preparation date.
- Receiving conditions (e.g., acceptable or deteriorated)

- Manufacturer's recommendations (e.g., package insert)
- Item initial acceptance records (e.g., validation / verification)
- Performance records confirming the ongoing acceptance for use (e.g., calibrators, internal quality, external quality and customer feedbacks).

5.19 Pre-Examination process

5.19.1 General

The laboratory shall have documented procedures and the needed information for the pre-examination processes to ensure effective patient care via reliable results.

5.19.2 Information for patients and users

The information needed for both patients and users should be available in each laboratory. The recommended information is:

- The laboratory location
- Laboratory working hours
- Laboratory contacts, e.g., fax, emails, extensions.
- Detailed list of laboratory examinations either in a manual or electronic format including patient preparation, sample collection, sample type, sample volume, precautions, turnaround time, reference ranges, result units.
- List of laboratory examinations that are referred to other laboratories either in a manual or electronic format.
- List of laboratory examinations offered outside normal working hours.
- Instructions for completion of the electronic or manual request form with an alert on the mandatory part that must be filled.
- Instructions on sample storage prior to transportation to the laboratory.
- Requirement for patient consent in certain clinical procedures.
- Criteria for sample acceptance and rejection.
- List of factors known to significantly affect the results, e.g., posture and time of collection.
- Availability of clinical review on test ordering and interpretation.

- Laboratory guidance on protecting personal information of patients, users, and health care workers
- Laboratory complaint procedure.

5.19.3 Request form information

The request forms (either electronic or paper form) shall include, but not be limited to, the following:

- Institution name and approved logo.
- Unique patient identification including: patient three names with tribe/family, gender, date of birth, institution patient ID, address and contact details.
- Name of authorized personnel to request the examination, the requesting location and contact details
- Type of primary sample and the origin when applicable
- The approved name of required examinations.
- Patient relevant clinical information
- Date and time of collection
- Date and time of receiving

5.19.4 Primary sample collection and handling

5.19.4.1 General

There shall be an available documented procedure for sample collection and handling for the personnel responsible for primary sample collection. Any deviations, exclusions or additions to the documented collection procedure shall be included in all documents containing examination results.

5.19.4.2 Instruction for collection activities

The laboratory instructions on collection activities shall include:

- Relevant clinical information.
- Determination of patient details on primary tube.
- Verification if patient meets the pre-examination requirements for example fasting, medication status, and time interval.

- Instruction for sample collection including labeling, container type and additives
- Recording details of person collecting the primary sample, date, and time.
- Instruction on storage and transportation of the primary samples until delivery to laboratory.
- Instructions on safe disposal of collection materials after use

5.19.5 Sample transportation

The laboratory shall have documented procedure on transportation of samples which shall be monitored well to ensure that samples reach laboratory:

- Within a recommended time frame
- At ideal temperature
- With maintained integrity
- Under safe condition for the sample carrier, public and laboratory staff

5.19.6 Sample reception

The laboratory shall ensure proper sample receiving to ensure the following:

- Details on forms or electronic data match the patient information on primary sample.
- Documented criteria of sample acceptance or rejection are applied
- Any sample errors e.g., mislabeling, delayed transportation, inappropriate transportation conditions should be recorded for further result interpretation.
- All received samples shall be recorded electronically or manually with sample receiver identification.
- Clear instructions are available at laboratory reception for urgent and unrepeatable (precious) samples handling.

5.20 Examination processes

5.20.1 General:

The laboratory shall have examination and validation/ verification procedures in which established / authoritative textbooks, peer-reviewed texts, or journals, or international, national, or regional guidelines are used to meet the clinical needs.

If there is a need for in-house developed procedures,they should be approved by expert in the related discipline.

5.20.2 Validation/ verification of Examination Procedures:

- The laboratory shall use examination procedures by a manufacturer.
- The laboratory shall verify the method performance specifications and manufacturer claims.
- Authorized trained laboratory personnel in each discipline shall review the validation / verification results.
- Validation / verification results shall be documented and archived according to local procedure.

5.20.3 Reference Intervals or Clinical Decision Values

Reference intervals and clinical decision values shall be periodically reviewed under the following conditions:

- If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed, if necessary, by corrective action.
- A review of reference intervals shall also take place when the laboratory changes an examination procedure or pre-examination procedure, if appropriate.
- Updates in international guidelines of professional bodies such as the National Institute of Clinical Excellence (NICE), National Cholesterol Education Program (NCEP), World Health Organization (WHO)_etgc. are referred to in certain cut-off and decision limits.

5.20.4 Documentation of examination procedures

- All procedures shall be documented in a complete technical procedure manual for each laboratory section and shall be available at the workstation for relevant staff.
- All procedures shall be listed in the table of Contents of the manual and are subject to the document control system.
- The laboratory shall maintain only current procedures at workstations.

- The instructions for use (i.e., package insert) shall be included in the examination procedures.
- Any method deviation or change shall be reviewed and documented. It should be explained and communicated to the users once needed.
- Note – Communication can be accomplished in any of several different ways, depending on local circumstances. The laboratory can use hospital information system board messages, test master to update users with changes.
- Each new version of examination kits with major changes in reagents or procedure shall be checked for performance and suitability for intended use.
- Any procedural changes shall be dated and authorized as for other procedures.

5.21 Ensuring quality of examination results

The laboratory shall ensure the reliability and the quality of the examination through running internal quality control and enrolment in external quality scheme. In addition, implementation and monitoring of pre-examination and post examination processes are required to ensure a reliable outcome. There shall be no result fabrication.

5.21.1 Quality Control

5.21.1.1 General

The laboratory shall develop a comprehensive IQC programme for both qualitative and quantitative examinations. There shall be a designed and well described internal quality control procedure to verify the performance of the intended quality of result.

5.21.1.2 Quality Control materials

The laboratory shall select quality control (QC) materials that mimic patient samples, and the concentrations around the clinical decision ranges, where applicable, to ensure the validity of decision made. Third party quality control materials are recommended to avoid potential bias.

5.21.1.3 Quality Control Data

The laboratory shall have a document procedure in case of internal quality control failure to avoid the release of wrong patient results.
If the internal quality control rules are violated, patient results shall be rejected and reexamined after quality control result correction. For better result management and confirmation, random selection of patient samples run after the last successful quality control shall be reexamined as well.
Quality control data shall be reviewed to ensure quality control performance and avoid any shift or trend in the result. The trend or shift in quality control results indicates examination system problem that requires a corrective and a preventive action.

5.21.2 Inter-laboratory Comparison

5.21.2.1 Participation

The laboratory shall participate in inter-laboratory comparison programs including external quality control (EQA) i.e., proficiency program that are relevant to the laboratory examinations. Each laboratory shall have a documented procedure for inter-laboratory comparison schemes which the lab is enrolled with. The inter-laboratory comparison result shall be monitored, and corrective actions shall be taken and recorded for unacceptable performance if needed.
The laboratory should cover the majority of their examinations with EQA programs

5.21.2.2 Alternative approaches

The laboratory shall have other approaches in case of unavailability of inter-laboratory comparison scheme, in order to provide evidence for determining the acceptability of examination results. Such materials may include:

- Certified reference materials;
- Previously examined samples;
- Exchange of samples / slides with other laboratories;

- Control materials that are tested daily in inter-laboratory comparison programs.

5.21.2.3 Analysis of inter-laboratory comparison samples

- The laboratory shall analyze inter-laboratory comparison samples as patient and treat them using same procedures.
- Inter-laboratory comparison samples shall be analyzed routinely by laboratory personnel who routinely examine patient sample.
- Inter-laboratory comparison sample results shall not be communicated with other participants before the submission date. Thus, comparison samples shall not be sent for confirmatory examination.

5.21.2.4 Evaluation of laboratory performance

The inter-laboratory comparison performance shall be reviewed by qualified laboratory personnel and discussed with pathologist for any clinical impact.

The poor performance reports shall be monitored and corrected. Preventive action taken shall be documented and monitor the action effectiveness.

5.21.3 Comparability of examination results

The laboratory shall have a means of comparing same or different procedures, equipment, and methods and locations and establishing the comparability of results for patient samples throughout clinically appropriate intervals. The users shall be notified in case of change of any procedures, equipment and method change or update.

5.22 Post-examination processes

5.22.1 Review of Results

Medical laboratories shall have established technical review process in place to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and as appropriate, available clinical information and previous examination results.

Any criteria established for automatic selection and reporting of results shall be reviewed, approved, and documented.

5.22.2 Storage, Retention and Disposal of Clinical Samples

Medical laboratories shall have written procedures for storage, retention, access, and safe disposal of clinical samples. The length of retention of all samples shall be clearly stated and it depends on type of sample and test as well as legal requirement. Safe disposal of samples shall be carried out in accordance with local regulations.

5.23 Reporting of Results

5.23.1 General

The documentation of examination standard operating procedures (SOP) provides details of specific reporting requirements for each examination. Medical laboratories shall ensure that a result from examination procedure is reported accurately, clearly, and unambiguously.

The laboratory shall state the format of reporting in the SOP. The electronic reporting is preferred as it maximizes accessibility and audit trail and reducing the potential for transcription errors.

The laboratory shall have documented procedures for notification of critical/high risk results and delayed reporting of results.

There shall be procedure to ensure the correctness of the transcription process.

Advice on examinations and interpretation of results should be available to meet the needs and requirements of users, by the inclusion of clear, concise, and unambiguous automatic comments on reports; the inclusion of comments in the report added manually by the clinical staff, users, and can seek further clarification by contacting the clinical staff.

5.23.2 Report Attributes

Laboratory shall ensure that the report attributes effectively communicate laboratory results and meets the users' needs and includes the following:

- Comments on sample quality that might compromise examination results should be added automatically according to the result and manually after results have been checked by clinical staff.

- Comments regarding the sample suitability with respect to acceptance/rejection criteria should be included to explain any non-reporting of results.
- Documentation of any communicated results in particular critical and high risk results.
- Interpretive comments on results, where applicable.

5.23.3 Report Content

Laboratory reports shall be formulated to include the following data items:

- Identification of the health institution
- Laboratory section and Laboratory number (specimen number)
- Patient identification and patient location on each page of the report.
- Identification of the requester and the requester's location.
- Date of the primary sample and (where appropriate and relevant) the sample collection and receiving time.
- The type of primary sample received
- The measurement procedure utilised (if appropriate)
- Examination results reported in SI units, units traceable to SI units, or other applicable units.
- Biological reference intervals, clinical decision values (if appropriate)
- Result interpretation (if appropriate)
- Cautionary or explanatory notes.
- Identification of the person reviewing the results and authorising the report release (if this information is not contained on the report, it is readily available from the audit trail on the Laboratory Information System).
- Date of report and time of release (if this information is not contained on the report, it is readily available from the audit trail on the Laboratory Information System)
- Page number to total number of pages (e.g., Page 1 of 5, etc.)

5.24 Release of Results

5.24.1 General

Medical laboratories shall state the authorization privilege for the release of each examination result. There should be clear instructions for the release of results, which consider the following points:

- If the quality of the primary sample received was unsuitable for examination or could have compromised the quality of the result generated.
- If an examination result falls within established critical/high risk values (Action, any difficulties, or failures during the notification)
- If the results are delayed
- If the results have transcription errors and that they have been made available only to those authorised to receive them.
- If the results are transmitted as an interim report.
- If results are distributed via telephone or other means

5.24.2 Automated Selection and Reporting of Results

Laboratories which use a system whereby some reports are selected for reporting automatically shall have specific protocols which cover how this process occurs. The protocol shall meet the following:

- The criteria to be used for automated selection and reporting have been defined and approved by the clinical head of department and are readily available and understood by the staff.
- The criteria have been fully validated for proper functioning prior to use and are verified following system changes or at periodic intervals to ensure suitable functionality is maintained.
- The impact that sample interferences (e.g., haemolysis) may have upon the examination results.
- The process for incorporating analytical warning messages from instruments into the automated selection and reporting criteria.
- The explanation of how results selected for automated reporting can be identified at the point of review, in advance of result release and include date and time of selection.
- The clarification of how the process can be suspended rapidly if required.

5.24.3 Revised Reports

Medical laboratories shall have written procedure for amending reported results in circumstances where it is found necessary to issue a revised report. This process shall ensure the following requirements:

- The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report.
- The user is made aware of the revision: If it is necessary to amend a result, a comment is attached to the result indicating that the result has been amended. If a significant anomaly is identified, the user is contacted and notified of the discrepancy.
- The revised record shows the time and date of the change and the name of the person responsible for the change.
- The original report entries remain in the record when revisions are made which can be subsequently accessed by those with suitable access rights if required.
- In circumstances where the results with significant change and affects the clinical decision, an adverse incident shall be recorded with an indication of the action taken to reduce the possibility of a recurrence.

5.25 Laboratory information management

5.25.1 General

The laboratory shall establish procedures for laboratory information management. The laboratory shall have also access to patient data and information needed to provide the service yet ensure confidentiality of patient information and security of data.

5.25.2 Authorities and Responsibilities

The laboratory shall define the authorities and responsibilities for all laboratory personnel and define the authorization and access levels in regard to result entry, modification, releasing and recall.

5.25.3 Information system management

The laboratory information system shall have a clear sitting for collection, processing, recording, reporting or retrieval of examination data that shall be:

- Validated by supplier and verified by laboratory

- Documented and protected from unauthorized access or loss
- Operated in a way that fulfil the manufacturer specification and provide alternatives when the system is non-computerized.
- Maintained properly to ensure the integrity of the data, the availability of failure recording systems and corrective actions.
- Managed by the informatics department and shall ensure it meets national and international requirements for data protection.
- Maintained well with presence of action plan to ensure providing a constant service during system upgrade or system failure.

6 Procedure

6.1. Organization and management responsibility

This procedure is not required

6.2. Quality management system

This procedure is not required

6.3. Document control procedure

This procedure is to define the methods used for identification, review, approval, and control of the documents related to the laboratory quality management system using the following guidance:

- Refer to the policy and procedure of documents development, MOH/DGQAC/P&P/001/Vers.01
- The laboratory management ensures that all staff has read and signed all approved Laboratory documents.
- The laboratory conducts a regular audit to monitor the implementation of the approved document.
- Review document as recommended in (appendix 1), consider any other local guidelines.
- Amendments may be made at any time in the case of a change in practice or legislation

6.4. Service agreement

Upon the request of additional, new test, or renew of service, use the following:

6.4.1. A service agreement review form with a structured checklist should be filled with preparation information. **Refer to form 10.2.1.**

6.4.2. The information in the form is reviewed to decide on the laboratory's capability to carry out the test requested. If the laboratory has the technical capabilities, carry on with the procedure.

6.4.3. The defined proposed requested test and items is purchased through the approved channels.

6.4.4. The request that contains a specific description of the products is sent for approval with the consideration of other related procedure.

6.4.5. Any significant changes and relevant discussions are reviewed and documented.

6.5. Selection of referral laboratories

This procedure is to provide a valuable guidance requirement for the selection of a referral laboratory, as per the guidance:

6.5.1. Planning for selection

- **Consideration**: There are several factors determine the selection of a referral laboratory importantly cost, turnaround time, salesperson claims, proficiency, and references, etc. While the cost of referral laboratory services may be an essential concern, the selection of a referral laboratory has to be based primarily on the quality of services provided.
- **Responsibility:** The laboratory director / assigned committee or team of the referring laboratory is responsible for selecting a referral laboratory and for its ongoing evaluation based on objective evidence of acceptable quality and responsiveness in consultation. Refer to referring laboratory selection checklist form.

6.5.2. Criteria for selection:

- The referral Laboratory shall be accredited.
- The referring Laboratory shall design a systematic approach for quality evaluation (refer to appendix form **10.2.2**.)
- The referral lab shall expect and permit an onsite evaluation of its facility during peak operating hours.

- Onsite laboratory evaluation is recommended and appropriate. It should be noted that evaluation of a referral laboratory must be an ongoing process, and it is therefore suggested that the referring laboratory set up meetings at regular intervals with the referral laboratory.
- During an onsite visit, examine the physical facility, general level of housekeeping, adherence to laboratory safety principles, and appearance, attitude, and general demeanor of the laboratory staff. Although the latter is a subjective determination, the appropriateness of the laboratory may significantly influence the quality of laboratory work.

6.5.3. The following criteria is to be Considered during evaluating the referral lab quality:

- **Facilities and Equipment**: Determine that the equipment, supplies, and instrumentation are consistent with the scope and capacity of testing being conducted and are validated to ensure accuracy of results. The Instrument Maintenance to be ensure by:
  - Examining documents of maintenance and repair records.
  - Concluding whether the existing instrumentation is adequate for the scope and volume of tests being referred.
- **Scope of Available Testing:**

  Some referring laboratories may require a specialty laboratory that only performs a few operations, while others will require a full-service facility. Referring lab should define particular clinical needs before the selection of referral laboratory. The contracts should include price list of all tests. If the referral laboratory refers specimens to another laboratory, the laboratory should be identified, accredited, their qualifications should be made available, and their name should appear on the report form.
- **Efficiency of Referral Laboratory Services:**

  When evaluating acceptable efficiency of a referral laboratory, the scope of available testing, specimen collection procedures, test ordering, transportation, and turnaround time (TAT) and content and language of reporting of results, including critical values, must be considered. The acceptability of each of these

elements will vary depending on the individual needs of the referring laboratory.

- **Specimen collection and test ordering**

  The laboratory must provide comprehensive instructions for patient preparation and collection of samples including quantity of specimen required, special handling needs including separate pediatric requirements, type of container, labeling, use of anticoagulants and preservatives, and the desired clinical information. The referral laboratory must have defined criteria for unacceptable or rejected specimens. Changes in specimen requirements must be communicated to the referring laboratory in advance. The referring lab should provide free of cost, necessary consumables that are required to meet all pre analytical requirements.

- **Transportation**

  The referral laboratory should have a defined transportation mechanism of specimens from the referring to the referral laboratory. A courier service should provide acceptable pick-up schedules to ensure the integrity of patient specimens in an appropriate packaging, temperature conditions and timely transportation. Special requirements, such as transportation of frozen specimens should be addressed and clearly defined. The referral laboratory must make the appropriate arrangements locally to provide this service and notify the client of any unscheduled delays.

- **Intra- laboratory Turnaround time (TAT)**

  The expected time for sample receipt and reporting results must be stated. Unanticipated delays must be communicated to the referring laboratory.

- **Resources**

  The reference laboratory must provide test related information such as type of method used and units of measurements which helps in selection of correct tests and interpretation of results. The referral laboratory is responsible to notify clients when any test information becomes available or modified.

- **Reporting of Results and Interpretations:**

The method of reporting of results should be:

- Selected by the client.
- Use electronic data communication system.
- Use Scientific English language to report the result. If the primary report is not in English, then approved translation is required.
- Defined address, name, and logo of the referring laboratory where the tests were carried out.
- Include Age and sex adjusted reference ranges and/or other therapeutic or diagnostic reference ranges.
- Communicate Critical values or unusual findings immediately.
- Respond to inquiries concerning test results and provide expert advisory service for interpretation, diagnosis, and treatment management.
- Provide the client with its written policies for dealing with inappropriate/precious (unrepeatable) / urgent specimens.
- Provide policies for corrected and amended reports.

- **Availability of Documents:** The referring lab shall check the documents and manuals of procedures instructions of the referral lab that demonstratethe quality of its service by supplying information in several sets of laboratory operations during the onsite visit.
- **Personnel:** Inspect the qualifications of the referral laboratory's director, professional staff, and pathologists. Information should include but not be limited to:
  - Licensure when appropriate, years of work experiences
  - Certification / qualification
  - Participating in training and continuing educational activities
  - Significant areas of special expertise.
- **Internal Quality Control:** Thequality of control materials is essential to ensure the accuracy of lab test. Review of control records includes:
  - Type and appropriateness of control material.

- Frequency of run of quality control materials.
- Appropriateness of control range and limits
- Controls evaluation system and monitoring by statistical records
- Procedure manuals to determine whether the procedure manuals meet the international examination guidelines and are practically followed by staff.

- **External Quality Assessment Activities (EQAS):**
  - The referral laboratory should provide the records of its performance of participation in laboratory proficiency testing programs.
  - A documented program for review of proficiency test results and a record of any corrective action taken should be available.
  - If requested, the laboratory should agree to split testing of specimens by the prospective referring laboratory.
- **Client Satisfaction:**

  Although reputation may be a very subjective indicator of quality, the referral laboratory should provide the names of clients as valuable references to gain information from current clients. The referral laboratory should also be willing to describe its internal program to assess and assure client satisfaction.
- **Other Quality Assurance/Improvement Issues:**

  Referring laboratory should assess the referral lab quality improvement program by reviewing the key performance indicators, and the quality assurance / Improvement program meetings that demonstrate the types of issues discussed and how resolution was achieved by the laboratory. The best laboratories actively involve all employees in quality planning of continuous improvement.
- **Communications Systems**

  Referral laboratories should use consistent communication protocols/systems of test entry and reporting of results. The communication system should be effective to meet the needs of the referring laboratory, preferably electronic.
- **Clinical and technical consultation**

The reference laboratory must provide expert clinical or technical advisors when needed.

- **CME**

  The reference laboratory can facilitate and participate in providing or sponsoring training workshops, courses and CME presentations.

- **Third party billing**

  It is valuable and cost-effective to have a reference laboratory that can afford third-party billing.

6.6. Services and supplies management procedure

This procedure is to define the management process and storage of services and supplies by the following steps:

6.6.1. Selection of new product

Select the registered and approved product by concerned department at MOH.

6.6.2. Ordering and purchasing of new Laboratory supplies:

- Once a laboratory requires a new item (equipment or consumables), the adhere to following procedure (consider the discrepancies between MOH and non-MOH laboratories):
  - The responsible staff writes the specification of the new required item to the laboratory management with workload based on stability, and test justification.
  - After Laboratory management approval, send the request through the appropriate channel for tender process.
  - Once the offers are received, the requester reviews them against the specification and tender requirements with comparison between the different offers which includes price, credibility of the supplier, consider the advantage and disadvantage of purchasing brand name compared to generic products.
  - **After the offer selection by the requester, send the tender to tender**committee for approval.
  - After Local Purchase Order (LPO), the laboratory is informed about the item order and the approximate delivery date.

- Label all the shelves which used for storage of reagent and consumables and record their number on the record logbook or standard form.
- Prepare or update logbook or standard form record.

6.6.3. Reception and storage of product:

- The received products to be checked for the correct quantities, certification, receiving condition (e.g. leaked, broken etc.) and to match the packing slip against the issue of voucher.
- If the product is accepted, it is logged in and stored with the following essential information:
  - item code
  - Location
  - supplier
  - issue of voucher
  - Name of the receiver
  - Date of receipt
  - Expiration date
  - Lot number
  - Quantity of the material received
  - Current stock balance.
  - Storage conditions.
- Record any discrepancy that could affect the quality of laboratory output and follow the needful corrective action.

6.6.4. Stepwise for inventory management:

- Use a standard item quantification method, e.g. consumption based method by determining actual usage and adding 5-10% of wastage
- Consider the expiration date: Store long expiry items behind the near expiry items or store new items behind the old items if expiry same.
- Monitor the product shelf life and stability: label the date of opening clearly
- Maintain and monitor the inventory and replenish laboratory with items regularly.

- Ensure storage conditions are in accordance with the manufacturer's instructions, importantly to temperature and safety requirements. Good practices to keep in mind are:
    - Keep the storeroom clean, well ventilated, organized and locked to protect the inventory.
    - Protect the storage areas from direct sunlight.
    - Use good shelving to support items
    - Arrange items in upright position if indicated
    - Avoid the usage of fridge's door.
- Organize items using sequenced labeling system on the shelves and ensure items are accessible to staff.
- Place the items in a safe and organized way. For example: heavier items bellow and new behind existing materials so that the older materials get used first (i.e. first in first out).
- Label different reagent with different color code so that it can be clearly differentiated if they look alike.
- Mark the reagents batch which passed the evaluation.

6.6.5. Inventory management system:

- Establish a system for receiving, inspecting and storing supplies.
- The system records and closely monitors all tests with their reagents and consumables that focusing on the following information such as monthly usage, items movement (usage) , receiving/ delivery frequency, and minimum stock
- Assign responsibilities to the staff to implement an inventory management program.

6.6.6. Equipment replacement

- Assign equipment life time based on local recommendation (e.g. average of seven years at MOH)
- Replacement of equipment can be in other cases of continual operational problems and malfunctioning, upgrade to better technology, no longer supports for parts or software updates, or supplies stoppage.

- Request for replacement or upgrade through the approved channels along with justification, workload and specification.
- Send the request through the appropriate channel for tender process.
- The requester reviews the offers against the specification and tender requirements with comparison between the different offers which includes price, credibility of the supplier, consider the after sales support.

6.7. Advisory Services

This procedure is not required.

6.8. Resolution of complaints and incidents

This procedure is to provide guidance on handling and dealing with complaints and incidents, as per the following:

6.8.1 Resolution of complaints

- Complaints can be received via different sources such as (patients, family members, health care workers, other state agencies, professional boards and just about anyone who becomes aware of possible regulatory violations within facilities
- Complaints can be received via different channels such as (Telephone, Fax, E-mail, social media, written and verbal)
- While reporting the complaint, the complainant should provide as much of the following information as possible:
  - Name, address of the laboratory, affected person.
  - Detail description of the complaint with the date, time, frequency and telephone number.
  - Any other details or documentation that will verify the problem
- Each complaint is assessed based on harm, age (old or recent) of the complaint and the relevance of the information given to regulatory violations.
- Each complaint is to be investigated by trained staff with good understanding and has relation to the concerned.
- In case of multidepartment major complaints occur, a meeting is conducted by all concerned under the supervision of institution's quality department to find root causes and resolve complaints.

- Investigator uses tools such as conducting meeting, interviews, reviewing records, policies and contrast and making observation of current conditions.
- Complaint may require on-site visits; some only require record / document retrieval, phone contacts to make compliance decisions.
- In case of electronic complaints, end users send complaints through online systems (e.g. Al Shifa hospital quality assurance module). The module is designed to comply with complaints resolution requirements:
    - The quality manager forwards the complaint to the section quality focal point.
    - The quality focal point ensures those relevant supervisors perform whatever corrections and investigations to identify root causes and record these details in an electronic module.
    - The quality manager /quality focal point performs follow-up verification to ensure the appropriate corrective action was taken and was effective and record verification.
- In case of receiving verbal complaints or call:
    - The staff receiving the complaint records the complaint and identifies it as an end-user complaint.
    - Forwards the complaints through the approved communication channel
    - Responsible laboratory personnel collaborate with the concerned to determine the proper corrective action and prevent recurrence.
- While resolving difficult complaintsthe concerned staff ensuresthe following:
    - Listen carefully and avoid interruption
    - Accept the fact that people have variable personalities.
    - Show you are willing to help. Take responsibility for the situation and give your name to break the ice.
    - Develop your skills (tone of voice and body language) using words such as" you are right, I agree, your comment is valid, etc." to deal better with people.
    - Pay attention to your way while sharing your views not to offend others

- Use the sandwich technique for tackling challenging conversations. In this tactic, offer a piece of negative feedback “sandwiched" between two positive ones, thus easing the blow of the critique.
- Maintain rapport with colleagues.
- Use questions (i.e., who, what, where, when, how) to the complainant to get the facts.
- Archive all complaints with their investigation and documentation.

6.8.2 Incident reporting

This process is customized from Policy & Procedure of Incident Reporting & Learning System (IRLS) number MOH /DGQAC/P&P/002/Vers.01 using the stepsbelow:

- Once an incident occurs, the involved staff or witness or the accountable person informs the in duty responsible staff verbally, ensuring the safety of personnel and environment.
- Then, record the incident on the approved system in the institution.
- The reporter selects the proper categorization (Refer to Incident Reporting & Learning System Category & Subcategory List in Al Ashifa).

Note: The incident types are divided into (general, near miss, and sentinel).

The incidents severity scoring is divided into (minor, mild, moderate, serious, very serious).

- General incidents scored as minor severity
- Near miss incidents can be mild, moderate, or serious
- Sentinel incidents are usually serious or very serious

- All incidents to be sent through the approved communication channels in the institutions.
- The accountable staff investigates the general incident or near miss if needed (depends on scoring severity and frequency) by using the RCA system and to investigate correctly (Refer to Contributing Factors Classification in Al Shifa system).
- Daily during working hours, all reported events are reviewed by event manager

- Ensure that all sentinel events have an RCA investigation, in which the event to be sent to senior patient safety officer (investigation team leader) by event manager to investigate the events, then based on the investigation, fill RCA and corrective action plan form, refer to corrective action procedure.
- Analyze the risk for all reported incidents according to the local risk assessment tool (for further guidance refer to MoH/DGQAC/GUD/001/Vers.01 Integrated Risk Management Guidelines), then use RCA and corrective action plan report form for sending report.
- Filled RCA and corrective action plan report for sentinel events (for general incidents and near miss if needed) are then directly forwarded to the event manager.
- After completing the investigation and reporting process for the sentinel event, the hospital event manager or and quality manager/ officer closes the event.
- Once the incident is closed, the Safety alert and lesson learned are prepared by the event manager (Refer to appendix form 10.2.3: Safety Alert and Lesson Learnt Form).
- Safety alert and lesson learnedis forwarded and disseminated according to local approved channel

6.9. Non-conformities identification and control procedure

This procedure is to describe the methods of Identification, handling, controlling and monitoring non-conformities (NC) using the guidance:

6.9.1. Non-conformance identification:

- Identify all non-conformances and bringto the attention of the responsible staff to take necessary steps to correct the situation.
- **Common non conformance sources are:**
  - Customer's complaints including negative feedback
  - Safety issues
  - Failure to meet the requirement of equipment performance.
  - Issues in stock management
  - Major power / computer failure
  - Internal and external quality controls

- Internal and external audits
- Results review
- Laboratory management reviews

6.9.2. Non conformance categorization:

- Categorize the non-conformance into (minor, major, severe).
- Minor NC: No harm, e.g. minor clerical errors
- Major NC: errors corrected before causes harm to the patient but satisfaction effected
- Severe(caused harm to the patient, e.g. repeat the test because of wrong result, wrong treatment established)

6.9.3. Non-conformance recording:

- A member of staff discovering a non-conformance (initiator) is required to record details of the problem by filling section 1 of the conformance form (NCF) refer to appendix from **10.2.4.**and inform responsible staff.
- The responsible staff is required to fill **section2** of the NCF.

6.9.4. Handling of non-conformance:

- Mark non-conformance sample in the system; if the quality of a test is affected by non-conformity, consider informing the requesting clinician if appropriate.
- Hold the patient result if the non-conformity is affecting the examination.
- Consider the medical significance of the non-conformities and decide on the corrective action.
- Recall the patient result if the non-conformanceis discovered after result release. Call the requesting clinician if the result is amended.
  Note: Details of corrective actions of nonconformity must be documented
- Decisions on action and non-conforming details are reviewed by quality officer / manager for root cause investigation.

6.9.5. Control and monitoring of Nonconformity:

- Prepare a regular periodic non-conformance report that includes:
  - The number of NC per section.
  - Analysis of most predominant category of NC

- Analysis of most common root causes.
- Trends and shifts.
- Effectiveness of corrective action measures.

- Discuss the performance of NC in a management review meeting

6.10. Corrective Action (CA)

This procedure outlines the required steps to initiate a corrective action system of defining the non-conformance, problem containment, and determining the causes before taking appropriate actions. Actions taken are reviewed to ensure that they have addressed the problem and root cause of the problem effectively. Throughout the corrective action process, entire details should be documented for accuracy, effectiveness, and future reference. The coming steps are considered during correction:

6.10.1. Immediate action: Action taken at the time of the nonconformity to mitigate its immediate effects is considered "immediate "action. It is the first action taken for immediate problem containment. The following steps guides to initiate an immediate action process:

Immediate action Steps	**Description**
1.Define the Problem:	The initiator describes the non-conformance by identifying what is wrong and detail the problem in quantifiable terms The containment action is defined, verified and implemented immediately to eliminate the effects of the problem.
2. Recording non-conformance	Record the reported non-conformance and complete first section in a non-conformance form (refer to non conformance procedure). Record relevant details as much as possible. Electronic recording can beused

6.10.2. Corrective Action:

- Action taken to analyze and remove the root cause of the problem that is causing the non-conformities. The following steps guides to initiate a corrective action:

*Corrective action Steps	Description
1.Establish an investigation team	Initiator with the quality manager / officer determines the frequency of occurrence of the non-conformance, the seriousness, extent, and consequences of the problem and he decides if a corrective action is needed.
2.Select corrective Action	The team with the help of the staff involved in the non-conformance examines the source of problem. Investigate the root causes to create the corrective action plan which include the risk assessment. **Note:** You may need to plan more than one short-term corrective actions to fully contain the problem.
3. Implementation of the corrective Action	-The action plan is recorded and prioritized under corrective action.(refer to appendix form **10.2.5**) .
4.verify the effectiveness of corrective actions	-Initiator, laboratory management with Quality manager / officer follows up on the effectiveness of the action taken and record it. - Act on appropriate modification for ineffective actions found during the follow up.

6.10.3. Control of actions:

- All time framed action plan to eliminate the non-conformance are to be monitored and followed up by quality officer.
- The effectiveness of actions taken is to be discussed and reviewed with lab management for process improvement.
- When necessary, extra measures are taken for planned actions which are delayed, incomplete, or ineffective.

6.11. Preventive Action (PA)

This procedure describes the system of preventive actions of organization, process, procedures, resources, personnel and the management of medical laboratory through the assistance of the next guidance:

6.11.1 The preventive action measures are applied in situations:

- Proactively for a potential problem.
- As a part of risk assessment process

6.11.2 Prior to implementation of preventive action, the lab hires a project manager who collaborates with the quality manager / officer to look for potential opportunity of improvement, set the preventive measures plan and document the process.

6.11.3 Project manager with the quality manager / officer find out sources for improvement using: Key performance indicators (KPI), non-conformances, feedback from employees, Results of audits, internal audits and customer audits.

6.11.4 The subsequent steps are to be followed for the initiation and monitoring of an improvement project:

- Selection of potential problem (or opportunity of improvement area).
- Documentation of the project details and forwards it to the quality Manager.
- Approval of the project by the laboratory management.
- Write up of a problem statement: involves brainstorm and gap analysis of the potential problem drivers by reviewing the background and development of ideas to write up a problem statement after whole member's agreement.
- Conduction of current situation analysis: to set improvement aims, the team uses data collection, process description, and problem statements. The quality tools that may be useful for this step includes Pareto Analysis, Affinity Diagrams, Bar Charts, Control Charts, Flowcharts, Gap Analysis", and Benchmarking Analysis.
- Conduction of a root- cause analysis followed by cost / benefit analysis to prioritize the highly needed improvement area using quality tools such as Cause and Effect Diagram/Fishbone, Pareto Analysis, Prioritization Matrix, Spreadsheet, and Value etc.

- Development of solutions action plan: the team set a group of solutions and priorities them by mapping solutions to root causes, assess barriers to implementation, identifying countermeasures to barriers, and finalize the action plan. The used quality tools include Gantt Chart/Action Plan, Benchmarking Analysis, Value Analysis, Force-Field Analysis, multi-voting and PICK-chart.
- The approval of final documented improvement action plan with the time frame for implementation.
- Conduction a pilot study for the Implementation of the solutions action plan.
- Evaluation of the pilot study results and revise the action plan to assess the effectiveness using tools such as Check sheets, Control Charts, Line Chart/Run Chart, Histograms, Pie Charts, Scatter Diagram, Gantt Chart/Action Plan, and Work Breakdown Structure.
- Re-implementation of the most applicable action plan to other areas of need and monitor the effectiveness.
- Regular submission of a summarized result for management review meeting.
- The project followed by clear control plan. For more details, refer to continuous improvement procedure

6.12. Continual improvement

This procedure describes the process of continual improvement of organization, process, procedures, resources, personnel and the management of medical laboratory using the following instructions:

6.12.1 Adapt a structured methodology in any institution to identify and implement improvements, for waste reduction and improving efficiency.

6.12.2 Consider the following fundamental principles for effective continual improvement:

- Long term commitment from management and involved members.
- The alignment of the processes with the vision of the laboratory.
- The active participation of all staff to contribute to continual process improvement.

- Usage of process improvement tools and techniques for project management and data gathering and analysis.
- Record of each step in the process of improvement methodology.

6.12.3 The management system is continually and constantly improved using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews

6.12.4 Select the process improvement project team leader for each project. The leader has importantly leadership and interpersonal skills to ensure a fair and smooth reassignment of project personnel.

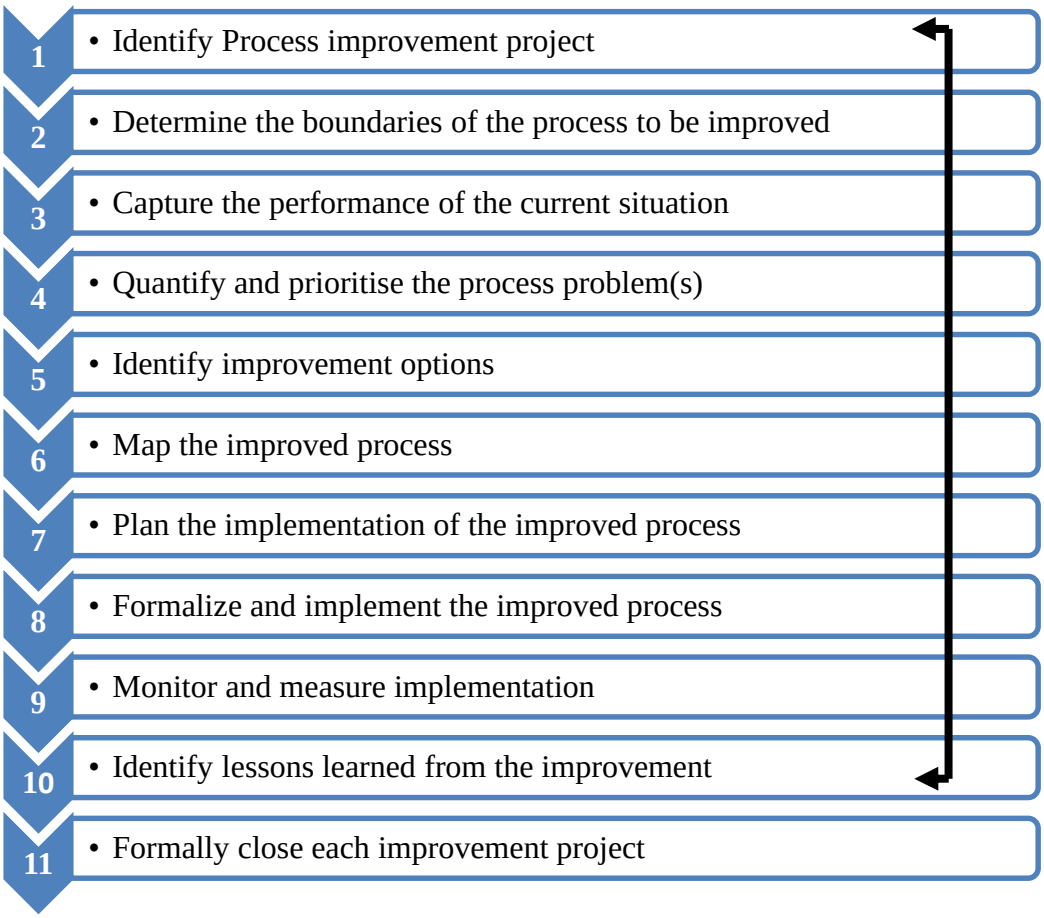
6.12.5 Train the staff on suitable quality tools such as Plan-Do-Check-Act (PDCA), SOWT analysis, Line / Run Chart, Gantt Chart, Cause and Effect Diagram, and Gap analysis...etc.

6.12.6 Utilize the available quality tools for assisting process improvements

6.12.7 Carry out the process improvements using tools and techniques.

6.12.8 Follow the steps bellow describing the process of improvement methodology as per the flowchart:

Flowchart.1. Improvement methodology process



Step 1 – Identify process improvement project using the overall process improvement goals which are agreed upon by the team.

Step 2 – Determine the boundaries of the process to be improved, considering the process scope either limited or the entire process and other parties.

Step 3 – Capture the performance of the current situation via tools e.g. detailed map of the 'as-is' process and data collection for quantifying the performance effectiveness. It is also important to seek out the views of the customers and suppliers of the process.

Step 4 – Quantify and prioritize the process problem(s).In order to quantify and measure valuable opportunity for improvement (OFI), use situational and trending analyses tools and techniques appropriate to the improvement initiative. Considering innovation and creativity set the performance indicators to compare (old process vs. new process).

Step 5 – Identify improvement options to correct true causes of process problems or to grab improvement opportunities. The potential improvement options should meet the following:

- The goals set for the project
- Focus on the true causes or particular aspects of good practices or ideas
- Customer requirements
- Value delivered to the organization
- Constraints such as regulatory requirements.

Note: any rejected options recorded to be revisited at later stage if possible.

Step 6– Map the improved process in logical way considering the instruction set up, constraints available, challenges encountered and potential progress

Step 7–Plan the implementation of the improved processusing project management techniques with the need for a pilot or trial for each improvement. Develop the documented project plan considering the consistency, extent, challenges, risks and communication.

Step 8–Formalize all supporting documents and then implement the improved process by process owners, who ensure that staff are competent, updated, knowledgeable and supportive. Strongly consider the merits of running both old and new processes in parallel until the new one is proven to be acceptable.

Step9 –Monitor and measure implementationusing the previously identified performance measures to demonstrate successful implementation. Assess the performance using self and independent assessments along with SMART measures. It is important to measure actual results and to compare them to expected results with verification on containing the goals and objectives

Step 10 –Identify lessons learned from the improvement project focusing on challenges /constrains/successes, to capture the improvements in revised documents or by replication. The learned lessons allow generalization of improvement to other areas of need.

Step 11–Formally close each improvement project after fully implemented and the lessons-learned applied. Subsequently, demonstrate to staff that the improved process is now part of normal operations.

6.12.9 Control of actions and projects via gathering and analyzing data during management meetings, a follow up of the status and the recorded execution dates of the previously submitted action plans is discussed.

6.12.10 Review and evaluation of submitted results is conducted to make decisions on the rightness of the selected causes and the applicability of the determined solution / action plan and the status of the completion of the plan.

6.12.11 The quality tools that may be useful for this process include Lessons Learned, Plan-Do-Check-Act (PDCA), and Planning Matrix.

6.12.12 Regular management reviews evaluates the long- term effectiveness of the Preventive actions and process improvements.

6.13 Control of records

This procedure is to state retention time and the storage format of different types of laboratory records. These records to be stored in either hard copies or electronic format, under the document control system and are easy to retrieve using the next guidance:

6.13.1 Electronic storage

Most of the laboratory records are located on the hospital information system server under the hospital IT department. There shall be a backup system to all electronic records. These records should include where possible the following:

- Request forms from the hospital and referral laboratories where applicable.
- Examination/test results and reports.
- Equipment records.
- Reagents and consumable records.
- Quality control records
- Calibration record.
- Complaints and action taken.
- Incident/accident records and action taken.
- Staff portfolio and competency result
- Risk management records
- Nonconformities, corrective and preventive actions taken.
- Internal and external audit records.
- Inter-laboratory comparison sample examination result.

- Records of quality improvement activities e.g. KPI.
- Meeting minutes and records of decisions made about the laboratory quality management activities.

6.13.2 Hard Copy storage

All hardcopies of the quality records that especially need evidence of signature should be stored in suitable locations to prevent deterioration, damage or loss.

6.13.3 Records Retention Time

The following guiding retention time as per recommendation, consider the local regulation.

Record Name	Retention Time
Request forms	All paper request forms from referral laboratories are to be kept for a minimum of **two years**. As this period may vary with local circumstances it is prudent to keep request forms until the authorized report or the requester has received reports on investigations arising from it.
Worksheets	2 Years
Laboratory working record of test results for named patients	2 Years
Internal Quality Control Records	Life of the analyzer; minimum ten years
External Quality Assurance Records	Five years
Equipment maintenance logs	Lifetime of the instrument; minimum ten years
Records of service inspection, maintenance of instrument	Lifetime of the instrument but minimum ten years
Calibration records	Lifetime of the instrument / device

Department Staff records	Employment plus 2 years
Lot documentation. Certificates and package inserts	Lifetime of the machines + 1 year
KPI improvement	Four years
Meeting minutes	Four years
Audits	Eight years
Non conformance	Four years
Management review	Four years
Incident / complaints	Four years

Note: recommendations from the Royal College of Pathologist (UK), the Institute of Biomedical Sciences (UK) and the Association of Clinical Biochemists (UK) published in their second edition report in the year, with some modifications to suit local circumstances

6.14 Quality Internal audit & indicators

This procedure describes the process of conducting quality internal audits in medical laboratory. Moreover, it describes how to design Quality indicators that measure and regularly monitor the effect of applying quality on medical laboratory services throughout important aspects of pre-examination, examination and post-examination phases considering the following:

6.14.1 Quality Internal audit

6.14.1.1 Internal audit Consideration:

- The internal audits of a specific process or a specific part of a process that focus on considerable depth.
- The laboratory audits cover technical and management aspects such as organization policies, document controls, management review, continuous improvement standards...Etc.

- The technical aspects include total testing process, equipment's, and assurance of examination...etc.
- The audit is conducted regularly and in any of the following:
  - new area
  - weakness in prior audits
  - risk assessment report
  - Customer complaint.
  - poor performance on a proficiency testing survey
  - increased number of unexpected abnormal results for a particular test
  - Increase in expected turnaround time.

6.14.1.2 Internal Auditing process steps:

- **Audit planning**
  - Design the audit structure which provides a defined referenced structure in a form of checklist (refer to appendix checklists**10.3**) that covers all elements of the Quality management system within 12-month period. It also Identifies the depth and frequency of each audit based on past audit history and working status of the area to be audited.
  - Select an auditor who are competent expert staff with adequate information about the process been conducted but are unbiased in their conclusions. The auditor preparation needs a comprehensive review of laboratory quality documents including policies, procedures, auditing prepared questions with checklist, nonconformance form and reporting method.
- **Initial plan creation**: Schedule an initial internal auditing plan including QMS element requires auditing, inspection area, auditor name and opening and closing dates. refer to appendix form **10.2.6**)
- Conduct anopening meeting with responsible staff of the area being audited that clarifies the QMS auditing element being tackled and the close date. During the audit, all staff are recommended to

facilitate the audit by answering questions, providing the required information, and documents that auditor needs them to review the process. The audit involves:

- Interviewing with individuals doing the work.
- Observing the work process.
- Ask opened question and open discussion
- Determining whether actual practices comply with the requirements of the documented policies and work procedure.
- Identifying issues and take notes using the prepared audit checklist
- Gathering evidence that supports the quality policies complement or violation.
- Reviewing previous audit report.
- Verifying whether the action taken previously was followed up.
- Verify the effectiveness of corrective actions implemented from the last corrective action by reissue a new form if the corrective action was ineffective.

- In preparation for report writing, categorize the findings into non-conformances and observations. Then, combine the observations that reveal a pattern of nonconformance into one.
- Write up finding report with evidence and completed checklist that summarizes positive aspects, opportunities for improvement, nonconformities, and other QMS issues. The audit report has to be completed, concise, consistent, and that all non-conformances and /or observations are factual and traceable to QMS elements.
- Conduct a closing meeting in which you present and discuss your findings verbally to the auditee. If appropriate, agree on time frame for a corrective and preventive action plan.
- Distributes the audit report to the audited work area's responsible staff within two weeks of the audit.

- Follow up on auditby responsible staff whoensures all finding are replied in a timely and proper way. Then, decide what needs to be revisited or re-audited.

6.14.1.3 Quality records of the audits:

Completed audit reports and auditing checklist are valuable to demonstrate the effectiveness of the auditing system and to set preventive actions. This permits the auditor to prepare for audits by reviewing the past reports.

6.14.2 Quality indicators

6.14.2.1. Quality indicators development process:

- Select group of key performance indicators that covers each laboratory processing phases and are justifiable, credible, supported by evidence in literatures, and feasible.
- Decide indicator and it's intervals of data collection based on reasons such as: the need of the indicator, test urgency, size of data collected, and impact of the KPI on quality improvement.
- Before setting up the indicators, check the availability of indicators requirements and other related structure elements.
- Design a quality indicator plan that defines the details and target goals, refer to related document section (9) .
- Start data gathering and evaluate laboratory performance in that indicator.
- Translate the data into appropriate visualization method.
- Monitor the indicator continuously or periodically based on agreed intervals.
- Communicate the indicator performance to all concerned departments including institutional quality department.
- Improve the efficiency by taking needed corrective and/ or preventive actions commonly used Plan- Do-check-Act (PDCA) cycle.
- Document all process results with the taken actions.

- Collaborate with institutional quality department and other concerned department for actions implementation.

6.14.2.2. Quality indicators categories:

- The following are suggestions of the most common set of quality indicators that covers total testing process (TTP):

Pre – examination phase	**Examination phase**	**Post – examination phase**
1.Acceptability of laboratory samples (sample rejection rate) 2.Sample received without test order	1. External QC assessment 2. Internal QC assessment	Urgent Tests Turnaround Time **(TAT)** such as: **1.Hematology**: Prothrombin time & hemoglobin **2.Biochemistry**: Troponin, Potassium **3.Microbiology**: Positive blood culture smears report, typical MDRO (Multi Drug Resistant Organism), CSF microscopy **4. Histopathology / cytology**: Histopathology urgent Cytology FNA
		Contamination of blood culture bottles
		Critical results notification
		Corrected Results
		Biopsy Correlation Performance

6.14.2.3. Examples of Quality Indicators scheme:

Indicator # 1	**Performance Indicator Title** Rejection of laboratory samples rate	**Dimension** Patient safety Efficiency
Description The rate of samples which are discordant from the acceptability criteria using the local laboratory protocols		

<table>
<tr><td colspan="3">Rational
• To reduce samples pre-analytical errors that endanger patient safety
• To utilize resources that affect the pre-analytical phase efficiency</td><td>Type
outcome</td></tr>
<tr><td colspan="4">Quality Indicator requirements:
1. Create a standardised rejection list of codes with the commonly used reasons for rejecting a sample.
2. Communicate the laboratory samples rejection reasons in form of manual to end users.
3. Create Samples accepting and rejecting S.O.P for laboratory personnel</td></tr>
<tr><td>Numerator
Total number of rejected samples received</td><td>Denominator
Total number of samples received</td><td colspan="2">Inclusion/ Exclusion Criteria
Exclude the un-entered samples and reagent not available rejection reasons from the indicators rate.</td></tr>
<tr><td colspan="2">Data Elements
1. Patients demography (age, gender)
2. Date
3. Categories of rejection
4. Source(location /department/ward /clinics/ in-house / referral /others
5. Investigation requested
6. Requester if feasible
7. Clinical details / diagnosis
8. Blood collection tubes
9. Sample type
10. Sample requirement if feasible</td><td colspan="2">Limitations
Count the number of rejected sample (not per test)
Data Source(s)
Using Laboratory Information System, Record the total number of Specimens received, and the number of rejected specimens for decided period, and the main reason each specimen was rejected.</td><td>Data Collection Frequency
To be decide by laboratory management</td></tr>
</table>

Performance Indicator Monitoring The laboratory management decide on the indicator monitoring duration and the name of responsible personnel	**Performance Indicator reporting Frequency** Based on laboratory management decision	**Performance Indicator reported in which report** The reporting method to be decided by the laboratory management. For example, the performance indicator may be reported in annual reports, annual service plans, quarterly performance reports, budget requests, or others.
Target Based on laboratory management rejection rate recommendation	**Benchmarking** Use national / international benchmark.	**Related Performance Indicator** Balanced set of indicators if relevant
Quality improvement: If the rate is unaccepted, find the main sources that submit unsuitable (rejected) samples, ensure that they have a copy of rejection criteria and create corrective actions accordingly to resolve the problem with the cooperation of the source, phlebotomist and quality department.		

Indicator # 2	**Performance Indicator Title** Appropriate intra-laboratoryTurnaround time (TAT) of urgent tests	**Dimension** Timelines Efficiency Patient centeredness

Description

The rate of urgent test samples which are within the acceptable intra-laboratoryTAT using the local laboratory standards

Rational	**Type**
• To improve the urgent test TAT that impacts the laboratory efficiency. • To increase the end users satisfaction in relation to urgent tests TAT.	outcome

Quality Indicator requirements:

1. Advised to create pre- examination manual that includes list of urgent tests with the agreed turnaround time for the end users and the laboratory staff.
2. Using available software that calculates TAT of urgent samples from the receiving until releasing of preliminary / final result and display the TAT.
3. Recommended TAT examples (but not limited): Troponin, Potassium, INR test, Hb test, Histopathology attention tissues, Fine Needle Aspiration, β-hcg test Coagulation, CSF microscopy, smears of positive Blood culture bottles, typical MDRO culture Infection control cultures (MRS, CRE..etc).

Numerator	**Denominator**	**Inclusion/ Exclusion Criteria**
Total number of particular urgent test which are within acceptable standard TAT	Total number of urgent specimens of particular test received	• Any recalled results • Samples received during Equipment breakdowns/ Computer / IT failure

Data Elements	**Limitations**
1. Receiving in lab time /date 2. Preliminarily / final realising date and time	• Unavailability of dedicated software to calculate the date / time in and out for particular urgent test • Unavailability of IT support

<table>
<tr><td rowspan="2">3. Samples type
4. Investigation requested
5. Samples location (referral /within institution)
6. Sample source (department/ward /clinics/others
7. Requester if feasible
8. Peak hours
9. Clinical diagnosis
10. Test remarks</td><td colspan="2"></td></tr>
<tr><td>Data Source(s)

Using Laboratory Information System, Calculate the TAT of particular urgent test, and record the specimens that are outliers of established reporting deadline.</td><td>Data Collection Frequency

To be decide by laboratory management</td></tr>
<tr><td>Performance Indicator Monitoring

The laboratory management decide on the indicator monitoring duration and the name of responsible personnel</td><td>Performance Indicator reporting Frequency

Based on laboratory management decision</td><td>Performance Indicator reported in which report

The reporting method to be decided by the laboratory management. For example, the performance indicator may be reported in annual reports, annual service plans, quarterly performance reports, management review, or others.</td></tr>
<tr><td>Target

Based on laboratory management TAT rate recommendation</td><td>Benchmarking

Use national / international benchmark.</td><td>Related Performance Indicator

Balanced set of indicators if relevant</td></tr>
</table>

Quality improvement: If the rate is unaccepted, correlate the exceeded time with the working hours threshold (morning time or out of hours) or frequently repeated staff to obtain the main sources of problem, ensure the adherence to the urgent list TAT manual and create corrective actions accordingly to resolve the problem

Indicator # 3	**Performance Indicator Title** Rate of unacceptable internal quality control performance	**Dimension** Patient safety Efficiency
Description : The rate of IQC performance which are discordant from the defined limits using local laboratory protocols		

<table>
<tr><td colspan="2">Rational

• To improve IQC recording and interpretation
• To assure appropriate IQC troubleshooting
• To assure the result’s reliability.</td><td>Type

process</td></tr>
<tr><td colspan="3">Quality Indicator requirements:

1. Internal quality control (IQC) sop
2. IQC monitoring system
3. IQC recording and archiving system
4. Non-conformance recording system with the corrective actions in case of violated IQC (failure, trends or shifts)</td></tr>
<tr><td>Numerator

Total number of IQC result outside defined limits</td><td>Denominator

Total number of all IQC result</td><td>Inclusion/ Exclusion Criteria
inclusion:
Inclusion: include all unacceptable IQC performance using local laboratory defined limits
Exclusion exclude all accepted performance of IQC using local laboratory defined limits</td></tr>
<tr><td rowspan="2">Data Elements

1. Date
2. Test menu(full name, short name)
3. List and type of all control material
4. Lot number, expiry date
5. defined Limits
6. QC monitoring rules
7. QC charts</td><td colspan="2">Limitations

IQC monitoring system calculation facility

IQC Archiving and retrieval system

IQC SOP improper implementation

Alteration in examination method (upgrade, replacement , modification)</td></tr>
<tr><td>Data Source(s)</td><td>Data Collection Frequency</td></tr>
</table>

8. QC recording sheets 9. Staff involved if possible 10. Corrective action taken	Using IQC recording system, Calculate the unacceptable QC results , and record the QC that are outliers as per defined limit	To be decide by laboratory management
Performance Indicator Monitoring The laboratory management decide on the indicator monitoring duration and the name of responsible personnel	**Performance Indicator reporting Frequency** Based on laboratory management decision	**Performance Indicator reported in which report** Indicate where the performance indicator will be reported. For example, the performance indicator may be reported in annual reports, annual service plans, quarterly performance reports, budget requests, or others.
Target Based on laboratory management recommendation	**Benchmarking** Use national / international benchmark.	**Related Performance Indicator** Balance set of indicators if relevant
Quality improvement: If the rate is unaccepted: 1. Check the IQC monitoring and recording system. 2. Monitor the implementation of IQC procedure 3. Continually educate the involved staff on where to record QC results. 3. Continually educate the involved staff on QC interpretation, troubleshoots and corrections. 4. Improve by root cause the frequently failed QC performance.		

6.15 Management review

This procedure is not required

6.16 Technical Competency assessment

The procedure is to guide the laboratory on the proper competency assessment of technical staff as instructed below:

6.16.1 Competency assessment interval

- Newly appointed laboratory staff or a current laboratory staff who is performing a procedure for the first time must demonstrate competency during the following competency assessment schedule.
- Initial training as per the individual training plan (refer to example form 10.2.7.1) covering the assigned tasks and competency of the newly assigned staff must be documented and accepted before that laboratory staff reports any patient results. Next competency assessments to be carry out at six months after the initial competency assessment and after that every year it must carry out.
- Competency assessments to be carry out every year for all the assigned laboratory staff.
- Whenever a new test method introduced in the laboratory or existing test procedure modified all the assigned laboratory staff must demonstrate competency to carry out new or modified test procedure.
- Competency assessments to be carry out if the laboratory staff did not perform laboratory test procedure for more than six months due to long holiday or study leave.

6.16.2 Assessment method

- Assessments of sample analysis to be carry out by verification of the reported results. Those can be achieved by re-testing of previously analyzed specimens, blind testing and internal or external proficiency testing specimen (refer to appendix form 10.2.7.2).
- Assessments to be carried out by direct observation (refer to appendix form 10.2.7.3) of the assigned staff during their routine patient test performance which includes specimen handling, processing and testing. Competent designated staff that is recently assessed for the competency can assess the other laboratory staff by direct observation.

- Laboratory equipment maintenance and function checks to be carry out by direct observation.
- By monitoring the recording and reporting of the patient test results. This can be achieved by reviewing the intermediate test results, record of the QC performance, proficiency testing results, record of the equipment including preventive maintenance and equipment performance and function validation.
- Assessment of the troubleshootingskill can be carried out by written test, oral queries and case study which cover all the important key elements required to perform the various laboratory task.

6.16.3 Evaluation, remediation and reporting results

Evaluation involves judgment and opinion. Based on evaluation, corrective actions to be taken like retraining of the staff for the staff competency.

- Fill the assessment form and sign it by the competency assessor at the time of the staff assessment.
- Maintain the records in the employee's personal file(refer to appendix form **10.2.7.4**).
- If a staff failed to achieve the performance according to the established standards, describe the detail information regarding this unacceptable staff performance in the competency assessment form.
- Identify the employee's problem such as methodology problem, staff did not perform test correctly, staff did not understand the clinical importance of the test, unable to solve problems, did not understand component of the test or instrument being used for the test, unable to perform QC or interpret the QC or staff performed task correctly but made error in documentation.
- Retrain and assess, the laboratory staff based on the problem identification subsequently.
- Records the retraining and competency assessment and maintain it in the employee's personal file.

6.16.4 Guidance for assessor:

During the evaluation of the technical competency, the following points to be consider:

- Understand the principles of the QC along with L-J graphs, Westgard rules and interpretation of QC.
- Knowledge regarding troubleshooting to be done in case of QC failure.
- Understand and interpret the meaning of flags, warning sign and error massage.
- Knowledge of the technical variables.
- Knowledge about the importance of the abnormal and critical results.
- To understand the hazardous risk associated with the procedure. Knowledge about operating computer regarding Al Shifa which includes Requesting, Work lists, Validation, Release, Addition of the testsKnowledge about back up plan for computer /system failure (downtime procedure) e.g operating printer including analyzer and department printers.
- Quality and quantity of the samples (invalid or inadequate samples).
- Knowledge regarding preparation, storage and expiration of reagents.
- Knowledge regarding operating analyzer which includes start up, shut down, auto-cleaning, priming, cassette loading and unloading, closed and open modes, changing reagents, interpretation of the flag which required re-running samples.
- Knowledge regarding disposal of the waste according to the MSDS.

6.16.5 Level of competence

Level of competence depends on the following criteria:

- In basiclevel of competence, staff requires some experience, practice or assistance.
- In intermediate level of competence, staff is competent and can perform independently.
- Advance level of competence, staff is competent and can perform independently and staff is also able to assess the competency of the other staff.

Note: Omani graduate undergoes 6 months training before the initial competency assessment

*Levels	Category	Scoring %	Description	Action

1	Not competent	<50%	no experience / limited experience	requires training, re-training
			Experienced	Requires: 1.consultation 2. work under observation 3. Supervision while performing critical tests.
2	Basic	51 – 65	Some experience /	can perform under supervision
3	Intermediate	66- 80	Competent	can perform independently
4	Advanced	>81 %	Competent and can supervise the competency of others.	Can perform independently. Able to train and assess

6.16.6 Competency assessment failure

Factors that affect the competency assessment and cause the competency assessment failure are as follow:

- During the competency assessment, if the laboratory staff fails at one or more area, competency assessor will analyze the cause of the competency assessment failure so that the appropriate corrective measures can be identified and implemented.
- Initialstep of analyzing problem is to analyze the protocol used for the laboratory practice. The laboratory protocol should be standard, clear and concise so that all laboratory staff easily understands and implement. If the protocol is inadequate or complicated, it can lead to competency failure.
- During proficiency testing, if the proficiency sample is inadequate or there is a problem with sample which leads to the competency failure is not the cause of staff competency failure.

- If the cause of the competency assessor failure is not due to protocols, then following points to be consider.
- Did the employee follow the test procedure properly and perform test correctly?
- Did the employee misunderstand the clinical significance of the performed test (an employee is not able to solve the problem or interpret the results according to the clinical situation)?
- The employee did not understand the test components or the instrument being used.
- Did the employee able to interpret and resolve the QC errors?
- The employee carried out the test accurately but did error in the documentation?
- For further action of the competency failure, the protocol to be discussed with the employee who fails the competency assessment and action to be taken accordingly. Verbal response of the employee may be sufficient to identify the cause of the competency failure.
- The following actions to be taken in case of an employee fails competency assessment:
- Let the employee read the protocol again and discuss it with the supervisor to understand and clarify any misinterpretations.
- To perform protocol properly, the employee can develop a flow chart to guide him or her.
- Let the staff observe the other competent staff while performing test.
- The employee can practice the failed protocol by using the known specimens.
- Check that the employee performs the retesting correctly with the original specimen which tested during competency assessment failure.
- If the above mentioned methods fail to confirm the competency of the employee, then employee can be send to other particular institute which specialized in that area where employee fails. For example, if staff fails in malaria parasite reporting, then staff can be sent to malaria control department for further training.

- It is necessary to repeat the competency assessment after the corrective measures taken for the competency failure. Once the competency assessment of the employee completed successfully, it should be documented.
- Test and QC procedure to be discuss with all the laboratory staff to make them understand how to avoid certain type of errors.
- According to the last competency assessment report, the employee can be shifted from specific duties to another work area where the employee is competent

6.17 Accommodation& environmental condition

This procedure is not required

6.18 Laboratory equipment, reagent and consumables

This procedure is to provide instructions for selection, purchasing and management of equipment**,** reagent and consumables at medical laboratories.

6.18.1 Equipment management

6.18.1.1 Setting up equipment Specification:

Each laboratory determines the specification that helps to achieve the goal from having the equipment. The following are examples of some points need to keep in mind:

- Determine throughput of the equipment
- Number of samples that can be run using the equipment
- The size and if any special pre-installation requirement
- If the machine is an open system
- Safety requirement, quality performance, detection limit and compatibility to link to LIS
- Capability of handling the future laboratory workload
- Current and predicted manpower availability
- Turnaround time before and after purchase
- Reproducibility and accuracy as compared with old method

6.18.1.2 Selection of the equipment:

Examples of laboratory equipment selection criteria to be considered are listed below:

- Cost of the equipment, consumables and reagents should be within the budget of the laboratory.
- Reagents should be readily available
- Manufacturer instruction should be available in a language that is understood by the laboratory staff.
- Supplier reputation and there should be retailer with the available services for the equipment in the country.
- Availability of after sale support, P.P.M.and technical support
- Cost of spare parts and repair
- Check manufacturer will install the equipment and train staff as a part of the purchase price.
- Cost of quality controls and possibility of running third part quality control (EQC)
- The equipment and reagents should be registered in medical DGPDC, FDA and CE approval obtained
- Type of contract LPO and if any items are free of cost (FOC)
- Pervious customer feedback about the manufacture and theequipment
- make sure that no recalling of the equipment or of any reagents or consumables
- Any advance specification available more than demanded
- Lab heat load

6.18.1.3 Pre Installation aspects:

Before equipment is installed, the following shall be verified:

- Assigned location with enough physical space or dedicated Physically Separate Areas (If using equipment for sequencing PCR amplicons)
- Electrical and Wattage supply
- Sufficient cooling system and ventilation
- Water supply

- Waste and drainage management
- Network Connections
- Door/Elevator/Access Point Clearance
- Required Power Protection (Uninterrupted Power Supply)
- External Data Storage
- Lab Bench Requirements

6.18.1.4 Installation:to consider are:

- The installation should be carried out by the manufacturer/supplier to gain the coverage of warranty and to ensure that the installation is performed properly.
- The vendor's responsibilities for installation should be confirmed in writing prior to installation process.
- The biomedical engineering department should test the equipment for electrical safety. A copy of installation should be handled to the lab supervisor.
- The equipment to be labeled with a unique biomedical number

6.18.1.5 Post installation:the following details to be addressed before putting the equipment into service.

- The engineering department is responsible for the acceptance of equipment after the supplier has satisfied all the requirements of both the laboratory and engineering including:
  - Soft copy / hard copy of the user manual.
  - Confirm that all equipment`s accessories, consumables etc. are delivered as per the offers
  - Installation certificate to be issued to lab
  - Provide the Content of two different levels of a training program including basic and advanced with troubleshooting skills for previously determined staff.
  - Perform a well-developed training program that includes essential needs to know and a regular re-training program when needed.

- Submit to the lab an equipment Logbook that will be used to record regular scheduled P.P.M.and malfunctioning incidences.
- Equipment sop that includes start up, calibration, loading/ unloading, maintenance and QC run.
- Provide free of charge of required consumables and reagents for equipment verification and validation.
- Assistance in seeking for most suitable third party External Quality Assurance (proficiency testing) program.

- Implement a written plan for calibration, performance verification and proper operation of the equipment. Follow Equipment validation procedure for equipment validation.
- Establish a scheduled maintenance programme that includes daily, weekly and monthly maintenance tasks according to manufacturer's operational manual.
- **Equipment calibration**: Follow Equipment calibration procedure.
- **Equipment and quality control:** Follow quality control procedure
- **Equipment maintenance, troubleshooting and repair services**: Follow Equipment maintenance, repair and service procedure.
- **Retiring and disposing of equipment:**
  - It is very important to have a policy and procedure for retiring old laboratory equipment. This will usually occur when it is clear that the equipment is not functioning and is not repairable, outmoded (outdated) and should be replaced with new equipment or reagent no longer available (supplied).
  - Once a piece of instrument is fully retired and it has determined that it has no further use, it should be disposed of in an appropriate manner.
  - For disposing any equipment or part of the equipment, consider the potential biohazards and follow all safety disposal procedures.

- **Temperature sensitive Equipment Validation Procedure:** Follow Temperature Sensitive Equipment validation procedure.
- **Documentation:**
  - Some of the important tools that help to keep the record of the equipment managements are charts, logs, checklists, graphs and service reports.
  - The logbook should be available to all the designated laboratory staff all the time during the entire life of the equipment.
  - For more details, refer to Control of Quality and technical records procedure

6.18.2 Equipment Calibration

This procedure specifies the schedule and requirements for the laboratory equipment Calibration, mainly thermal or mechanical, adjustment or standardization to ensure compliance with a certified reference or standard.

6.18.2.1 Calibration of equipment needs to be carried out on a regular basis considering the following:

- The manufacturer's recommendation and the required operating conditions.
- Documentation of calibration traceability to refer to it when needed.
- Calibration and recalibration shall be carried out as per manufacturer and assay performance.
- Calibration status and date of recalibration shall be documented.
- Assurance previous calibration factors are correctly updated especially when there is a need for correction.
- Prevention calibration alteration or manipulation that might affect result reliability.

6.18.2.2 The lab formulates procedures for thermal and mechanical equipment calibration. 6.18.2.3. Frequency of calibration would depend on the tolerance value which is varying for each instrument depending on

many factors including industry sector and country in which calibration is performed.

6.18.2.3 When the objective of the measurement is critical, calibration needs to be carried out more frequently and with great accuracy.

6.18.2.4 Types of Calibration:

Instrument calibration is performed for different types of instruments across sectors; the table is recommended but not limited

Type of calibration	**Examples of instruments**	**Calibration interval**	**Remark**
General service equipment	blenders, ovens, hotplates, furnaces, stirrers	Annually	
Volumetric equipment	Class A glassware, mechanical and automatic pipettes and burets	Annually	Note: A manufacturer's certificate of graduation accuracy for Class A glassware may be accepted. Other volumetric equipment, including mechanical and automatic pipettes and burets, are calibrated by the

			laboratory's procedure.
Measuring instruments	balances, chromatographs, spectrometers, thermometers	Annually	
Physical standards	reference weights and reference standards	Annually	

6.18.3 Equipment validation

This procedure provides guideline on equipment validation in order to verify the manufacturer claim and ensures optimal performance; thus, deliver consistent qualitative and quantitative results. It is performed prior to use of a new equipment to ensure manufacturer claims using the following instructions:

6.18.3.1 For new instrument, all tests should be validated before running patients samples.

6.18.3.2 Validation can be done by parallel comparison study between existing and the new methodology using patient samples.

6.18.3.3 The number of samples that should be included in validation depends on manufacture`s recommendation, international guidelines and other factors including availability of an external validation panel and the prevalence of the disease.

6.18.3.4 The internal and external controls should be included in the validation test run.

6.18.3.5 The validation acceptance depends on the review of all comparison results compared to predetermined quality goals. System or software upgrade should be validated as per the manufacturer's instructions.

6.18.3.6 Re-validation should be done for any instruments that have undergone repair, spare parts replacement and preventive maintenance.

6.18.4 Equipment maintenance/servicing and repair

This procedure outlines the scheduled servicing, maintenance and repair of laboratory equipment to ensure that all the laboratory equipment produce accurate reliable results. Equipment maintenance is done as per manufacturer recommendation, in conjunction with biomedical engineering, at regular intervals. A formal system of maintenance is followed to ensure that routine servicing and regular inspection are carried out on regular basis. This system is covering the following aspects:

6.18.4.1 User servicing or user care and maintenance

All the maintenance and servicing of the equipment should be based on Handbook that supplied by the manufacture. The user servicing should be limited to that which is within knowledge, training and capability of the person performing the task. For electrical and mechanical equipment, the following tasks can include but not limited:

- Decontamination, disinfecting and cleaning
- Functional check\calibration check
- Adjustments, lubrication and permitted replacement
- safety check

Note: Equipment decontamination shall be done before service, repair or if equipment removed from service. The laboratory shall provide suitable space and appropriate personnel protective equipment for equipment repair.

6.18.4.2 Scheduled servicing or PPM

It shall be performed at scheduled regular intervals by well trained biomedical engineer/ technician to prevent the potential for breakdown, confirm safety and ensure it is efficient in operation. It shall involve the following tasks but no limited:

- Comprehensive inspection
- Replacement of certain run-time related parts
- through lubrication
- Calibration

- Performance / endurance testing
- Final functional check
- Safety check

6.18.4.3 Unscheduled servicing or emergency repair

Good maintained and well serviced equipment shall have less breakdowns or failures. There are certain signs e.g. method CV prior to breakdowns, that necessitates emergency repair. In case of breakdown, the emergency service should be attended by the supplier. The authorization is required for repair that occurs, in equipment not under service contract.

6.18.5 Laboratory Reagents and Consumables contingency plan

This procedure provides instructions of laboratory reagents and consumables management in case of supply interruptions or shortages as follows:

6.18.5.1 Contingency plan

- The contingency plan is activated in many cases including batch delay (out of stock), lot defect (QC failure), exchanging manufacturer, improper storage if kits and expired reagents. In those cases, each lab section should maintain a minimum number of reagents and consumables in lab store.
- In case of presence of expired reagents, the end user or requesting physician should be notified to stop requesting the test and test should be released as “test not available”. The Lab store or medical store has to be informed immediately in order to provide non-expired reagents. The lab has to be notified by medical store staff about awaiting reagent arrival.
- If the reagent is not delivered to lab immediately, then the following action should be taken:
- If reagent supply arrived within acceptable time limit e.g. according to sample stability and storage capacity, then reserve the samples in proper storage temperature and analyse them on arrival of reagent.

- If reagent supply exceeds the acceptable time limit e.g. according to sample stability and storage capacity, then the physician should be notify to stop requesting the test and test is temporarily not available.
- If the test is needed urgently then if possible to arrange for samples to be analysed at another laboratory according to any prearrangement service agreements.

6.18.6 Laboratory new reagent batch validation

This procedure provides instructions on laboratory reagents batch validation to ensure the accuracy and reliability of laboratory results prior to use during the following situations:

6.18.6.1. When reagent batch number/lot number has changed, the following aspects to be followed:

- Run the controls with the new reagent.
- Run 3-5 previously tested patient samples with the new reagent and record any justification for any violation e.g. rare samples or less quantity, or non-variable
- Perform statistical or regression analysis for quantitative tests to confirm that the results are within the acceptable range.
- If all the above aspects have been confirmed, then the reagent can be used.
- All the obtained results from this new batch validation aspect should be recorded and signed by the responsible staff(refer to appendix form **10.2.8**).

6.18.6.2. When reagent performance not within the expectation, the following steps to be followed:

- Re-run by using another kit/pack with same new batch/lot number
- If the results fall within the acceptable ranges, then reagent can be used to perform the tests.
- If the results are still not acceptable, then reject the batch/lot number and do not perform any tests using this reagent.

- Notify the responsible staff and write a non-confirmatory report against the same batch/lot number.

6.18.6.3. This procedure is applicable for new consumable batching e.g. urine container, blood collection tubes and pipette tips.

- The aspects for consumable validation shall follow the acceptance criteria for each consumables considering manufacturer claims e.g. transparency of slides or absence of any defects.
- Wherever possible, a comparison of outcome using the new and old consumable is recommended e.g. Comparison of test result between different blood tubes.

6.18.7 Temperature Sensitive Equipment Validation

This procedure provides guidelines for validation, calibration and monitoring of the temperature sensitive laboratory equipment to ensure that they meet the manufacture`s performance claims in order to preserve samples, reagent and other materials. Although validation procedure might differ according to the local regulations, but a standard validation procedure is to perform validation and calibration for all new prior to use temperature sensitive equipment (such as: refrigerators, freezers, incubators, slide heater and water bath...etc), after repair or spare part replacement, and at least once a year afterwards. Check performance according to the instructions below:

6.18.7.1 Calibration and validation

- Use calibrated and certified thermometer or temperature probe for temperature measurement performed by a well-trained / certified staff.
  - Prepare the device for calibration by evacuating the content and seal in advance (time)
  - Place the thermometer or temperature probe in the device at different positions depends on size of the device. For 1000 Ltr capacity devices, use 5 thermometers (4 in each corner and the fifth atthecentre). For bigger capacity devices, use 9 thermometers (4 at the top four corners, 4 at the bottom four

corners and one at the centre). The position of the thermometer should be 10 cm away from the device wall.

- Switch ON the power supply of the device.
- Select the temperature setting of the device and set for desired temperature.
- After stabilizing the set point temperature, record all thermometers reading simultaneously at regular intervals of time for at least of 10 reading.
- Refer to manufacturer or international guidelines for the expected temperature values and temperature tolerance
- If the recorded temperature is outside the expected range, then corrective action should be taken.

6.18.7.2 Temperature Sensitive Equipment Monitoring:

- Monitor the temperature of all equipment on daily / shift basis including weekends and holidays.
- Maintain a separate sheet for each device to record the following data; measured temperature, temperature range, date, time, monitor`s initials and corrective action.
- Place the recording sheet where it is visible, accessible and assessable by concerned staff. Archive the sheet according to the retention time of documents as mentioned in the document control procedure
- In case of device/ equipment failure, prepare a contingency plan to ensure proper items storage area.

6.19 Pre- examination processes

This procedure is to guide on pre-examination processes (primary sample collection and handling). It should be customized by each laboratory according to their setting

6.19.1. Information for patient and users

- **Laboratory location**

  The exact laboratory location in the institution should be specified including which floor, at which side of the institution..etc. If a particular department is away from the main lab building, the location should also be specified.

Example A: The laboratory is located at the middle of the institution. As you enter the main institution entrance, take your left and continue to walk along the corridor then turn left. The laboratory will be at your left hand side.

Example B: A diagram can be used to specify the laboratory location within the institution.

- **Laboratory working hours:**

  Specify the laboratory working hours (both routine and outside normal working days). If some departments are having different working hours/days, they should be specified too.

- **Laboratory contact numbers**

  Include the laboratory postal address, email, fax number and phone numbers with extensions, Institution name, Department of Laboratory Medicine and Pathology, P.O Box, Post Code, Wilayat name, Governorate name, Sultanate of Oman.

  The phone number list should include the department name (if applicable), different lab staff name with the designations (if applicable), phone extension, and email.

Laboratory Department	Lab staff name /designation	Phone extension	email

- **Laboratory departments and offered tests:**

  The laboratory should provide a list of all the offered lab tests with the all necessary information included in the table to the end users

Lab Department	Test name	Test short name	Test requirement	Turnaround time (TAT) *	Reference Intervals				Processing condition∞	Transportation condition
					Gender	Age	Unit	Reference range		

*TAT of urgent and routine sample should be mentioned

∞ Processing conditions include processing site and days (in-house or referral)

In addition, the laboratory should keep detailed information list about tests referred to other institutions

Lab Department	Test name	Test requirement	Referral institution	Turnaround time	Storage condition

Note: The storage condition referred to storing samples until sending to other institutions

6.19.2. Sample collection and handling:

6.19.2.1. Sample collection:

- Each laboratory cooperates with the concerned departments according to the local setting in formulating sample collection procedures
- Such procedures include importantly the following but not limited
    - Patient identification at all stages of care (inpatient, outpatient and emergency)
    - Sample labelling
    - Any patient preparation
    - Test scheduling if assigned
    - Phlebotomy services according to the local setting
    - Detailed focused procedures of blood sample collection (venous and arterial)
    - Highlighting special considerations in these collections
    - Special tests procedures that mandate earlier arrangement with the laboratory e.g. frozen section etc.

6.19.2.2. Sample transportation

- Each laboratory establishes local sample transportation procedures that details within institution and referral sample
- Such procedure provides the instructions during transportation that preserve sample stability through the trip towards it final destination towards analysis

6.19.3. Criteria for sample acceptance and rejection

- All specimens/samples are inspected according to acceptance/rejection criteria.
- The laboratory provides the updated acceptance/rejection criteria in detail to the end users.

- The laboratory rejects specimens/samples, which are not suitable for processing.
- In case of critical specimens/samples, the laboratory discusses with the requestor before rejecting the sample either by phone or electronic alert system
- Samples that have reached the laboratory must not be given back to the end users for correction.
- All rejected samples should be documented. Specify in detail the laboratory action during this situation.
- The following are the most frequent rejection reasons:
    - Insufficient sample quantity for testing.
    - Request for test is not received either hard or electronic.
    - Sample received in wrong condition (not matching sample requirement):
    - Sample with no patient unique identification.
    - Samples with mismatching identification (wrong label)
    - Leaked sample.
    - Incorrect sample type for the requested test.
    - Sample packed with the needle used for collection.
    - Sample received with other reasons for rejection, for example hemolyzed, clotted sample, grossly lipemic etc.
- **The unrepeatable sample (precious sample)**
    - Write the list of unrepeatable samples received in the laboratory
    - Write the laboratory detailed action when rejecting an unrepeatable sample
    - In case of rejection, the end user have to be informed
    - Use the declaration form (refer to appendix form 10.2.9) in case of unsuitable sample, eg. wrong label or mismatching, wrong sample / test type.

6.19.4. Sample transportation

- The laboratory contributes to the institutional sample transportation guidelines including delivery of the sample to the laboratory, used pack/box, time frame, handling of highly infectious samples. Details of sample transportation requirements are explained in earlier section.
- The laboratory follows the local transportation guidance of transporting samples to referral laboratories.
- The assigned samples courier should be trained on the local institutional sample transportation guidelines to avoid sample deterioration
- Specify if there are certain days, time or special packaging consideration of frozen and non-frozen samples.

6.19.5. Request form information

- Paper request forms:

  The laboratory investigation should be filled in an official lab request form with the minimum information needed (refer to the related pre examination policy). The form has to be signed by the requester and should be allocated in a separate part of the sample bag. All Urgent requests should be labelled clearly.
- Electronic request form:

  The request forms and other additional check lists should be available in the system.

6.19.6. Verbal requests

The usage of verbal requests should be limited and frequently practiced as add-in tests. The following are the acceptance criteria:

- Request should be made by an authorized clinician
- The sample has to meet the requirement/rejection criteria
- The sample has to be within the accepted window time for accepting the tests based on stability.

Note: Each laboratory has to prepare the list of the tests with the window time for acceptance after consulting the concerned pathologist in each specialty

- Verbal order should be followed by requesting test (manual or electronic) within the day of collecting the samples.
- Document the details of the verbal request and the followed laboratory actions.
- In case of critical results, the laboratory should call the requester to inform the result and document it.

6.20 Method validation / verification

This procedure is to provide guidance on instrument/method initial verification to conclude if the method is suitable for its purpose.

6.20.1 Indication of method validation / verification:

- Once a new test method / instrument introduced to the laboratory
- Resume back a test to routine service.
- Following a major instrument maintenance / replacement of major part
- Relocating the instrument
- Equipment Upgrading

6.20.2 Method validation / verification procedure:

6.20.2.1. Quantitative tests:

- Set a Validation **/ verification** plan (refer to appendix form **10.2.10**) for each test method which includes the following :
  - General validation information: departments, equipment location, staff involved and needed resources in the validation project (consumables and reagents).
  - Operational evaluation: throughput, and turnaround time test, and test prioritization.
    Examination requirement: type and number of samples (at least 20) used levels of controls and measuring range.
    Note: if affordable, run the samples in duplicate to eliminate random errors
  - **Acceptance criteria** to confirm that the system meets defined quality requirements (e.g. Medical decision

levels, precision and accuracy goals, published total error goals (TEa) (you can check Data innovation website (https://datainnovations.com/allowable-total-error-table) or Westgard website (https://www.westgard.com/biodatabase1.htm)

- **Documentation: includes references and raw data.**
- **Time-lines** for completing the validation project. Evaluate both methods timely over the course of 10-20 days. The laboratory can choose a shorter period (considering samples stability and storage).
- **Validation experiments** to be used are at least inaccuracy, imprecision, and linearity**.**
- **Justification** for and plan deviation to be included**.**

- **Validation / Verification steps:**
  - Document the validation by recording all the information collected during the evaluation (refer to appendix form **10.2.10**).
  - Determine the analytical measuring range (AMR) by selecting reference material or patient specimens with value "near" the lowest value necessary for clinical use, a mid value, and the highest value needed for clinical use (within the instrument capability). Compare the observed AMR range with the range specified by the manufacturer
  - The established AMR should not exceed the manufacturer's specifications
  - Determine the precision of the assay. Determine within run precision by analyzing sample material 5 to 10 times. Calculate mean and SD and assess acceptability by comparing to the manufacturer's precision specifications and clinical need.

- Determine the accuracy of the method by comparing the results of the candidate method with a reference method, performing a recovery experiment using assayed material or, if appropriate, comparing the result of the candidate method with the validated method being replaced.
- Review (or test if necessary) the specificity of the new method by assessing or reviewing the known interference caused by substances regularly found in blood samples, such as bilirubin, lipids, anticoagulants, and common drugs. This information is provided by the method manufacturer.
- Establish the reference interval of the analyte if applicable. If the results from both the candidate and old methods are comparable, the reference interval used with the old method also is used with the new one. For new tests or improved tests, the manufacturer's reference intervals may be used if they agree with published literature or the patients studied by the manufacturer are similar to the patient population that will be tested.
- In addition to assessing the performance of the candidate method, the laboratory should perform the following:
  - Write or revise the procedure
  - Prepare in-service training materials and instruct personnel on how to perform the test:
  - All staff personnel who perform the test should study the test description and demonstrate competency in its performance after individualized instruction
  - Implement quality control procedures and the established control limits.
  - Prepare documentation for staff members, including instructions on specimen collection, hours of test

availability, expected turn-around time, reference intervals, and potential interfering substances.

- Prepare a communication plan for the medical and nursing staff if performance parameters or reference ranges change significantly.

- **Validation / Verification statistical tools:**
  - Utilize common statistics including: correlation, regression, and Bland-Altman. For example, Spearman coefficient of Correlation, Paired test for difference, linear regression as Deming regression or Passing-Bablok regression and Bland-Altman analysis.
  - Use electronic statistical methods validation tools such as Westgard method validation tools (https://www.westgard.com/mvtools.htm), med- cal (https://www.medcalc.org/) , and EP evaluator tool (https://www.datainnovations.com/ep-evaluator-0).

6.20.2.2. Qualitative and semi-quantitative Tests:

Such examinations produce nominal or ordinal results, must undergo a verification process prior to their implementation for routine clinical laboratory testing. Standard method validation parameters used for quantitative assays cannot apply in these types of test. Rather, contingency tables, Bayesian statistics and statistical hypothesis testing must be used.

- Qualitative assays are used for a variety of applications in the clinical laboratory, ranging from screening to diagnosis and disease monitoring.
- Examples of Qualitative and semi-quantitative assays: HIV antigen, Hepatitis Ab & Ag test, Brucella Ab titration, Histology and cytology.etc.

  Note: There are many commonly used items in laboratory that are not considered as instruments, kits or test systems and

may not require verification prior to use (e.g. Catalase, Oxidase in microbiology). Instead, these items may be monitored through the QC protocols of the laboratory.

- Validation of qualitative test (such as: HIV, HB, CMV etc) it differs from quantitative test.
    - **Precision** :Within run and between run precision will be determined by running the negative control and positive control as follows:
        - For within run, at least 20 replicates of negative control and at least 20 replicates positive control will be tested in one run.
        - For between run reproducibility, both negative and positive control will be tested at least once per day but not more than 5 times per day to obtain a total of 20 replicates each.
        - Acceptability criteria: The results obtained from the negative and positive controls will be used to calculate the CV and compared to the manufacturer's claims for reproducibility. The laboratory CV should be less than or equal to the manufacturer's stated CV. In the event that an assay does not perform as expected, the Laboratory management will determine acceptability.
    - **Accuracy**: a minimum of 10 samples for each expected result. For example, if a test method gives results of "Positive/Negative", the accuracy study must include 10 known positives and 10 known negatives.
        - **Acceptability criteria:** The performance of qualitative tests is most commonly described in terms of sensitivity and specificity. The table below is a contingency table that compares the results of a

qualitative test with the outcome of the diagnostic accuracy criteria. The entry in each cell of the table represents the number of specimens corresponding to the labels in the margins

Method being Validated	Diagnostic Sensitivity and Specificity (Results from Comparison Study)		**Total**
	Positive	Negative	
Positive	***# true positive (TP)***	***# false positive (FP)***	***TP+FP***
Negative	***# false negative (FN)***	***# true negative (TN)***	***FN+TN***
Total	***TP+FN***	***FP+TN***	***N***

- Calculate the estimated Diagnostic Sensitivity(True positive rate) = 100 x [TP/(TP+FN)]
- Calculate the estimated Diagnostic Specificity(True negative rate) = 100 x [TN/(FP+TN)]
- Calculate the percent Positive Agreement (Positive Predictive Value)
- =100 x TP/(TP+FP)
- Calculate the percent Negative Agreement (Negative Predictive Value)
- =100 x TN/(TN+FN)
- Compare the results calculated above with the manufacturer's stated claims for Sensitivity, Specificity and Agreement found in the test kit package insert.
- Results must be equal to, or greater than, the manufacturer's claims for the method to be considered accurate.

- Qualitative test do not require linearity ,AMR or reference range studies .For an FDA approved , unmodified methods ,

the laboratory can accept the manufacturers interference claims

- **Culture Identification (ID) agreement / Accuracy:**
  - Comparing the new method with the existing or reference method can be done using ATCC strains and patient's bacterial isolates.
  - The identification (ID) verification of species and genera of the bacterial isolates is evaluated for :
    - Accuracy: By comparing fresh growth of microorganisms that are commonly encountered in the institution's patient population with different ATCC control isolates and external QC samples.
    - Accuracy is expressed mathematically as:

$$Accuracy = \frac{\text{No. isolates match reference method}}{\text{total No. of isolates tested)}} * 100$$

    - Precision: By repeating conrol strains / patients isolates 4 times for 5 consecutive days.

$$Precision = \frac{\text{No. of repeated results in agreement}}{\text{Total no. of results}} * 100$$

    - Refer to manufacturer specification of the system to check the acceptability of the accuracy and precision.
    - In case of discrepancies in ID, consider the following reasons: Old growth of ATCC strains or isolate, or mucoid or dry colonies, McFarland ..etc.
    - Verification of ID comparability, agreements should not be less than 90%.
- **Antimicrobial Susceptibility Test Methods (microbiology):**
  - Evaluation of the test method should be done using fresh isolated microorganisms that are commonly encountered in the institution's patient population.

- The included microorganisms should be susceptible, and resistant to the antimicrobials routinely prescribed at the health care facility.
- The evaluation needs to be designed to allow detection of the following types of errors:

Type of error	**Reference method**	**New method**
Very major	Resistance	Susceptible
Major error (ME)	Susceptible	Resistance
Minor (MINE)	Resistance or susceptible	Intermediate

- Overall, there should be less than 5% major errors (ME) and an overall essential agreement and category agreement of more than or equal to 90%. Both ME and minor errors (MINE) should be a combined less than10%.

6.20.2.3. Report of validation: See appendixform10.2.10: Validation /Verification Plan and Protocol and summary report, raw data has to be kept with related graphs, statistical calculation.

6.21 Internal Quality control management & External quality assurance procedures

The purpose of these procedures is to provide guidance on how to select, run and monitor internal quality control and external controls.

6.21.1 Internal quality control management

6.21.1.1 Selection of Internal Quality Control Products:

Choosing the right QC product requires careful consideration. Criteria that should be taken into account when choosing IQC materials are the following:

- **Shelf life and Stability of the internal QC material**

- An important aspect when considering the choice of IQC material is a long- term stable sample matrix with minimum bottle to bottle variation.
- Where possible, at least a one-year supply of the same lot or batch number is purchased.

- **Concentration of analytes:**

  Materials utilized for IQC purposes are selected to have a compatible matrix and analyte concentrations or cut- off in qualitative QC that simulate clinical relevant decision levels e. concentrations close to those critical for the clinical interpretation of a test.

- **Quality control materials**
  - The lab is recommended to use independent internal controls (third party control) where possible as the dependent controls (Instrument manufacturer controls) are less sensitive to changes in analytical performance.
  - Dependent control are most commonly used and can obey similar internal control quality rules
  - In-house QC from pooled patient samples can be used with limitation in case of absence of independent or manufacturer QC.

    In-house QC can be prepared:
    - Select samples with the required analytical range.
    - Pool all the samples and measure the analyte concentration.
    - If the required concentration is reached, aliquot the pooled samples and freeze them.
    - If the required concentration is not reached, add a sample with lower concentration or higher concentration as per your requirements.
    - Follow the instruction of establishing mean, SD.

- The lab can use either assayed or un-assayed control depending on local quality practice.

- **Establishment of mean and standard deviation:**
  - Establish laboratory mean and standard deviation for all quality control material (IQC) as follows:
    - Run each level of IQC materials 20 times for 20 consecutive days. If QC material has a short half-life, or is not feasible, each QC level can be run 4 times a day for 5 consecutive days.
    - Using the Excel sheet, tabulate all the results and calculate the mean, standard deviation (SD) and coefficient of variation (CV %) refer to appendix form 10.2.11.1.
    - Monitor your QC data as recommended for 120 runs and then change your mean and SD to the cumulative mean and SD. If it is not feasible, change your mean and SD after 40-80 run. Refer to Appendix 2 for QR code and excel sheet.

- **Storage conditions**

  IQC materials are to be stored appropriately. For commercial IQC materials, comply with conditions recommended by the manufacturer considering the expiry date and shelf life.

6.21.1.2 Handling and preparation

- Consider all IQC materials as hazardous and take appropriate precautions when handling and disposing.
- Store, prepare and use IQC materials according to conditions recommended by the manufacturer.
- Use the IQC within the stated expiry date. The usage of expired control material is prohibited under any circumstances.

- Report the expired control materials to the concerned department and do needful correction.

6.21.1.3 Running Internal Quality Control

- Run internal quality control before any patient samples according to the lab standards (daily or after daily, weekly).
- Run IQC after test calibration or equipment maintenance.
- The frequency of IQC runs varies between labs depending on:
    - Suggested QC runs as per Lab workload:
        - Less than 50 samples per day - apply at least one level QC once a day.
        - Between 50-100 per day - apply two level QCs at least once a day.
        - More than 100 per day - apply two level QCs at least twice a day for such analytes.
    - Assay performance: Consider the application of Six Sigma (σ) principles and metrics if feasible.
    - Manufacturer recommendations.

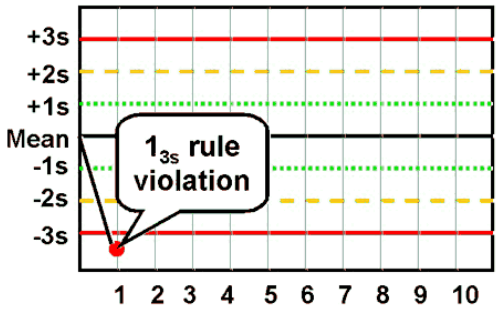
6.21.1.4 Reviewing and monitoring internal quality control data:

Keep records of all QC processes and a corrective action is necessary for continual improvement of the laboratory quality system.

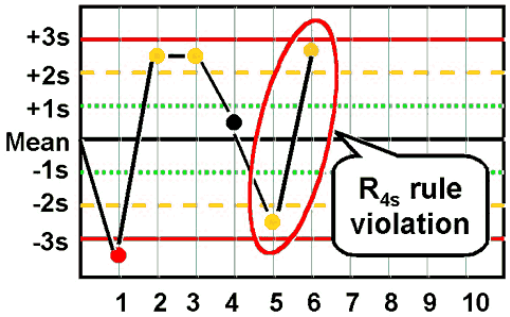
- IQC Monitoring and Assessment
    - Plot Quality Control result using Levey-Jennings chart with the established laboratory data (mean, 1SD, 2SD and 3SD)
    - QC charts can be done automatically through analyzer software or laboratory information systems.
    - QC plot gives a clear view for QC performance assessment.

- Look for systematic or random errors and decide whether to accept or reject the QC run result.
- False Rejection:
  - With 2 control levels, there is ~ 10% chance that the run will be rejected when the QC run is fine
  - With 3 control levels, there is ~ 15% chance of rejection when the QC run is fine.
- Use Westgard rules for quality control result assessment based on our assay performance.
- All control values are within 2 SD limits, QC accepted.
- Two control values are within 2 SD limits and one is within 3 SD limits, Accept your QC run.
- Consider the following Westgard rejection rules
  - **Precision flagged (random error)**

    1_{3s}: One control value is outside 3 SD



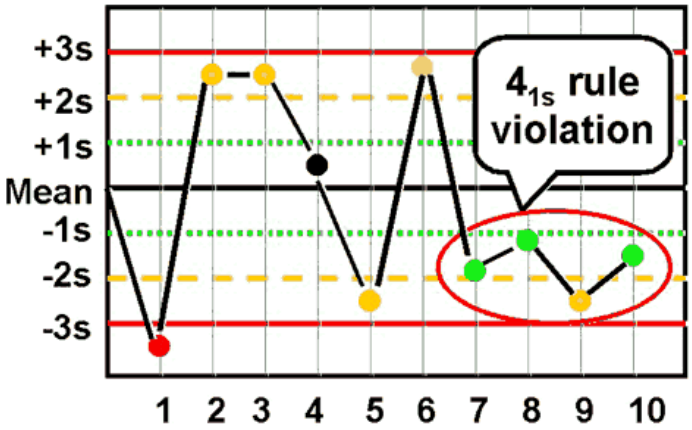
R_{4s}: The difference between the maximum and the minimum QC values exceeds 4 SDs in the last QC run



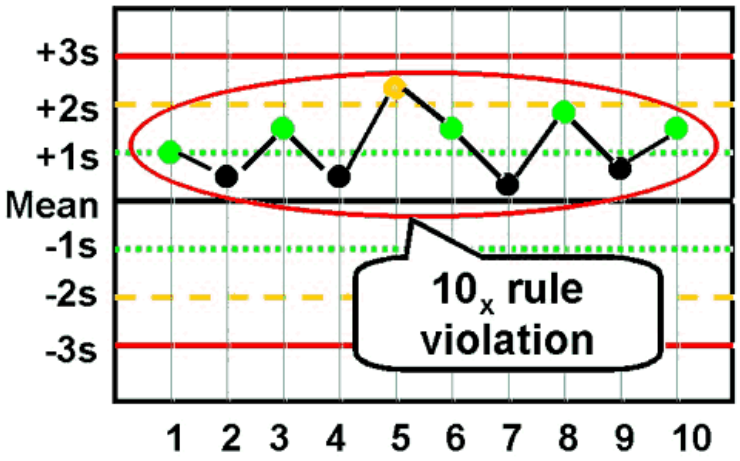
- **Systematic errors (Bias, Shift & Trends)**

2_{2s}: Two consecutive control runs are outside the same SD, e.g.± 2 SD (Bias)

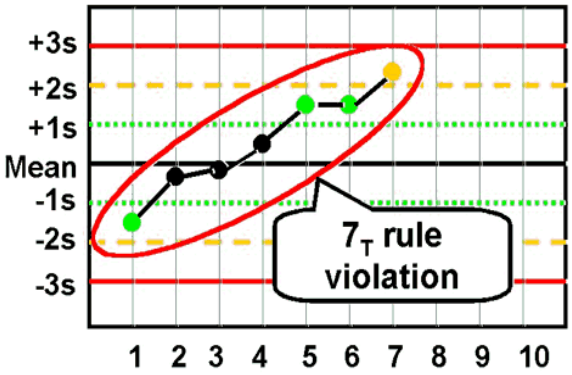
4_{1s}: Four consecutive control values are on one side of the mean and further than 1 SD from the mean e.g.> +1 SD or < -1 SD (Shift)



10x: Ten consecutive control runs are on one side of the mean (shift)



7_T: Seven control results falling in a pattern, high or low (Trend)



- Monthly QC review:
  - Review the QC results to evaluate accuracy and precision and performance at all levels monthly compared to referenced target quality goals (e.g. Biological variation, or CLIA).
  - When cumulative QC results are sustained higher or low compared to the QC limit and external QA samples are acceptable and there is no assay/instrument or reagent/QC/Calibrator factors involved, a reassessment of the assigned mean and SD may be required.

6.21.1.5 Actions to be taken when QC result is rejected:

- **Patient test results:**

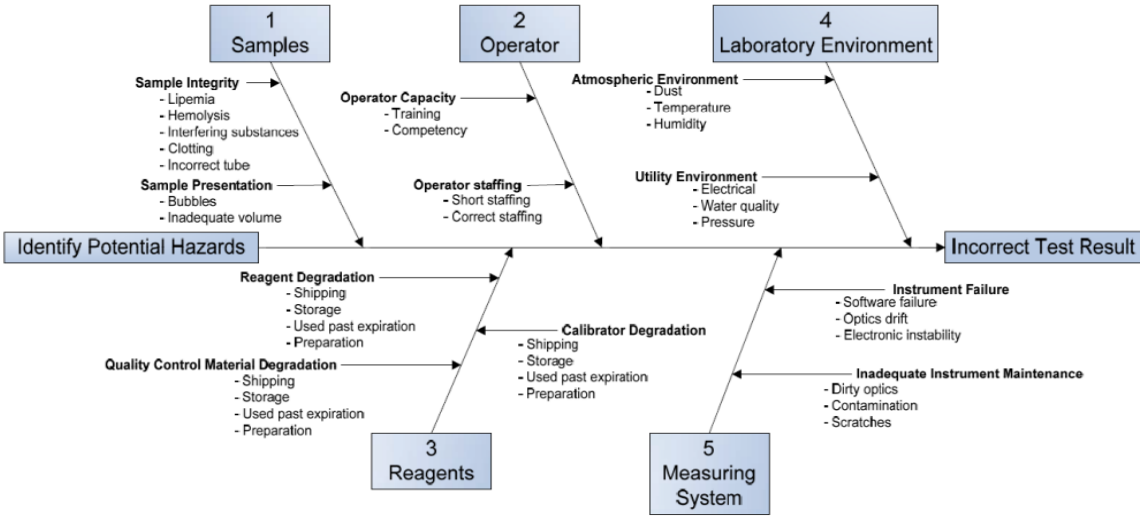
- Hold testing or reporting patient results when control results are not acceptable.
- Establish a procedure for patient result monitoring when control results are rejected.
- In case of QC failure, review all patient samples analyzed since the last successful QC run and correlate clinically.
- Repeat random samples run before QC result rejection depending on test stability.
- In case of persistent QC rejection, run a group of 5 to 6 samples on another comparable analyzer and compare the results. If the results are comparable, run can be accepted.

- **Control Failure Investigation:**
  - If QC results are unacceptable, investigate the possible causes and record the problem along with its corrective actions.
  - Avoid the habitual repeating of the control.
  - Use IQC investigation checklist,(refer to appendix form **10.2.11.2**)
  - Review the control chart and assess your QC based on Westgard rules when applicable and act accordingly.
    - False rejection: 1_{2s}
    - Random error: 1_{3s}, R_{4s}
    - Systematic error: 2_{2s}, 4_{1s}, 10_{x}, 7_{t}
  - If random error is detected, re-run the QC with fresh QC material to exclude human error. Accept the run if the repeated result is within the control limit and run patient samples.

- If the QC results are out of limit after fresh material run, investigate and correct the error based on random error factors.
- In-case of systematic error, investigates the cause, correct it and document it before repeating the QC.
- Report any QC result issue to the responsible staff.

- **Root Causes of Systematic and Random Errors:**
  - Investigate the error source as following :

Systematic Error	Random Error
Change in quality control material lot number. Change in test reagent lot number. Change in calibrator lot number Incorrect calibrator value Improperly prepared reagent Reagent/ calibrator deterioration Inadequate storage of reagents and calibrators Analyzer pipette maladjustment/ misalignment Temperature change of incubator and reaction blocks Photometric light source Change in procedure from one operator to another	Bubbles in reagent bottle or reagent aspiration line Inadequate reagent mix Unstable temperature or incubation. Unstable electrical supply



6.21.1.6 Important consideration in Qualitative and Semi-quantitative internal quality controls:

- Consider different types of controls such as:
    - **Built-in Controls**: For some kits may indicate that all the reagents impregnated into the device are active and working properly, whereas built-in controls for other kits may only indicate that a sample was added and solutions flowed through the device correctly (verifies procedure only).

      Note: It is important to carefully read the instructions provided by the manufacturer to understand what the built-in controls monitor, and to determine whether additional controls may be needed.

      Examples of built-in controls: rapid tests such as human immunodeficiency virus [HIV], infectious mononucleosis, drugs of abuse, pregnancy or faecal occult blood. Other assays are now coming with positive and negative control within the package, which

can be run as needed or as per manufacturer instructions. e.g., is Rapid test for SARS CoV2 kit.

- **Reference strains control organisms**: The control strains such as: American Type Culture Collection (ATCC), National Type Culture Collection (NTCC, United Kingdom)..etc have predictable reactions to verify that stains, reagents and media and antibiotic susceptibility discs and strips are working correctly.
  - For media that is prepared in-house, this evaluation must be conducted for each batch prepared
  - For all commercially prepared media, the performance verification will be performed for each new lot / batch delivered.
  - In all cases, media should be carefully checked for physical and chemical properties:: sterility, appearance by checking the turbidity, dryness, evenness of layer, abnormal color, pH, ability to support growth, ability to inhibit growth, and that the color indicator is working well in each appropriate strain.
  - For selective media, inoculate both control organisms that challenge the media's inhibition ability as well as one that should grow. Investigate the cause of any failure and accordingly decide regarding accepting or discarding the media batch.
  - For differential media, inoculate the media with control organisms that should demonstrate the required reactions. For example, inoculate both lactose-fermenting and non-lactose-fermenting organisms onto MacConkey agar to verify that the colonies exhibit correct visual appearance.

        - For the media that remains in the store for weeks, repeat the verification in an intermediate period to check their sustained appropriateness as per manufacturer protocol.
    - Some laboratories may choose to use isolates from their own laboratories for QC. If so, they should be monitored closely to verify regularly that tested biochemical reactions and the organism characteristics are sustained over time. In this case these isolates must be carefully characterized in terms of identification (ID) /susceptibility (AST) /biochemical reactions using reference methods.

      Note: It is important to keep careful records for media that is prepared in the laboratory and its QC performance.
- Use positive and negative controls to monitor the effectiveness of test procedures that use special stains or reagents and tests with end-points such as agglutination, color change or other non-numeric results.
- For agglutination procedures, include a weak positive patient sample as a control beside the negative and positive control.
- For tests with an extraction phase, such as some rapid group A Streptococcus tests choose controls that are capable of detecting errors in the extraction process.
- Use the controls once each day of testing, or at least as often as recommended by the manufacturer.

6.21.2 External Quality Assurance management

6.21.2.1 The laboratory value the EQA to:

- Allow comparison of performance and results among different test sites.

- Provide early warning for systematic problems associated with kits or operations.
- Provide objective evidence of testing quality.
- Indicate areas that need improvement.
- Identify training needs.
- Acquire accreditation.
- Creates a network for communication, and enhancing a national laboratory network.

6.21.2.2 Selection of External Quality Assurance Products:

- Consider different types of EQA**:**
  - **Proficiency testing:** gives a good, objective measure of the laboratory performance. It can be organized to address most kinds of laboratory testing and used frequently.
  - **Inter-laboratory comparisons (Rechecking or retesting):** is useful when it is difficult or impossible to prepare samples to test all of the testing process. Ensure the comparison is done with accredited laboratories or with an accepted performance of proficiency testing programs.
  - **On-site evaluation:** if the previous types of EQA are not attainable, consider external audit to ensure real-time guidance for improvements that are needed. However, the cost depends on the following: requiring staff time, travel time and expenses of those performing the evaluation.
- Establish the criteria of selection for external quality assurance considering the aims of the programs, range of services and other important managerial and technical consideration e.g. number of EQA participants, number of cycles/ dispatches, EQA sample storage requirements.
- Treat the EQA samples always as regular patient samples and include them in the usual daily analytical process in the

laboratory with no special consideration such as: assigning staff for running EQA.

6.21.2.3 Handling and preparation

- Verify that the received EQA samples are in a good condition.
- Use the same safety precautions as for the patient's samples.
- Register the EQA samples in similar manner to the patient samples.
- Prepare, store and use the EQA samples according to manufacturer recommendations.

6.21.2.4 Examination of External Quality Assurance:

- Analyse external quality assurance EQA samples using the same procedure used for processing the patient samples according to the schedule provided by the EQA scheme.
- Store the EQA sample post analysis appropriately following the manufacturer recommendation.

6.21.2.5 Post examination of EQA:

- Report EQA in the same manner as patient's samples (e.g. Laboratory information system or printed copy) to ensure archiving of EQA results.
- Feedback to the EQA provider is entered using the proficiency program website where applicable.
- Follow up with the EQA providers the result depending on the type of programme (qualitative, semi-quantitative or quantitative) specific statistical procedures are used.
- Keep the EQA results confidential. A summary is generally provided and allows comparison to the overall group.

6.21.2.6 Reviewing and monitoring external quality assurance data:

- Review the EQA feedback regularly.
- Troubleshoot the EQA result if the performance is not acceptable.

- Establish an EQA troubleshoot form as in appendix form **10.2.12**.
- Consider the following possible errors in EQA performance:
    - Pre-examination*:*
        - The sample may have been compromised during preparation, shipping, or after receipt in the laboratory by improper storage or handling such as wrong sample preparation.
        - The sample may have been processed or labelled improperly in the laboratory.
    - Examination:
        - The EQA challenge materials may exhibit a matrix effect in the examination system used by the participating laboratory.
        - Possible sources of analytical problems include reagents, instruments, test methods, calibrations, and calculations.
        - Analytical problems should be investigated to determine whether error is random or systemic.
        - Competency of staff will need to be considered and evaluated.
    - Post-examination:
        - The report format can be confusing.
        - Interpretation of results can be incorrect.
        - Clerical or transcription errors can be sources of error.

    Note: Incorrect method classification by the EQA proficiency program provider is another possible source of error.

6.22 Post Examination processes

This procedure is not required

6.23 Notification of critical results

This procedure describes the communication of critical laboratory reports.

6.23.1 Clarify the critical results conditions and recommended time frame

6.23.2 Ensure that the critical result have been verified and reviewed

6.23.3 Establish customized local list of critical results in alliance with international guidelines and agreed with clinicians.

Note: The list kept available for users and staff.

6.23.4 Define the communication channels (to whom to contact, communication mode e.g. phoning, electronically) for different users and destinations along with alternative channels if failed to communicate.

6.23.5 List the contacts for channels including out-hours, internal and external users according to the health care facility.

6.23.6 Reporting conversation steps as :

- Introduce yourself.
- Give patient three names and tribe/family along with patient ID
- State the critical result clearly
- Ask the name and family/tribe of critical result receiver and if needed ask name spelling. Note: If feasible ask for staff number
- Ask the receiver of critical result to read-back
- Document the critical result communication with details including: date, time, receiver, trails (passed /failed) ,and read-back .
- In case of communication failure, record and raise the event to the responsible staff.

6.24 Delayed & amended laboratory reports procedures

These procedures describe the guidance on handling delayed laboratory reports. In addition, they provide instructions for amendment of previously released laboratory results when correction is needed due to unintentional error or interpretation alteration**.**

6.24.1 Delayed laboratory reports procedures

- Consider direct verbal notification for delayed results if urgently needed/high risk patient

- In case of expected result delays, inform the end-users, regarding the delays effects and time frame using approved communication channels.
- Handle the delayed reasons accordingly.
- Activate the relevant contingency plan e.g. QP Laboratory Reagents and Consumables contingency plan procedure, and Information system failure procedure.
- Raise non-conformance in case for such delays in issuing reports with corrective actions needed

6.24.2 Amended laboratory reports

Amendment procedure differs between laboratories and between different specialities. However, there are general principles using good laboratory practice as follows:

- The revised report is clearly identified as an amended report and includes reference to the date and patient's identity in the original report;
- The user is made aware of the amendment: If it is necessary to amend a result, an explanatory comment is attached to the result indicating why the result has been amended.
- If a significant change is identified, the user must be contacted immediately verbally and notified of the discrepancy. This communication should be documented.
- The revised record shows the time and date of the change and the name of the person responsible for the change and the name of the informed end user.
- A copy of the original report entries should be kept electronically or as a hard copy for future access by authorized personnel if required.
- In circumstances where the results have been made available for clinical decision making prior to amendment, an adverse incident must be recorded with an indication of the action taken to reduce the possibility of a recurrence.

6.25 Hospital Information System validation & failure procedures

These procedures provide guidance on interface and calculation validation of the hospital information system (HIS)in relation to laboratory information system (LIS) and guide on operation during failure.

6.25.1 Hospital Information System validation

6.25.1.1. Hospital Information System interface validation:

- The check points for interface validation includes (but not limited) the followings:
  - Information transferred from HIS to LIS.
  - Information uploaded from LIS to instrument.
  - Information downloaded from instrument to LIS.
  - Information transmitted LIS to HIS.
- **The verification of these check points includes the following:**
  - Instruments and test mapping interface by cross-referencing of instrument test codes against LIS test codes by performing a one-to-one validation of each test upload and result download.

    Note: consider verification of individual test in any multiple tests profile.
  - Accurate identification of result formats such as numbers, decimal points, numeric rounding, alphanumeric, letters, symbols and codes.
  - Accurate identification and categorization of normal and abnormal results. For instance, critical high and critical low, delta check, abnormal, invalid or zero value etc.
  - Auto-verification of transmitted result.
  - Alerting system of abnormal results and error messages.
  - Data uploading of specimen related information and requirements: patient demographics that may determine

which sex- or age-specific high/low flags or reference ranges are downloaded with results.

- Data uploading of related test information including sample type, department, requirement of results authorization, unit, and reference range etc..
- Identification and transfer of qualitative results
- Validation process is performed during implementation, in case of any change in the system parameter and annually.

- **Interface validation samples selection and performing:**
  - **Criteria to be considered when selecting the samples include:**
    - Type of sample: consider sample type for every test.
    - Type of test: For every type of test, select 3-5 samples
    - Priority of samples: routine and urgent samples.
    - Source of the sample: In-house or referral samples.
    - Result range/ category: normal, abnormal ranges, critical, sensitive or resistant isolates.etc
    - Examination method: automated / manual testing examples: staining, microscopy transcription errors to be considered.
    - Non electronic Original reports i.e. printed or faxed results to be included.
  - **Steps of interface validation:**
    - Selection of samples according to the given criteria.
    - Check of the uploaded patient request information in the analyzer.
    - Comparison of the results from the analyzer with LIS and HIS.
    - Matching the laboratory report content with the report released to end-users.

- Documentation of the interface validation result in a form (refer to appendix from 10.2.13.1)
  - If the validation is acceptable, save the printout and records.
  - If not acceptable, record the issue, and notify the problem for quality assurance troubleshooting and resolution. Then record the action taken
- Staple all database printouts to the HIS interface validation form and save them.

- **Hospital Information System calculation validation:**
  - During application and validation of laboratory calculations, ensure the following**:**
    - The programming of the calculation in the system to sustain the accuracy and reproducibility of the results.
    - The verification of each calculation independently.
    - The approval of each calculation by the responsible staff in each department.
    - Validation process is performed during implementation, in case of any change in the equation and annually.
    - The documentation of the name of staff that entered or updated the equations and the date.
    - The inclusion of all result range (normal, low and high).
- **Instruction of calculation validation:**
  - List the calculations that require the validation.
  - Review the calculation requirements and updates (e.g. age, gender, and ethnicity).
  - Print out the installed formula from the HIS.

- Record the tested values included in the calculation.
- Compute the result using manual or referenced software.
- Compare the data obtained from information system calculation against the manual system or reference software calculations.
  - Document the calculation validation result in a form (refer to appendix from 10.2.13.2).
    - If results are matching, the validation is acceptable, save the printout and records.
    - If not matching, hold the automated calculated result, record the issue, and notify the problem for quality assurance troubleshooting and resolution. Then record the action taken
- Staple all raw data printouts to the HIS calculation validation form and save them

6.25.2 Information system failure

- Create an Information system failure contingency plan to ensure the continuity of services during computer failure.
- Include in the plan: affordable timeframe for report generation, a list of emergency contact numbers, and crucial equipment to be reprogrammed, restarted or recalibrated once the computer function is restored
- Orient all the laboratory staff ahead.
- Ensure that the emergency contact numbers are displayed at a prominent location.
- Ascertain the maintenance of regular updated data backup and availability of sufficient storage for laboratory information.
- The laboratory should ensure the confidentiality of patient data if there is any system failure
- Assure proper sample handling during computer failure as follows:
  - **Within affordable timeframe:**

- Accept manual request forms along with the samples
- Record and Label all received sample during the computer failure.
- Prioritize the processing of urgent and precious samples only, as that might affect the immediate patient care.
- Defer routine testing and store the samples appropriately for processing after failure resolution.
- Print and label sample reports from the analyzers and verify patient identification prior to sending to the requester.
- Verbal request is prohibited during failure.
- Deliver the samples reports through approved channel.
- Once system restored, ensure that the samples processed during failure are registered and result transmitted.

- **Exceeding the affordable timeframe:**
  - Record and then refer all the samples to approved institutions for examination.
  - Once system is restored, ensure that the results of the referred samples during failure are transmitted.

7. Responsibilities

7.1. Organization

Refer to policy (5.1.)

7.2. Quality management system

Refer to policy (5.2.)

7.3. Document control

The Laboratory responsibility of document control process depends on the type and level of document. For further details, refer to policy and procedure of documents development MOH/DGQAC/P&P/001/Vers.01

7.4. Service agreement

7.4.1. Lab management shall:

- Review of new / additional needs of service users.
- Request for replacement or upgrade through the approved channels

- Collaborate with responsible staff for filling the required item specification on the service agreement review form.
- Approves and send the request through the appropriate channel
- Facilitate the new service / test process
- Review and document the service agreement with relevant changes and discussions.

7.4.2. Quality manager / officer shall:

- Participate in setting the service agreement
- Participate in filling the service agreement review form
- Record non-conformance related to service agreement and follow the needful corrective action.
- Monitor the implementation of the procedure regularly

7.4.3. Responsible staff shall:

- Participate in review of additional needs of service.
- Suggest the replacement or upgrade of a service.
- Raise the non conformance to laboratory management

7.4.4. All laboratory staff shall:

- Implement the service agreement procedure.
- Report non compliance of service agreement procedure

7.5. Selection of referral laboratories

The laboratory management / assigned committee or team of the referring laboratory is responsible for selecting a referral laboratory and for its ongoing evaluation based on objective evidence of acceptable quality and responsiveness in consultation.

7.6. Services and supplies management

7.6.1. Lab management shall:

- Review of additional needs of service users.
- Request for replacement or upgrade through the approved channels
- Collaborate with responsible staff for setting the required item specification

- Approves and send the request through the appropriate channel for tendering
- Participate in tenders offers selection
- Facilitate the new items enrolment process
- Approves items or equipment verification report

7.6.2. Quality manager / officer shall:

- Participate in setting the items specification
- Ensures the verification of the new item or equipment
- Record non conformance and follow the needful corrective action.
- Follow up the staff training on new items after installation
- Monitor the item test performance regularly

7.6.3. Responsible staff shall:

- Participate in review of additional needs of service.
- Suggest the replacement or upgrade of a service.
- Recommend items specification
- Ensure the condition and quality of the items received
- Supervise the items verification.
- Encourage the staff to attend the onsite training
- Monitor the item test performance regularly
- Supervise the inventory management
- Assures proper items storage

7.6.4. All laboratory staff shall:

- Inspect the condition and quality of the items received
- Raise the non conformance to responsible staff
- Implement the verification procedure.
- attend the onsite training
- verify the item test performance regularly
- inform any issues in the inventory management to the responsible staff
- maintain proper items storage

7.6.5. Medical store shall:

- Collaborate with laboratory for new item enrolment
- Verify the condition and the quality of the item received
- Raise any discrepancies or customer feedback to the concerned department
- Ensures proper inventory management process

7.6.6. Supportive department shall:

- Facilitate the management process and storage of services and supplies.

7.7. Advisory services

Refer to policy (5.7)

7.8. Resolution of complaints & incident report

The responsibilities as follows:

7.8.1 Resolution of complaints

7.8.1.1 Laboratory management shall:

- Be informed regarding complaints
- Attend the meeting with end users and quality department
- Monitor the required actions correction

7.8.1.2 Lab quality focal / manager shall:

- Receive and record all raised complaints
- Analyze the complaints and find the sources causes
- Participate in the RCA closure meeting
- Record all the required corrective action.
- Follow up with quality department about the RCA closure.

7.8.1.3 Investigation Team leader shall (quality department) :

- Moderate the meeting of RCA closure with all involved departments.
- Set up the possible solution and corrective action
- Ensures the closure and complainer satisfaction

7.8.1.4 Public Relation Department shall

- Receive and record all raised complaints through approved channels.

7.8.1.5 All laboratory staff shall:

- Be familiar and adhere with this policy & procedure.
- Raise and record any verbal complaints

7.8.2 Incident report

7.8.2.1 laboratory management shall:

- Raise the awareness of staff towards implementing the incident reporting procedure.
- Ensures continuous training for incident reporting procedure.
- Assure the periodic submission of cumulative incident reports through the approved channel

7.8.2.2 Responsible laboratory staff shall:

- Ensure that all employees are aware of the incident reporting procedure.
- Respond and follow-up the incidents immediately.
- Carry out any further incidents investigation for general incidents/near miss events by using Root Cause analysis and Corrective Action Plan.
- Discuss incidents to the concerned department about RCA findings and corrective action plan.

7.8.2.3 Investigation Team leader shall:

- Review the incident and investigate the needed and Sentinel Event.
- Ensure completion of a Root Cause Analysis and Corrective Action Plan.
- Follow up the implementation of corrective action plan.
- Fill the safety alert and lesson learnt form.

7.8.2.4 Senior Patient Safety Officer shall:

- Lead the investigation team in case of sentinel events.

- Submit the Root Cause analysis and Corrective Action reports to Hospital Director, DGs and to concern departments.
- Disclose the incident to the patient/Family.

7.8.2.5 Event Manager ,Quality manager, quality officer, focal point shall:

- Support all staff on how to report incidents and when needed.
- Review all reported event in daily basis.
- Ensure all incidents are properly managed and in timely manner.
- Follow up, validate all corrective action plan with the concerned department, and coordinate directly with departmental incident focal point.
- Identify changes and improvements that could be made in system and processes based on investigation team report.
- Provide periodic report of cumulative incident reports through the approved channel.
- Review and rate the incidents based on severity.
- Investigate the incidents according to the Risk assessment tools.

7.8.2.6 All laboratory staff shall:

- Be familiar and adhere with this policy & procedure.
- Report all incidents.

7.9. Non conformities identification & control

7.9.1 Laboratory management shall :

- Follow up the performance of NC in a management review meeting

7.9.2 Quality manager/ officer shall :

- Encourage the initiation of non-conformance reporting,
- Follow up the NC handling, controlling, and implementation.
- Regularly analyze the NC report.
- Keep all the NC records.

- Discuss the NC report to lab management.

7.9.3 Initiator shall:

- Fill the NCF and inform to responsible staff.
- Participate in the investigation and action implementation.

7.10. Corrective action

7.10.1 Laboratory management shall:

- Participate, supervise and review the process implementation.

7.10.2 Quality manager/ officer shall:

- Encourage the initiation of non-conformance corrective action process, record it, and follow up the plan and implementation.
- Regularly report the corrective actions to lab management for reviewing their effectiveness.

7.10.3 Responsible staff / initiator shall:

- Participate in the immediate action, root cause and the implement of the corrective action process.

7.11. Preventive Action (PA)

7.11.1. Laboratory management / institution administration shall:

- Discuss and approve the action plan.
- Review the process implementation
- Responsible for the final decision making on selected measures.
- Monitor the implementation status.

7.11.2. Project manager and Quality manager/ officer shall:

- Conduct gap analysis and other quality tools to find an appropriate area of improvement.
- Encourage brain storming and conducts root – cause analysis
- Initiate of preventive measures process
- Record, and follow up the plan timeline and implementation.
- Evaluate the actions effectiveness.
- Regularly report the actions and results for management review

7.11.3. Team members shall:

- Participate in the brain storming.
- Report results to project manager and quality manager / officer.

7.12. Continual improvement

7.12.1. Laboratory management shall:

- Discuss and approve the action plan.
- Review the process implementation
- Responsible for the final decision making on selected measures.
- Monitor the implementation status.
- Collaborate with project team leader

7.12.2. Project manager and Quality manager/ officer shall:

- Conduct gap analysis and other quality tools and input of quality data to find an appropriate area of improvement.
- Encourage brain storming and conduct root cause analysis
- Initiate preventive measures
- Record, and follow up the plan timeline and implementation.
- Evaluate the effectiveness of the actions.
- Regularly report the actions and results to lab management for reviewing their effectiveness.

7.12.3. Team members shall:

- Participate in the brain storming to find solutions and the implementation of the preventive action process within the timeframe.
- Report results to project manager and quality manager / officer.

7.13. Control of records

The Laboratory responsibility of controlling the records depends on the type, level of document and the local recommendations applied. Consider the guidance in the policy and procedure of documents development MOH/DGQAC/P&P/001/Vers.01

7.14. Quality Internal audit & indicators

The sections below contain the responsibilities:

7.14.1. Internal quality audit:

7.14.1.1. Lab management shall:

- Support the induction of the audit
- Encourage the staff for the full cooperation and commitment
- Approves the final auditing report
- Review the correction in a regular management review meeting.

7.14.1.2. Auditor / quality manager / officer shall:

- Design a structured referenced auditing mechanism and checklist.
- Create a scheduled auditing plan
- Select and Prepare auditors.
- Conduct an opening and closing audit meetingwith responsible staff of the area being audited.
- Observe work, interview staff and Collect evidences.
- Fill the checklist and raise final auditing report with finding and observations.
- Review the audit report to ensure that it is complete, concise
- Distributes the audit report to the audited work area's responsible staff
- Discuss the finding with the needed correction within a timeframe in a management review meeting.
- Follow up and monitor the closing of the finding.

7.14.1.3. Responsible staff of the area being audited shall:

- Encourage the staff to cooperate and provide all information
- Attend and facilitate opening and closing audit meetingwith auditor.

- Collaborate with auditor to create a scheduled correction plan for finding.
- Discuss the finding with the needed correction with auditor and all staff in the area
- Follow up the corrective action of the finding within the time.

7.14.1.4. All staff shall:

- Facilitate the audit by answering questions, providing the required information and documents that auditor needs them to review the process
- Collaborate with auditor and responsible staff to close all findings.
- Provide auditor with required records and evidences that closes the finding.

7.14.2. Quality indicators

7.14.2.1 Laboratory management shall:

- Supervise and review the process implementation and outcomes
- Ensure the quality indicator requirement availability
- Communicate the quality indicators to concerned department.

7.14.2.2 Quality manager/ officer shall:

- Ensure the quality indicator requirement availability
- Perform the correct data collection with the IT support.
- Monitor the approved quality indicators.
- Coordinate with laboratory staff to ensure target achievement.
- Encourage the initiation of non-conformance corrective action process, record it, and follow up the implementation in case of failure to achieve target.
- Conduct root cause analysis accordingly.

- Record, and follow up the plan timeline and implementation.
- Evaluate the actions effectiveness.
- Regularly report the actions and results to lab management for reviewing their effectiveness.
- Communicate the quality indicators to all laboratory staff.

7.14.2.3 Responsible staff shall:

- Implement the related laboratory quality policies and protocols to the indicator.
- Facilitate the data collection.
- Collaborate with quality manager/ officer to ensure target achievement.
- Participate in the immediate action, root cause and the implement of the corrective action process.

7.15. Management review

Refer to policy number (5.15)

7.16. Technical Competency assessment

7.16.1. Laboratory management shall:

- Identify training necessities.
- Establish a written policies and procedures
- Assure that each designated staff receives regular in-service educational update and training according to type and complexity of the testing service
- Approves the assessment report.

7.16.2. Responsible staff shall:

- Assure the implementation of the policy periodically
- Evaluate the competency of all assigned staff
- Conduct the competency assessment and documentation of the competency assessment.
- Assure that staff maintains their competency under the guidance of senior medical laboratory scientists.

7.16.3. The quality manager/officer shall:

- Participate in the implementation of the policy
- monitor the competency of each assigned laboratory staff that performs their duties in the laboratory
- Audit the availability of competency evaluation evidences of each staff performing clinical tests.

7.17. Accommodation & environmental condition

Refer to policy number (5.17)

7.18. Laboratory equipment, reagent and consumables

The responsibilities as follows:

7.18.1. Laboratory equipment management

7.18.1.1. Lab managementshall:

- Set up the specification of the equipment
- Take part in the selection, pre installation, installation, and post installation of the equipment with the cooperation with the concerned departments.
- Follows up the installation, post installation and the end users training.

7.18.1.2. Refer to other equipments related sections (7.18.2, 7.18.3, 7.18.4)

7.18.2. Equipment Calibration

7.18.2.1. Lab management shall:

- Ensure that the equipment calibration is conducted.

7.18.2.2. Assigned monitors (e.g. Third party, trained lab staff or biomedical engineering) shall :

- Ensure that equipment calibration is done according to the requirement.

7.18.2.3. Quality officer / manager shall :

- Monitor timely calibration and maintain the calibration certificates with the raw data.

7.18.2.4. All staff working in the Laboratory shall:

- Regularly check the calibration due date and notify the responsible staff.

7.18.3. Equipment validation

7.18.3.1. Lab management shall:

- Ensure that the equipment validation is conducted.

7.18.3.2. Assigned monitors (e.g. Third party, trained lab staff or biomedical engineering) shall :

- Collaborate and participate in the implementation of the equipment validation procedure.

7.18.3.3. Quality officer / manager shall:

- Monitor and audit the implementation of validation and maintain the report with the raw data.

7.18.3.4. All staff working in the Laboratory shall :

- Perform the validation as per approved procedure.

7.18.4. Equipment maintenance/servicing and repair

7.18.4.1. Lab managementshall :

- Ensure that the equipment scheduled servicing, maintenance are conducted.
- Verify that arrangements made for maintenance, repair and servicing in conjunction with medical store, biomedical and the vendor.

7.18.4.2. Assigned monitors (e.g. Third party, trained lab staff or biomedical engineering) shall :

- Ensure that equipment repair, scheduled servicing, maintenance are done according to the requirement.

7.18.4.3. Quality officer / manager shall :

- check and audit the availability of all documents completion of service or repair reports, computer logs and examine log books etc

7.18.4.4. All staff working in the Laboratory shall:

- Regularly perform the needed maintenance
- Check the due date of PPM servicing
- Notify the responsible staff.
- Verify that the needed repair is done regularly, promptly and satisfactory.

7.18.5. Laboratory Reagents and Consumables contingency plan

7.18.5.1 Lab management shall:

- Ensure that the contingency plan is available and implemented in case of laboratory reagents and consumables shortage.

7.18.5.2 Assigned monitors (e.g. third party, medical store, DGMS) shall:

- Ensure that there is uninterrupted supply of reagents and consumables.

7.18.5.3 Quality officer / manager shall :

- Ensure the implementation of the procedure

7.18.5.4 All staff working in the Laboratory shall :

- Check the available stock periodically
- Notify the responsible staff

7.18.6. Laboratory new reagent batch validation

7.18.6.1 Lab managementshall :

- Ensure that the reagents batch validation is conducted.

7.18.6.2 Quality officer / manager shall:

- Ensure the reagents and consumables batch validation is conducted
- Maintain the record of batch acceptability form.

7.18.6.3 Designated staff working in the Laboratory shall:

- Perform the batch validation.

7.18.7. Temperature Sensitive Equipment Validation

7.18.7.1 Lab management shall:

- Ensure that the validation, calibration of temperature sensitive laboratory equipment is conducted.

7.18.7.2 Quality officer / manager shall:

- Check and audit the availability of all documents completion of temperature calibration and validation reports, and temperature monitoring records.

7.18.7.3 Designated staff working in the Laboratory shall:

- Perform the validation, calibration and monitor the equipment temperature.

7.18.7.4 Engineering department shall:

- Support validation, calibration process
- Cooperate in the needed corrective action in case of device calibration or validation failure.
- Adjust of the required temperature ranges of the devices and environment in case of alteration of the range.

7.19. Pre- examination processes

7.19.1. Laboratory management shall:

- Support the development of this document, the implementation and update the end users.
- Ensure end user collaboration in adherence to this procedure

7.19.2. Quality manager/ officer shall:

- Collaborate in development of this document
- Audit its implementation by end-users

7.19.3. All Laboratory staff shall:

- Contribute to the document development update once necessary.

7.20. Method validation / verification

7.20.1 Laboratory management shall:

- Ensure that the validation/ verification is conducted
- To Liaise with the supplier the support needed in verification / validation process for example: providing the laboratory with required free of cost items, and references.

- Approve the method validation / verification report.

7.20.2 Quality officer / manager shall:

- Design the validation/ verification plan of each method with laboratory staff.
- Ensure the implementation of the validation/ verification procedure
- Modify the validation/ verification procedure when needed.
- Maintain the validation/ verification raw data and records.
- Submit the validation/ verification final report for approval.
- Conduct regular internal audit.

7.20.3 Responsible staff shall:

- Create and implement a specific validation plan of each method.
- Monitor the implementation of the validation/ verification procedure
- Analyze the validation/ verification result with the quality manager
- Finalize the validation/ verification report with the raw data and submit it to quality manager

7.20.4 All Laboratory staff shall:

- Implement the validation / verification procedure.
- Coordinate with the responsible staff to accomplish the validation/ verification task.
- Follow the manufacturer recommendation during the examination process.

7.21. Ensuring quality of examination results

The responsibilities as follows:

7.21.1 Internal quality control management

7.21.1.1. Lab management shall:

- Ensure the implementation of IQC procedure.
- Collaborate with concerned department in the selection and continuous supply of IQC material.
- Maintain regular IQC performance discussion.

7.21.1.2. Quality officer / manger shall:

- Review the IQC procedure implementation
- Periodically review IQC records
- Periodically review of IQC non-conformance records
- Investigate the QC failure root cause
- Ensure implementation of corrective actions.
- Discuss IQC performance regularly

7.21.1.3. Responsible staff shall:

- Implement the IQC procedure
- Supervise the IQC running and assessment
- Train the staff on IQC handling, reviewing, and troubleshooting.
- Archive of IQC data.
- Verify IQC recording and needed correction

7.21.1.4. All Lab staff shall:

- Run of the control as per laboratory standard
- Monitor the IQC performance
- Maintain the IQC records
- Report QC failure to responsible staff

7.21.2 External Quality Assurance management

7.21.2.1 Lab management shall:

- Ensure the enrolment in EQA program.
- Collaborate with concerned department in the selection and continuous supply of EQA material.
- Maintain regular EQA performance discussion.

7.21.2.2 Quality officer / manger shall:

- Guide the selection and enrolment to EQA program
- Review and evaluate the EQA result
- Investigate the EQA failure root cause
- Ensure implementation of corrective actions.
- Discuss EQA performance at managerial level regularly
- Monitor the EQA performance regularly

- Share the performance with the laboratory staff.

7.21.2.3 Responsible staff shall:

- Implement the EQA procedure
- Supervise the EQA running and assessment
- Train the staff on EQA handling, reviewing, and troubleshooting.
- Archive of EQA data.
- Verify EQA recording and needed correction

7.21.2.4 All Lab staff shall:

- Run of the EQA as per the proficiency scheme providers requirements
- Participate in the EQA evaluation and troubleshooting.
- Maintain the EQA records where applicable.

7.22. Post Examination processes

Refer to policy number (5.22)

7.23. Notification of critical results

7.23.1. Laboratory management shall:

- To ensure the implementation of communication of critical results
- To coordinate with end-users for approval of the critical list and its related channels
- To collaborate with concerned department towards achievement of closed loop communication

7.23.2. Responsible staff shall:

- To ensure the adherence critical result communication procedure
- To facilitate the alternative channels once needed

7.23.3. Quality manager /officer

- To follow up the implementation of the procedure
- To monitor regularly communication of critical results and raise non-conformance with corrective action once needed.

7.23.4. All lab staff shall:

- To adhere to the procedure.

- To document communication as recommended
- To report communication failures or incidents

7.24. Delayed & amended laboratory reports procedures

The responsibilities are as subsequent sections:

7.24.1. Delayed laboratory reports

7.24.1.1. Laboratory management shall:

- Ensure the procedure implementation
- Coordinate with end-users for activation of contingency plans

7.24.1.2. Responsible staff shall:

- Ensure the procedure adherence
- Inform expected delays and urgent result

7.24.1.3. Quality manager /officer shall:

- Follow up the procedure implementation
- Raise non-conformance with corrective action once needed.
- Monitor regularly turnaround time (TAT) of urgent tests

7.24.1.4. All lab staff shall:

- Adhere to the procedure.

7.24.2. Amended laboratory reports

7.24.2.1. Laboratory management shall:

- Ensure that the procedure of amendment of laboratory reports is in place.
- Set limitations of the authorization privilege in amending reports

7.24.2.2. Quality manager /quality officer shall:

- Follow up the procedure implementation
- Encourage reporting of non-conformance in case of significant change.
- Monitor regularly amendment of reports

7.24.2.3. Staff responsible for amendment shall:

- Contact the user verbally for amendment
- Document the amendment communication according to the instructions given.
- Raise incident /non-conformance when required

7.24.2.4. All lab staff shall:

- Ensure compliance with the amendment procedure
- Sustain the closed communication loop with the responsible staff

7.25. Hospital Information System validation & failure procedures

The responsibilities are as per the coming sections:

7.25.1. Hospital Information System validation

7.25.1.1. The laboratory management shall:

- Approve the implementation of HIS interface validation, programmed calculation and the final validation reports with needed corrective action.

7.25.1.2. The responsible laboratory staff shall:

- Conduct the validation process.
- Ensure the correct programming of the calculations.
- Document the HIS validation results
- Implement the corrective action taken in case un - acceptable performance.

7.25.1.3. Quality manager / officershall :

- Support and monitor the overall validation process.
- Ensure proper documentation of the validation.
- Initiate RCA in case of unacceptable performance
- Supervise the implementation of any corrective action taken.

7.25.1.4. Information Technology department staff shall:

- Ensure proper functioning of HIS, LIS interface.
- Support programming and maintenance of used calculation.

- Facilitate the validation process
- Support the Lab for the needed corrective action.

7.25.2. Information system failure

7.25.2.1. The laboratory management shall:

- Support and approve the contingency plan of the computer failure.
- Disseminate the contingency plan to all concerned department.
- Collaborate with other institutions to maintain service continuity.

7.25.2.2. The responsible laboratory staff shall:

- Develop the document.
- Provide the guide for staff on how to use it.
- Supervise the implementation of the contingency plan.
- Ensure proper documentation during the process implementation

7.25.2.3. Quality manager / officer shall:

- Follow up the overall handling of the computer failure.
- Ensure proper documentation during the process implementation.
- Raise non-conformance and investigate the possible root causes to develop appropriate preventive actions

7.25.2.4. Information Technology department staff shall:

- Ensure timely handling of the system failure.
- Confirm proper data archiving.

8. Document History and Version Control

Version	Description	Review Date
1	Initial Release	August 2025

9. Related Documents:

9.1.Policy and procedure of documents development, MOH/DGQAC/P&P/001/Vers.01

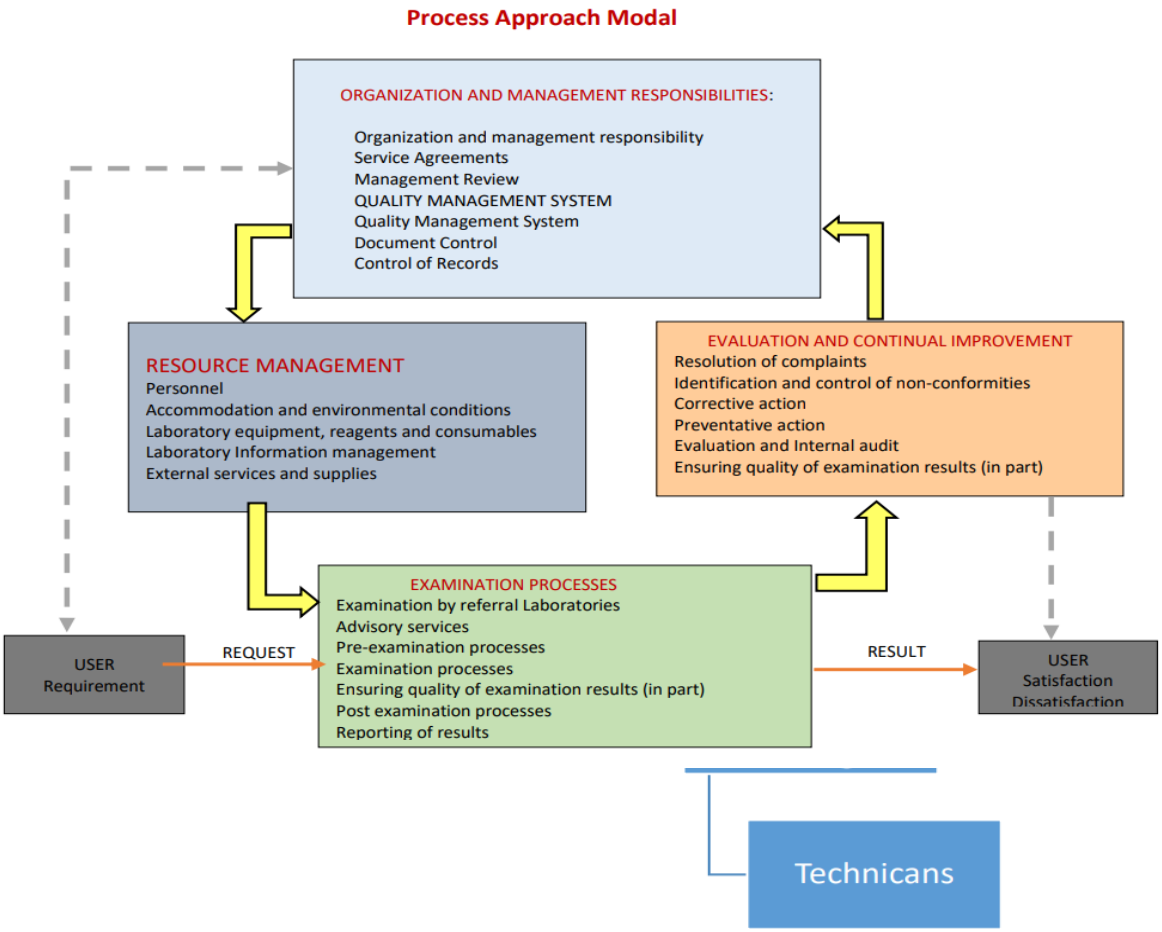
9.2.Policy & Procedure of Incident Reporting & Learning System (IRLS) number MOH /DGQAC/P&P/002/Vers.01.

9.3.Procedure of Corrective Action, MoH/DGQAC/SOP /005/Vers01.

10. Appendix

10.1.Charts &Tables

10.1.1 Example of organization chart



10.1.2. Quality Management System approach chart

10.2. Forms

10.2.2. : Service agreement review form

A. Service Requester (End user , Lab)	
Name of contact person	
Job title :	
Address / Tel / Fax :	
Email:	
B. Basic details of service	
○ **First Time**	○ **Review**
Requested analysis	
Qualitative , semi quantitative, limit of detection:	
Purpose of analysis:	
Critical alert intervals:	
C. Expenses :	

○ Planned expenses (if first time)	○ Current expenses (if reviewed)
Reagents, controls and calibrators:	Reagents, controls and calibrators:
Consumables (collection tubes / containers, reaction curvets	Consumables (collection tubes / containers, reaction curvets
Equipment:	Equipment:
Staff (working hours) :	Staff (working hours) :
Cost Benefit Analysis	Cost Benefit Analysis :
D. Turnaround Time (TAT) completion / schedule	
○ **First Time**	○ **Review**
Date of intermediate results / reports	Date of intermediate results / reports
Deadline for final results / report :	Deadline for final results / report :
E. Sample handling:	
Requester source: in- patient / out- patient / referral- in / referral- out	
Number of samples:	
Running mode: individual sample / Batching	
Special requirements (i.e. medication history, fasting, exercise)	
Transport conditions (temperature, time , mood, sample tube positioning)	
Turnaround time :	
F. Reagents information	
Name of the reagent :	
Intended use:	
Reagent constituent:	
Packaging / stability :	

MSDS
Special requirements (storage / transport / stabilization):
Pretreatment / preconditioning :
Reference materials / reference samples:
G. Analyte method information :
Details of method used for sampling , sample preparation, measurement :
Standard / reference method :
Original method / customized method
Validation required for method :

10.2.3. Examination by referral laboratories form

Please attach supporting documents as and when necessary

A. Laboratory's Capabilities (maximum 25 points)

1**. Background (1-5 points): --**

a) Does the laboratory have a reputation for high quality and integrity? ……..

b) How long has the lab been in business (e.g. 5 years, 10, more)? ……..

c) What are clients' general observations regarding the lab's services? ……..

2. Experience and references (1-5 points): --

a) Has the laboratory provided a list of References? …….

b) How long have clients been served by the lab? ……..

3.Quality Management (1-5 points): --

a) Is the Laboratory accredited? Is the documentation available? ……..

b) Does the lab have a QMS? ……

c) Does the Lab have a Quality Assurance Plan? …….

4. Equipment (lab and data handling) (1-5 points): --

a) Is the testing equipment adequate for the scope and volume of services offered? ……..

b) Is there adequate backup in the event of equipment failure? …….

c) Does the automated data processing equipment capability appear to be adequate for the scope of the work contract (e.g., direct transmissions, online result reporting)? ……

5. Accreditation and certifications (1-5 points): --

a) ISO 15189 standards? ……

b) Other? ……..

Total points for section A: …….

Document where the lab was lacking: .....

……

B. Quality assurance (maximum 25 points; assign 1-5 points for each question)

a) Is a written, organized, comprehensive quality control (QC) program in place? --

b) Is there a process for remedial action when QC tolerance limits are exceeded? --

c) Is an ongoing monitoring program in place to review, detect, and correct system errors?

d) Is a copy of proficiency testing (PT) results available for at least the previous 24 months, and for deficiencies noted, were appropriate and timely corrective actions documented? Attach copies

e) Does the laboratory have a written, clearly defined protocol for notifying clients of critical values?

Total points for section B: --

Document where the lab was lacking:

……

C. Efficiency of referral services (maximum 25 points; assign 1-5 points for each question)

a) Does the lab offer a sufficient range of services to satisfy our needs?

b) Does the lab provide a written TAT for each test performed, and does the TAT meet our needs?

c) Are data elements for each test complete?

d) Operational systems: (1-5 points for each item below)

1. General management/overall assessment of policies/procedures
2. Methods used for testing/reporting results
3. Specimen handling policies/procedures. Includes clearly defined, comprehensive instructions for preparing specimens as well as criteria for rejecting unsatisfactory specimens
4. Equipment maintenance policies
5. Information and data handling policies/procedures
6. Printing of reports via computer or printer in participating lab (is printer provided?)
7. Adequate specimen pick-up service?
8. Does the lab have a written protocol for reviewing test reports for possible errors?
9. Is the test report format clear and can it be read easily?
10. Does the lab provide client consultation services on a daily basis, including client services, technical advice, and medical consultation concerning appropriate test ordering and interpretation of results?

Points for d) should be awarded subjectively, based on past experience, if possible. If not, call references for information.

Total points for section C: --

Document where the lab was lacking: .....

.....

D. Personnel (maximum 30 points; assign 0-5 points for each question)

1. Percentage of senior to junior technicians: [is greater than] 75% (5 points); 50% (3 points); [is less than] 25% (0 points)
2. Does the lab employ a qualified supervisor during all hours of operation? Yes (5 points); No (0 points)

3. Are specific staff members assigned to assist us at all times? Yes (5 points); No (0 points)

4. Are doctoral-level scientists or pathologists available for consultation? Yes (5 points); No (0 points)

5. Does the technical staff have expertise in all areas required? Yes (5 points); No (0 points)

6. Does the technical staff receive continuing training, education, competency assessment on an ongoing basis and is this documented? Yes (5 points); No (0 points)

Total points for section D:

Document where the lab was lacking: .....

E. Results for method and instrument comparison studies (validation):

Acceptable0/Unacceptable0.

Explain:

.....

.....

.....

.....

Evaluator's comments:

.....

.....

.....

Lab Manager:

Comments: .....

.....

Lab Approved / Not Approved

Signature: ..... Date: .....

10.2.3. Safety Alert & Lesson Learnt Form:

Incident no:_____ Incident Type:_____ Issue Date:_____

Event Description	Direct & Contributory Factors:
Event Photo	Preventive/Corrective Actions to Be Taken:
Lesson Learnt	

10.2.4.Nonconformance form:

Section 1: Fault / Error category: Details : Initiator name …. Date Fault occurred:
Section 2: Immediate action: Done by: Date:
Immediate action executer: ..... Responding time.....
Problem solved? Y / N Solved by: ..... Date solved …….. Reasons/ sources for problem 1…….. 2……. 3…….

Corrective action taken: 1. 2. 3. Done by : Date :

10.2.5. Corrective action form

Service/ section:

NCR number	Proposed Corrective Action	Responsibility (s)	Time frame	Status	Outcome/Remarks	signature

10.2.6. Internal audits plan form:

Management audit						
Clauses	**Elements**	**Open date**	**Close date**	**Inspection area**	**Auditor**	**Status**
5.1	Organization and management responsibility					
5.2	Quality management system					
5.3	Document control					
5.4	Service agreement					
5.5	Examination by referral laboratories					
5.6	External services and supplies					
5.7	Advisory services					
5.8	Resolution of complaints					
5.9	Identification and control of Nonconformities					
5.10	Corrective action					
5.11	Preventive action					
5.12	Continual improvement					
5.13	Control of records					
5.14	Evaluation of audits					
5.15	Management review					

Technical audits						
Clauses	**Elements**	**Open date**	**Close date**	**Inspection area**	**Auditor**	**Status**
5.16	Personnel					
5.17	Accommodation and environmental conditions					
5.18	Laboratory Equipment, reagents and consumables					
5.19	Pre-examination processes					
5.20	Examination processes					
5.21	Ensuring quality of examination results					
5.22	Post examination processes					
5.23	Reporting of results					
5.24	Release of results					
5.25	Laboratory information management					

10.2.7.1.Example of individual training plan form

Staff name: ……	Staff No: …….
Designation: …….	
Orientation to staff and place	Date ..... person .....

Training plan title	**Start date**	**End date**	**Status**	**Trainer sing**	**Trainee sign**
Reception					
Stool section training plan					
Urine section training plan					
Cobas urisys1800 machine operation					
Wound section training plan					
Sputum section training plan					
Blood culture training plan					
Bactec training plan					
Bactecfx training plan					
Cytospin 4 training plan					
Antibiotic section training plan					
Phoenix training plan					
Nephlometer training plan					
Serology section training plan					
Architect training plan					
Multiscan unit training plan					
Plates washer training plan					

Microscopes training plan					
Slide dryer training plan					
Safety cabinet training plan					
Vortex training plan					
Shaker training plan					
Centrifuge training plan					
Fridges and freezers training plan					
Incubators training plan					

10.2.7.2.Example of competency assessment by unknown sample: Beta- lactum

Name of laboratory/sub section:	Date:

Name of the employee/ Staff number:		Name of competency assessor:	
Name of the assay assessed : Beta Lactum		Source of unknown sample (please select) -Pre-analyzed patients sample -Known samples Examples EQC, IQC	
Sample	Old value	New value	Score
B lactum positive control			
B lactum Negative control			
Unknown sample			
Competency evaluation			
Remediation required			
Reviewed and Approved by:		Date:	

10.2.7.3. Example of competency assessment by direct observation method:

Name of the hospital/ laboratory:	Date of competency assessment:
Name of the assessor/ staff number:	Name of the assessor assistant/ staff number:
Name of the employee / staff number:	Name of the test/ procedure:
Type of evaluation (initial evaluation/re-evaluation):	Evaluation period: _____To_____

	C	N	ATN	Comment
Reading and understanding of the relevant portions of the SOP				

Direct observation				
Work station preparation				
Work station neat and organized				
Follows policies, procedures and rules according to relevant assignments				
Specimen handling and preparation				
Reagent handling and preparation				
Calibration /QC handling, preparation, interpretation and trouble shooting				
Equipment handling and preparation along with maintenance activities and flag interpretation				
Follows the MSDS and guidelines for waste disposal				
Knowledge of LIMS, interface				
Knowledge of acceptable specimen criteria				
Knowledge of unacceptable specimen criteria				

C= Competent, N= Not trained, education plan required

ATN= Addition training required

10.2.7.4. Competency assessment log book.

Competency assessment log book Name of the Laboratory:

Name of the employee/ staff number	Assessment Date	Assessed Task	Assessed result		comment
			acceptable	Re-assess	

10.2.8. New batch acceptability form:

Instrument/Method	Item name	Acceptance Criteria:

Tested lot Number	Date/Time	Performance Report					
		Materials (QC& samples)	Expected Result	Tested result	Accepted/Unaccepted	Corrective action	Verified by
		1					
		2					
		3					
		4					
		5					

Item's Expiry date	
Justification reason for not complying with the procedure	

10.2.9. Declaration form

I am …… hereby taking up the responsibility of **changing the patient identification** from …… To ……

Or other reason

……

……

……

……

As the Department of Laboratory Medicine is not responsible for any allegations

Name of the staff:

Staff No#:

Ward:

Designation:

Signature:

Date:

10.2.10. Method Validation / Verification form

Laboratory: (laboratory name)

Method Validation / Verification Protocol for (insert method name, document number, and document revision, instrument name and serial number)

Section I: Validation /Verification Plan and Protocol

Purpose and Rationale:

To provide objective evidence that the (method name) will meet the laboratory's acceptance criteria and intended use. (method name) provides (quantitative, qualitative, or both quantitative and qualitative) results for the (identification, diagnosis, surveillance, etc) of (analyte(s)).

Statistical methods defined later in this planner designed to address the specific needs of the verification. (method name) is an unmodified FDA approved or cleared test. (method name) is expected to perform in accordance with manufacturer's performance specifications.

Method Description/Intended Use:

See the attached manufacturer's package insert for (Method name), document number (manufacturer's document number), and revision number (manufacturer's revision number).

If applicable, include any limiting factors, such as scarcity of samples that will impact the verification parameters. Also include any application(s) of the method that will not be utilized and thus will not be verified.

Acceptance Criteria:

(Record the expected performance specifications provided in the manufacturer's package insert and the expected performance during laboratory use. In many cases, the performance of a test in a laboratory will not match the manufacturer's claims for performance. It is acceptable for the laboratory to establish lower performance specifications. If the manufacturer does not address a specification, record "N/A", but still provide the laboratory specification)

Specification	Manufacturer's Stated Performance	Laboratory Expected Performance
Accuracy	(enter the percentage)	(enter the percentage)
Precision/ Reproducibility	(enter the percentage)	(enter the percentage)
Reference Interval	Qualitative: (enter whether the analyte is expected to be present or absent in the target population) Quantitative: (enter the range of values that are expected to be seen in the target population)	Qualitative: (enter whether the analyte is expected to be present or absent in the target population) Quantitative: (enter the range of values that are expected to be seen in the target population)
Reportable Range	(enter your the value or range of values as applicable)	(enter your the value or range of values as applicable)
Any other performance characteristic required for test performance	(row may be deleted if not applicable)	(row may be deleted if not applicable)

Sample Requirements:

Required Sample Summary: (rows may be deleted if not applicable)

Total positive samples	#
Total negative samples	#
Sample volume (units**)**	#
Sample matrix	(serum, sputum, spinal fluid, etc.)
Sample matrix	(add rows for each matrix to be verified)

Qualitative Analysis Requirements: include the graphs

Specification	Number of samples	Planned Calculations
Accuracy	(# of positive samples and # of negative samples) will be measured	$\frac{\text{\# of correct results}}{\text{total \# of results}} \times 100\%$
Precision/ Reproducibility	(#) of positive samples and (#) of negative samples will be measured in (#) separate runs over at least (# ≥ 3) days	$\frac{\text{\# of results in agreement}}{\text{total \# of results}} \times 100\%$
Reference Interval	(# of normal population samples) will be evaluated	(manufacturer's suggested range)

Quantitative Analysis Requirements: (table may be deleted if not applicable)

Specification	Number of samples	Planned Calculations
Accuracy	(# of quantifiable samples at specified concentration levels) will be measured	$\frac{\text{result} - \text{true value}}{\text{true value}} \times 100\%$
Precision/ Reproducibility	(# of quantifiable samples at specified concentration levels) will be measured in (#) separate runs over at least (# ≥ 3) days by (# ≥ 2) operators	$\frac{\text{standard deviation}}{\text{measured value}} \times 100\%$
Reference Interval	(# of normal population samples) will be evaluated	average value ± 2 standard deviation
Reportable Range	Quantitative: (# of quantifiable samples at specified concentration levels) will be measured	(linear or polynomial regression)

Origin of Samples / controls/ calibrators:

Sample Material	**Source**	**Description/ Characterization (Lot number / expiry date)**
	(internal or supplier name)	(ATCC Strain #)

Roles and Responsibilities: (Example not intended to be all inclusive)

(Insert name) is responsible for preparing the Method Verification Plan

(Insert name) is responsible for performing the Method Verification

(Insert name) is responsible for Document Management

(Insert name) is responsible for review and approval of the Verification Protocol prior to testing.

(Insert name) is responsible for review and approval of the Verification Protocol upon completion.

Timeline:

Identify expected timeframe for each experiment and establish a timeline for completion of the verification and approval of the method for implementation by the laboratory to report results.

Section I: Plan and Protocol Approval (prior to testing)

_____

Name Date: Title: Quality Manager

_____

Name Date: Title: Team Leader

_____

Name Date: Title: Laboratory Leader

Section II: Summary Report

_____

Statement of Suitability:

The (method name) is an unmodified FDA approved or cleared test for the (quantitative, qualitative, or both quantitative and qualitative) (identification, diagnosis, surveillance, etc) of (analyte(s)). The (method name) is designed to be (a stand-alone analysis or in conjunction with confirmatory procedures listed here).

The method verification is applicable to the documents listed within this summary report.

The method verification of (method name) has been completed according to the documented protocol. The (method name) meets all of the acceptance criteria and is approved for use in the (Insert name) Laboratory.

Limitations/Deviations:

(The method is not appropriate to determine…) and/or (The method is not appropriate for use under… …conditions)

Option 1: The verification protocol has been performed a second time without changes to the procedure or protocol. The reason for the retest is…. All data are attached.

Option 2: The verification protocol has been performed a second time using the revised draft of the procedure. The reason for the revision is…. All draft revisions and data are attached.

Option 3: The test performance cannot meet the originally prescribed laboratory expected performance specifications. The acceptance criteria have been adjusted. (Detail the changes to the criteria.) The reason for relaxing the criteria is….The impact of the changes to the method's intended use is….

Summary of Results (Qualitative)

(Copy/Paste the Manufacturer's Stated Performance and the Laboratory Specification/Expected Performance from the Acceptance Criteria table in Section I. Provide the numbers of samples recorded as positive/negative, as well as the total number of samples used in the calculations)

Acceptance Criteria	**Manufacturer's Stated Performance**	**Laboratory Specification/ Expected Performance**	**Actual Performance**
Accuracy	Copy/Paste from Section I	Copy/Paste from Section I	# positive samples out of # measured positive # negative samples out of # measured negative Overall percentage of correct samples: ##%
Precision/ Reproducibility	Copy/Paste from Section I	Copy/Paste from Section I	# positive samples out of # measured by # scientists over # days were in agreement # negative samples out of # measured by # scientists over # days were in agreement Overall percentage of samples in agreement: ##%
Reference Interval	Copy/Paste from Section I	Copy/Paste from Section I	N/A
Reportable Range	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)

Summary of Results (Quantitative)

(Copy/Paste the Manufacturer's Stated Performance and the Laboratory Specification/Expected Performance from the Acceptance Criteria table in Section I. Provide the numbers of samples recorded as positive/negative, as well as the total number of samples used in the calculations)

Acceptance Criteria	**Manufacturer's Stated Performance**	**Laboratory Specification/ Expected Performance**	**Actual Performance**
Accuracy	Copy/Paste from Section I	Copy/Paste from Section I	The average results of # measurements taken is ##, a ##% difference from the expected value ##.
Precision/ Reproducibility	Copy/Paste from Section I	Copy/Paste from Section I	The Coefficient of Variation (CV) for # measurements is ##%.
Reference Interval	Copy/Paste from Section I	Copy/Paste from Section I	Normal range is ## to ##
Reportable Range	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)	(for quantitative analysis only, row may be deleted otherwise)

Changes to Related Documents:

Section II: Summary Report Approval

_____

Name Date: Title: responsible staff

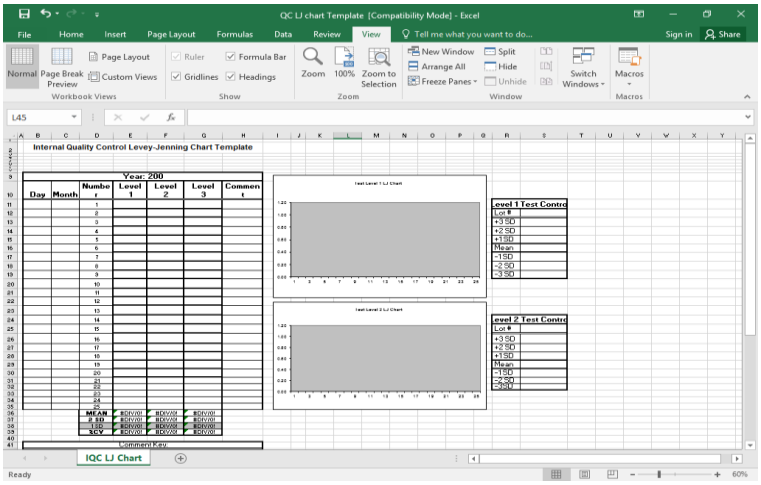
_____

Name Date: Title: Quality Manager

_____

Name Date: Title: Laboratory management

10.2.11.1.Data collection form for establishment of IQC mean and standard deviation (QR code provided)



10.2.11.2. Internal Quality Control Investigation and Troubleshooting form

No	Tasks	Yes	No	N/A	Hints	Comments
1.	QC result is out for more than one parameter.				It could be due to QC material deterioration or instrument problem	
2.	QC result is out on more than one analyser.				It might be due to environmental causes or improper QC material storage.	
3.	Is it a new reagent lot, new QC lot or new calibrator lot?					
4.	Maintenance done?					
5.	Any recent instrument repair?					
6.	Check your environmental conditions: • Check laboratory temperature • Humidity • Materials storage conditions					
7.	Check instrument performance: • Check instrument last service and update. • Check maintenance log sheet • Visual inspection of hardware: 1. leak 2. build up 3. disconnected tubing 4. bent probes 5. worn-out components					

8.	Check Reagent/ Calibrator/ Control Materials: 1. Check the material lot number 2. check material storage conditions 3. check materials stability 4. check the material expiry date 5. Check the materials preparation. 6. Check Calibration and control values 7. check last calibration and last control results					

10.2.12. External Quality Control Review Form

Section:	**Quality Control Officer:**
Scheme Name:	
EQA Prepared by:	**Date:**

Sample Identification		**Sample Assay Date**
Tests	**Cycle No.**	
Date result reported (attach a copy of the results):		Date report received (attach a copy):
Report discussed with (staff name):		Date report discussed:

Actions to be taken				
Analytes	**Action to be taken**	**by whom**	**Expected completion date**	**Date resolved**
	Reviewer signature:			

Participant Number:		**EQA Program:**	
EQA Cycle No.		**Return Date:**	
Reviewed By:		**Review Date:**	
Discussed with:		**Date Discussed:**	
Observations:			

Sample No.	Analyte/Unit	Assay Date	EQA Target Value	Method Median/ Mean	Your Lab Result	Repeated Result

Investigation	Checked By	Target Date	Observations
Check for transcription error from analyzer print out			
Check for errors in unit reporting			
Check for transcription error by scheme organizer			
Check analyzer maintenance log			
Check last calibration date			
Internal QC: Are IQC Ok on EQA analysis day?			
Internal QC: Are QC limits too wide? Use manufacturer mean / SD or established laboratory mean / SD			
Reagent status (stability / expiry date)			
Observations from repeat analysis on different analyzer (if required)			
EQA sample preparation (wrong: reconstitution, thawing, vortex.etc)			
EQA sample processing method (pipetting, sample quantity, dilution method..etc)			
Qualitative sample result interpretation			
Check staff competency and training			
Comments from the In-charge of the section:			

Reviewer Conclusions:	
Signature:	**Date:**

10.2.13.1. Interface Validation Report (HIS & LIS)

Tested component:----------

Test name (if applicable):----------

Date:----------

Sample ID	Download of patient demographics	Download of specimen details (type, time, institution etc.)	Download of tests ordered / short forms	Upload of Results with unit/ reference range/ comments	Result format		Review / Provisional release (if applicable)	Auto release of results	Results & comments appearance to end users
					Values/ qualitative/	Normal/ Abnormal view with alert			

Note: The table content can be modified according to the department work requirements. Put **tick** if validation is correct, **cross** if it is not, and **dash** if not applicable.

Continuation of form number 10.2.13.

Conclusion:

□ Acceptable

* Acceptable criteria: No discrepancies found, No extra work is needed

□ Not acceptable

* Unexpected outcomes:

Reason:----------

Corrective action:----------

Retested by:----------Date:----------

Result:

Conclusion: acceptable Not acceptable

Reason:----------

Interface validated by:----------

Date of validation:----------

Approved by:----------Date:----------

10.2.13.2. Calculation Validation Report

Test name:----------

Date:----------

Conclusion:

□ Acceptable

* Acceptable criteria: No discrepancies found, No extra work is needed

□ Not acceptable

* Unexpected outcomes:

Reason:----------

Corrective action:----------

Retested by:----------Date:----------

Result:

Conclusion: acceptable Not acceptable

Reason:----------

Calculation validated by:----------

Date of validation:----------

Approved by:----------Date:----------

10.3. Checklists

10.3.1. Management / organization and management responsibility checklist:

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partial comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.1.1.General the following management elements are available in the quality manual (QM) : • **Organizational chart (s)** The chart is Clear and displayed.					
• **Legal Entity** Is stated and if applicable licensure information					
• **Ethical conduct** agreements ensuring the following: o Compliance with health policies, laws and regulations local or international.					

○ Maintenance of Confidentiality & privacy					
○ Respecting human rights, colleagues and patients.					
○ Accountability of Medical Laboratory personnel					
○ Application of clinical research ethics through approved bodies.					
○ Freedom of Management and personnel from any undue commercial, financial, or other pressures affecting work quality**.**					
• **Lab director/HOD/Manager** ○ Name, documented trainings, qualification and accountability in line of command, are available					
○ Clear roles and responsibilities of administrative, professional, advisory, organizational, scientific and educational.					
○ Delegation to staff in focused areas e.g. Deputy Lab					

management, quality management, health and safety..etc.					
○ Ensuring of quality policy implementation					
○ Ensuring clinical advice provision					
○ Designing and implementing contingency plan during emergency					
5.1.2 Management responsibility • **Management commitment** laboratory management obligation towards application and improvement in quality management system(QMS) is available and effective via the following: ○ Staff needs and users requirements are met					
○ Quality policy is founded					
○ lab quality objectives are planned and established					
○ Responsibilities, authorities and interrelationships are					

described for all personnel					
○ Communication channels are set					
○ Quality manager /officer is assigned					
○ Management reviews leading					
○ Staff competency for their assigned activities					
○ Adequate resources are available for total testing process					
• **Needs of user** Management commitment to provide the service is available through documents covering customer focus (i.e. complaints, and incident reports), advisory and interpretative services, service agreement and assessment of user satisfaction					
• **Quality policy** Is available and as following: o Appropriate to the purpose of the organization					
o Including a commitments					

towards good professional practice, compliance with the requirements and continual improvement					
o Provision of framework for establishing and reviewing quality objectives					
o Communicated and understood within organization.					
o Reviewed for continuing suitability					
• **Quality objectives and planning:** Launched to meet user requirements within the organization.					
Measurable and consistent with quality policy					
Integrity of QMS ensured in case of any change					
• **Responsibilities, authority and interrelationships** Are defined, documented and communicated.					

Importantly organizational chart, personnel policies and job descriptions.					
• **Communication** Is effective with staff through regular meetings e.g. management review, departmental meetings, quality management and health safety.					
All meeting minutes recorded and stored.					
Communication externally including : patients, healthcare providers , suppliers and referral laboratories					
• **Quality Manager / Officer** Is selected and identified to the lab					
Reissue of QM section in case of change position holder					
The responsibilities as follows : o Ensuring QMS established, implemented and maintained					
o Ensure maintenance and distribution QM					

and associated documents					
○ Maintain a master list of current versions of quality documentation					
○ Establish quality team as needed with defined responsibilities					
○ Manage continuous improvement programs including internal audits					
○ Coordinate laboratory accreditation activities					
○ Train personnel on QMS activities					
○ Monitor QMS via monitoring of quality objectives and plans					
○ Reports QMS performance to management					
○ Monitor Internal and external quality programs					
○ Mange incidents , complaints and non-conformances					

10.3.2. Management / Quality Management System checklist:

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**		**Rating**		
		Comply (1)	Partial comply 0.5	Not comply (Zero)	Not applicable

			OFI	NCR	
5.2.1. General Requirements • Documented implemented quality management system (QMS) which complies with Quality manual requirement					
• QMS achieves the quality policy objectives to meet the needs of the users					
5.2.2 Documentation requirements **5.2.2.1 General** The QMS documentation includes: •Statements of quality policy and quality objectives •The Quality Manual					
•Plans					
•Quality processes					
•Quality procedures •Technical procedures					
•Forms					
•Minutes					
•Checklists					
•Charts					

•Reports					
•Audits					
•Non-conformances					
•Notifications					
•Job description					
•Health and safety document					
• Other applicable regulations and guidelines documents					
5.2.2.2.The Quality Manual (QM) • QM is established and maintained					
• QM contains the needed policies for establishing QMS.					
• QM outlines the structure and scope of QMS.					
• QM states the quality policy, quality objectives, and other supporting managerial and technical procedures.					
• QM defines the roles and responsibilities of managerial, technical and quality personnel					

• All staff has access to and is instructed on the use and application of the QM and the referenced documents.					

10.3.3. Management /Document controlchecklist

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partial comply OFI 0.5	Not comply NCR Zero	Not applicable

Laboratory Document for quality management system framework is available					
All documents written preferably as per the ministry of health document control process					
Ensure all elements available in laboratory documents • Document Title					
• Document code on each page					
• Date of the latest version					
• Version number					
• Page number to total number of pages					
• Elements of the templates					
• Authority for issue					
• All documents issued as part of the QMS are reviewed and approved by authorized personnel before issue.					
• Only (latest) approved version is available					
• Updating the documents periodically or if required					

• Updated amendments are maintained, marked, initialed and dated.					
• Active controlled documents maintained including soft or hard copy.					
• Inactive or obsolete documents marked, removed and archived					
• Backup of all laboratory documents maintained					
• Master list for all documents maintained					

10.3.4. Management / Service agreement checklist

Laboratory / section name: **Date of audit:** **Name of auditor:**

		Rating

Clause & Requirement	**Comment, Observations, evidences**	Comply (1)	Partial comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.4.1. Establishment of service agreements Availability of documented procedure for the establishment and review of agreementswith laboratories					
The consideration of the request acceptance as an agreement is available.					
All needed details are specified by requester are available					
The agreement ensures following conditions: • facility and resources are meeting the requirements					
• Meeting end users requirements by defining, specifying and documenting the used examination method.					

• The staff performances are supported by skills and expertise.					
• The selection of examinations based on user's requirements and clinical needs.					
• Deflection is notified timely to the end user					
• Reference is made to any work referred to a referral laboratory or consultant					
5.4.2 Review of service agreements periodically or as needed review the agreements, considering all testing aspects and workload					
Record and maintenance of Statistics and significant minutes reviews					

10.3.5. Management / Examination by referral laboratories checklist

Laboratory / section name: Date of audit: Name of auditor:

			Rating

Clause & Requirement	Comment, Observations, evidences	Comply (1)	Partial comply 0.5 (OFI)	Not comply NCR (Zero)	Not applicable
5.5.1 Selecting and evaluating referral laboratories and consultants: • Documented procedure for selecting and evaluating referral laboratories is available for non – MOH lab					
• The procedure fulfilled the following conditions: o Evaluation of referral laboratories and referral consultants' qualification, as well as controlling service consistency.					
o Agreements / contract is checked and evaluated regularly					
o Periodic reports are recorded and kept.					
o Both referral laboratories and experts are listed.					

○ Details of requests and results of all referred samples are stored.					
5.5.**2 Provision of examination results** • Ensuring that the referral laboratory examination results and findings are provided to the test requester.					
• All important elements of the referral laboratory's findings are included without changes					
• The test report includes the referral laboratory or Lab specialist names.					
• The authors of any remarks are identified.					
• Suitable reporting method is used (e.g. language, processing times, measurement accuracy, transcription procedures, and interpretative skills)					

10.3.6. Management / External services & supplieschecklist:
Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partial comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.6 • Purchased items and suppliers selection met the laboratory's quality requirements.					
• Documented procedures are available for: Selection and purchasing of external services.					
Equipment management					
Reagents and consumable supplies management					
• Laboratory select, approve and evaluate the suppliers					
• Records of evaluations of suppliers are maintained.					

10.3.7. Management / Advisory servicechecklist:

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partial comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.7 Test manual or a website offering advisory services for the users is available on the following: • Choice of examinations and use of the services, e.g. type of sample, indications, limitations and frequency of requesting)					
• Individual clinical cases					
• Professional judgments on the test result interpretation					
• effective service utilization					
• Consulting on scientific and logistic matters					
Trained pathologist provides clinical advice and interpretive comments.					

In case of no pathologist, Laboratory collaborates with the nearest higher hierarchy institutions to offer clinical advice.					

10.3.8. Management requirements / Resolution of complaints checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partial comply (0.5-OFI)	Not comply (Zero-NCR)	Not applicable
5.8 Procedure for the handling of and dealing with complaints is available					
Feedbacks and claims (from staff, clinicians, patients, suppliers or other parties) are documented alongwith : Investigations					
Corrective actions					
Preventive actions					
Archiving					

10.3.9. Management /Identification and control of nonconformities checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Not comply (NCR Zero)	Partial comply (0.5-OFI)	Not applicable
5.9. Nonconformities handling and management procedure is available.					
• Responsibilities of nonconformities are designated					
• Potential sources of NC are Identified					
• immediate actions taken are defined					
• The significance and the extent of NCRs are determined.					
• NCR examination results are held or recalled if already released					
• The root causes are defined and eliminated					

• Review of records at regular intervals to detect trends and initiate corrective action.					

10.3.10. Management requirement / Corrective action checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partial comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.10. Documented procedure of corrective action process is available. The procedure involves : • Reviewing the detected nonconformities (NC). • Determining the root cause of NC when needed • Determining and implementing corrective action • Recording the results, and evaluating effectiveness of corrective action.					

• Monitor the recurrence of the problem • Take the necessary action (remedial and corrective) • Otherwise if the problem is detected before the error occurs, take preventive action. • Keeping and maintaining all NC records as a reference.					

10.3.11. Management / Preventive action checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partial 0.5 OFI	Not comply Zero NCR	Not applicable
5.11. Documented procedure for preventive action (to eliminate the potential causes of nonconformities (NC) and to reduce the likelihood of the re-occurrence) is available.					
Proactive Preventive action process is activated by: • Data review and analyze (trends, risk analysis and EQC).					
• Determination of root cause(s) of impending NC.					

• Evaluation of the need for preventive action					
• Implementation of needed preventive action					
• Recording results of preventive action					
• Review the effectiveness of the preventive action					

10.3.12. Management / Continual improvement checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partial comply (0.5) OFI	Not comply (Zero)	Not applicable
5.12. Laboratory quality management system effectiveness is continually monitored for improvement.					
Continual improvement program has commitment, planning, structure, leadership, participation and engagement					

Laboratory regularly ensures: • Contribution in quality improvement process					
• Planning, developing, and implementing of the documented actions					
• Reviewing action effectiveness					
• Approval of changes in quality management system before implementation					
• Provision of quality indicators					

10.3.13 Management / Control of records checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	Comment, Observations, Evidences	Rating			
		Comply (1)	Partial comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.13 Quality and Technical Records The laboratory has a well-established procedure for identification, collection, indexing, access, storage, maintenance, amendment and					

safe disposal of quality and technical records.					
Examination records created concomitantly for all activities affecting the quality of examination.					
Records amendment time and date are documented along with the assigned personnel identity.					
Records retention time are defined					
Safe and suitable storage conditions prevent records from damage and deterioration.					
Records shall include, at least, the following: • Supplier selection & performance. • Staff portfolio & competency. • Examination request forms • Reagents & materials information, e.g. lot documentation, certificates of supplies, package inserts. • Examination results • Instrument maintenance records. • Calibration records • Quality control records					

• Incident reports & action taken. • Risk management records • Nonconformities, corrective and preventive actions taken. • Internal and external audit records. • Inter-laboratory comparison sample examination result. • Records of quality improvement activities. • Meeting minutes and records of decisions made about the laboratory quality management activities. • Management review records.					
All records are accessible and available for quality management review					

10.3.14. Management / Evaluation of audits checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partial comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.14.1General Activated plan for the process of quality assessments evaluation and QMS internal audits.					

The results of evaluation and improvement activities discussed in the management reviews					
5.14.2 Periodic review of requests, and suitability of procedures and sample Systematically review samples requests and evaluate the appropriateness of the volume and methods used for the test.					
Maintaining periodic updates of sample requirements by authorized reviewer.					
5.14.3 Assessment of user feedback Customer feedbacks are regularly collected, analyzed and reviewed to meet the needs of users.					
Satisfaction surveys are available					
Results of the survey are used to design the quality objectives yearly					
Records of information kept and actions taken.					
5.14.4 Staff suggestions Staff suggestions are encouraged for the improvement					

A suggestion is discussed and evaluated during departmental meetings.					
Minutes records maintained					
5.14.5 Internal audit Documented procedure for internal audit is available.					
Formal auditing process is carried out by a well trained auditor					
Staff avoids auditing their own activities.					
Auditing cycle is completed in one year.					
When NC is identified, Corrective action is taken.					
The results of internal audits are submitted to laboratory management for review.					
5.14.6 Risk management • Critical work processes and potential failures on examination results are assessed					
• Possible risk that endangers staff safety is identified.					
• Modification of the processes to reduce or eliminate the detected risks.					
5.14.7Quality indicators Quality indicators are monitored to evaluate performance of critical aspects in total testing processes (TTP).					

Indicators are periodically reviewed, to ensure their continued appropriateness.					
When outliers are identified, appropriate corrective actions are taken and documented.					
5.14.8 Reviews by External auditors: Audits are performed periodically by external auditors.					
When non-conformities are identified, appropriate corrective actions is undertaken and documented					

10.3.15. Management / Management review checklist

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement		**Rating**			
		Comply (1)	Partial comply (0.5)	Not comply (Zero)	Not applicable

	Comment, Observations, Evidences		OFI	NCR	
5.15.1: General Laboratory management LQM review of system carried out at regular intervals to offer standard testing services					
The outcome of the review is placed into a plan that includes goals, objectives and action plans.					
5.15.2. Review input Management review importantly includes : • Action taken from the feedback of the previous management reviews					
• Periodic review of pre-examination requirements and procedures					
• Assessment of user feedback					
• Staff suggestions					
• Internal and external audits					
• Risk management and H&S audit					
• Quality indicators					

• External quality assurance scheme (EQA)					
• Analysis and resolution of complaints					
• Nonconformities					
• Continual improvement outcomes					
5.15.3. Review activities All information responsible for causing nonconformities, trends and patterns are analyzed and Updated including quality policy and quality objectives					
The contribution of the laboratory to patient's care is evaluated objectively					
5.15.4.Review output The management review output documents decisions and actions taken: • Improvement of the quality management system and its procedures.					
• Improvement of the laboratory services to patient care.					
• New quality indicators to be established with new quality objectives					
• Requirements of the resources					

Feedback of reviews and required actions is recorded, reported to the laboratory staff and completed within defined time.					

10.3.16. **Technical / Personnel checklist**

Laboratory / section name: Date of audit: Name of auditor:

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.16.1 general: Documented procedure for personnel management is available					
5.16.2 Personnel qualifications The qualification requirements meet the institutional regulations & guideline					
Availability of records for the personnel relevant educational and professional qualifications					
The educational qualifications, training, experience and further skills relates to test performed.					
5.16.3 Job description The laboratory personnel designations follow health system regulations for medical and biomedical work					

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
The laboratory management provides job descriptions for all personnel					
5.16.4 Personnel Induction program All new employees went through the Induction program within early stage and before being assigned to any duties					
Aspects of induction program included during orientation: • Institution's roles and regulations					
• Infection control and prevention program orientation					
• Occupational health and safety program orientation					
• Fire safety program orientation					
• Information technology (IT) system orientation					
• Library facility orientation					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.16.5 Training Each staff have an individual training plan covering the assigned tasks that includes : • Quality management system • Assigned work processes and procedures • laboratory information system • Health and safety • Confidentiality of patient information • Ethics					
Training plan is flexible once needed in shifting or reassigning staff in crisis or staff shortage.					
Training Supervision is available for all personnel at all times					
Effectiveness of the training plan is reviewed and evaluated regularly.					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.16.6 Competency assessment Competency assessment shall be conducted following the training at regular basis or when needed.					
The content of competency designed based on tasks					
The competency assessment performance evidence recorded and saved.					
Re-Training performed and recorded when the result of competency assessment is not within the expectation.					
5.16.7 Review of staff performance The formal appraisal of the overall performance is periodically done for each staff					
The assessment covers work needs, individual skills & plans and achieving work objectives towards improving productivity					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.16.8 Continuing education and professional development Each lab staff who participates in the examination processes takes part in continuing education program					
The effectiveness of the program is periodically reviewed by responsible staff					
5.16.9 Personnel records Individual file for each staff is maintained securely and confidentiality that remains accessible as needed and relevant staff					
The following list of records for each staff includes : • Employment details including; National identity card, CV and emergency contact information					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
• Copy of certification, educational, work experience and professional qualifications					
• Health information, including records of work injury or exposure to occupational hazards, vaccination history					
• Job descriptions document with staff signature indicates that staff is agreed about all contents					
• Competency assessments performance					
• orientation of new staff to the laboratory environment					
• Records of continuing education attended, training and achievements					
• Individual Training program with date and signature oftrainee and trainer.					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
• Review of staff performance					

10.3.17. Technical / Accommodation and environmental conditions

Laboratory / section name: Date of audit: Name of auditor**:**

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.17.1. **General** The laboratory has the basic facilities that ensures performing laboratory work under quality and safety and occupational measures					
laboratory space ensures the quality of services					

Laboratory personnel trained for Health & safety					
The laboratory collaborates with the concerned departments to maintain the same regulations at sample collection and examination sites.					
5.17.2. Laboratory and office facilities • The entrance to laboratory areas is regulated					
• The laboratory authorizes the access to medical information, patient samples and laboratory resources					
• The laboratory has facilities that are suitable to perform laboratory examinations including uninterrupted energy resources, water supply, ventilation etc.					
• The laboratory communication system is compatible with the size and complexity of lab work					
• The laboratory has safety facilities and devices and regularly maintained (including eye wash, emergency shower, alarm system					

for fire and freezer/fridges)					
5.17.3: **Storage facilities** The laboratory has: Sufficient storage space with regulated conditions for work, integrity of sample materials, documents, equipments, reagents, consumables, recodes, results and other items.					
Cross-contamination prevented during storage					
Proper storage and disposal facilities for dangerous and hazardous material					
5.17.4. Staff facilities Set up for sufficient facilities that include: rest room, washing room, drinking water, storing personal places with adequate ventilation and lightings					
5.17.5 Patient sample collection facilities The patient sample collection facilities are appropriate for staff , patient and accompanying person					
The reception/waiting area is allocated separately from collection areas					
The reception/waiting areas are provided with first aid kits, disabled access, privacy, and comfort and toilet facilities					

Equipment for resuscitation are available, maintained and under local regulations					
Presence of appropriate facilities and procedure for collection that ensure valid results and good quality of the examination					
5.17.6 Facility maintenance and environmental conditions Monitor, control, and record environmental conditions (temperature, humidity, noise etc..)					
The laboratory area is clean					
The laboratory eliminates the factors that invalidate the results or adversely affect the quality of the examination (lightning, hazardous fumes, workflow, vibration)					
Examination with special/sensitive procedures or highly hazardous materials are processed in a segregated room					
There are allocated locations for work that require quiet and uninterrupted work environment such as cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing and review of molecular mutation results					

10.3.18. Technical / Laboratory Equipment, Reagents and Consumables
Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
Equipment 5.18.1. **5.18.1.1. General**					

Laboratory is equipped with needed instrumentation					
Documented procedures for the equipment management is available					
Laboratory has the access to equipment contract					
5.18.1.2 Equipment acceptance testing Equipment acceptance testing is performed according to validation/verification procedure					
validation/verification is carried out to all new, upgraded, majorly repaired or re-allocated					
Validation/verification for temperature sensitive equipment is carried out.					
Each items of the equipment is labeled with unique identifier					
5.18.1.3. Equipment instructions for use Clear and up to date guidance on handling the equipment is available and accessible					
Equipment is operated by authorized , and trained staff					

Laboratory collaborates with suppliers for staff training					
5.18.1.4 Equipment calibration and metrological traceability Procedure for the equipment calibration is available					
Procedures for thermal and mechanical equipment calibration is available					
5.18.1.5 Equipment maintenance and repair All lab equipment has maintenance, repair and decontamination procedures					
Equipment maintenance and repair carried under needed safety measures.					
Equipment repair performed by authorized staff					
Equipment is clearly labeled as out of order and hold testing until it gets repaired.					
Once the equipment is repaired, the laboratory ensures the equipment performance.					
All equipment maintenance, repair, defects and decontamination is documented					

5.18.1.6Equipment adverse incident: Error or fault detected in the equipment investigated by the concerned staff and the manufacturer.					
Faulty result released during equipment breakdown, is recalled and the change is informed.					
contingency plan during the breakdown is available					
The plan is activated to maintain the needed services.					
5.18.1.7 Equipment records Maintains documents and records of all the equipment and its items according to local guidelines that include: • Equipment identification • Date of installation. • Location. • Condition (new, used or reconditioned). • Validation/ verification record. • PPM records. • Failures, malfunctioning and repairs. • Other records e.g. (equipment calibration, package inserts, controls)					

• Important contacts					

5.18 Technical / Laboratory Equipment, Reagentsand consumables

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.18.2. Reagents & consumables **5.18.2.1. General**: Documented procedure for purchasing, reception, storage, acceptance testing and inventory management of reagent and consumables is available.					
Documented procedure for contingency plan is available					
5.18.2.2 Reagent and consumables reception and storage Receiving location is adequate with proper handling conditions					
5.18.2.3 Reagents and consumables acceptance testing Documented procedure for batch validation is available.					
A new reagent lot or new shipment or any change in reagent and procedure is verified prior to use					
Reagent defect is recorded and raised					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.18.2.4 Inventory management for laboratory reagents and consumables Inventory control system is available					
Inventory control system activated to timely follow up the stock including (uninspected, expired or unacceptable).					
laboratory reagents and consumables contingency plan is available and implemented					
5.18.2.5 Instruction for the use of the laboratory reagent and consumables Instructions are available and accessible.					
5.18.2.6 Adverse incident for reagents and consumables For unaccepted items, incidents are investigated and reported					
Erroneous result release is recalled and informed the change					
Activation of contingency plan during interruption					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.18.2.7 Records for reagents and consumables Record keeping system is available and containing: • Item code • Quantity requested / issued • Price of item • Item manufacturer's name /batch /lot number • Supplier /manufacturer Contacts • Dates of receiving, expiry & usage (starting & ending) • Receiving conditions (e.g., acceptable or deteriorated) • In-house prepared reagent traceability record with the person initial and preparation date. • Manufacturer's recommendations (package insert) • Item initial acceptance records (e.g. validation / verification) • Performance records IQC, calibrator, customer feedbacks , EQC) confirming the ongoing acceptance for use					

10.3.19. Technical / Pre-examination process

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.19.1General The laboratory has documented procedures and needed information for the pre-examination processes ensuring reliable results.					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.19.2Information for patient and users The laboratory has recommended information available for patients and users: • laboratory location • Laboratory working hours • Laboratory contacts • List of examinations • List of referred examinations • List of examination offered outside normal working hours • completing request form • sample storage prior to transportation to the laboratory • Requirement for patient consent • Criteria for sample acceptance and rejection • List of factors affect the results • Clinical review on test ordering and interpretation • guidance on protecting personal information • complaints procedure					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.19.3Request form information The request form has the minimal required information including: • Institution name and approved logo. • Patient identification including: patient three names with tribe/family, gender, date of birth, institution patient ID, address and contact details. • Name of authorized personnel to request the examination, the requesting location and contact details • Type of primary sample and the origin • The approved name of required examinations. • Clinical information • Date and time of collection • Date and time of receiving					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.19.4 Primary sample collection and handling **5.19.4.1general** Documented procedure for sample collection and handling is available for personnel responsible for sample collection					
Update for any deviations, exclusions or additions					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.19.4.2 Instruction for collection activities The laboratory instructions on collection activities include: • Clinical information. • Patient details on primary tube. • Verification if patient meets the pre-examination requirements • Instruction for sample collection (labeling, container type and additives) • Details of person collecting the primary sample, date and time. • Instruction on storage and transportation of the primary samples until delivery to laboratory. • Instructions on safe disposal of collection materials after use					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.19.5 sample transportation The laboratory has documented procedure on transportation of samples which is monitored well to ensure samples reach laboratory: • Within a recommended time frame, • At ideal temperature • With maintained integrity, • Under safe condition for the sample carrier, public and laboratory staff					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.19.6 Sample reception The lab reception checks the following • Correspondence of forms details with primary tubes • documentation of Acceptance/rejection criteria • Record for samples errors • Record for received samples • Availability of instructions for handling urgent and unrepeatable (precious) samples					

10.3.20. Technical / Examination processes checklist

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.20.1. General use of published referenced guidelines for developing : - Examination procedures - Validation / verification procedure					
In-house developed procedures are approved by experts.					
5.20.2. Validation/ verification of Examination Procedures: • Manufacturer examination procedures are used					
• Method performance specifications and manufacturer claims are Verified					
• Validation / verification results are reviewed by authorized trained staff.					
• Validation / verification results					

are documented and archived					
5.20.3. Reference Intervals or Clinical Decision Values Reference intervals and clinical decision values are periodically reviewed under the following conditions: • Inappropriate for the reference population					
• laboratory changes an examination or pre-examination procedure					
• Updates in international guidelines of professional bodies					
5.20.4. Documentation of examination procedures • All procedures are documented and available at workstation					
• All procedures are listed and subjected to document control system.					
• Only Current procedures are maintained in workstations					
• The instructions for use (i.e. package insert) are included in the examination procedures					

• Any deviation is reviewed and documented.					
• The deviation is explained and communicated to the users					
• Each new kit version with major changes is checked for performance and suitability for intended use.					
• Procedural changes are dated and authorized.					

10.3.21. Technical / Ensuring the Quality of examination results checklist

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	Comment, Observations, Evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.21. The laboratory ensures the reliability and the quality of the examination through running internal quality control and enrolment in external quality scheme.					
Laboratory ensures Implementation and monitoring of pre examination and post examination processes for reliable outcome					
There is no result fabrication.					
5.21.1.Quality Control **5.21.1.1 General**: The laboratory has a designed and well-described internal quality control procedure to verify the achievement of					

the intended quality of result.					
5.21.1.2 Quality Control Materials The laboratory selects quality control (QC) materials that: mimic patient samples, Concentrations around the clinical decision ranges Third party quality control materials are preferable					
5.21.1.3 Quality Control Data The laboratory shall have a document procedure for IQC failure					
Ensures the rejection and reexamined after quality control result correction in case of IQC rules violated,					
Ensures re-examination of randomly selected patient samples after the last successful IQC run					
Review the IQC data for shift or trend along with corrective and a preventive action					
5.21.2 Inter-laboratory Comparison **5.21.2.1 Participation** The laboratory participated in external quality control (EQC) program					

EQC documented procedure is available					
Laboratory monitor and Corrective action taken if needed for any unacceptable performance					
5.21.2.2. Alternative approaches The laboratory has other approaches in case of unavailability of inter-laboratory comparison scheme, in order to provide evidence for determining the acceptability of examination results. Such materials may include: • Certified reference materials; • Previously examined samples; • Exchange of samples / slides with other laboratories; • Control materials that are tested daily in inter-laboratory comparison programs.					
5.21.2.3 Analysis of inter-laboratory comparison samples • Analyzes the EQC samples as patient samples by same procedure and laboratory personnel who routinely examine patient sample.					
• Comparison results not to be communicated with other participants					

before the submission date.					
5.21.2.4 Evaluation of laboratory performance The laboratory has a procedure for reviewing comparison reports with corrective and preventive actions needed.					
5.21.3 Comparability of examination results Compares results of same or different procedures, equipments, and methods and locations Notifies end users in case of any procedures, equipment and method change or update					

10.3.22. Technical / Post–Examination Processes checklist

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**	**Rating**			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero)	Not applicable

5.22.1. Review of Results Technical review process is established to ensure that authorized personnel review the results of examinations before release.					
Established criteria for automatic selection and reporting of results are reviewed, approved and documented.					
5.22.2 Storage, Retention and Disposal of Clinical Samples Written procedure for storage, retention, access and safe disposal of clinical samples is available					

10.3.23. Technical / Reporting of Results checklist

Laboratory / section name: **Date of audit:** **Name of auditor:**

		Rating

Clause & Requirement	**Comment, Observations, evidences**	Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.23.1 General Details of specific reporting requirements for each examination are available in the SOP.					
Result of examination is reported accurately, clearly and unambiguously.					
The format of reporting is stated in the SOP.					
Notification procedure of critical and high risk results available					
Notification procedure of delayed reporting of results is available					
Procedure to ensure the correctness of the transcription process is available.					
Advice on examinations and interpretation of results is available and meets the following: The inclusion of clear, concise and unambiguous automatic comments on reports The inclusion of manual comments added by clinical staff					
Further clarification is provided once sought					

5.23.2 Report Attributes Report attributes meets the users' needs and communicate the result effectively and includes the following : • Comments on sample quality that might compromise examination results is added					
• Comments regarding the sample suitability (acceptance /rejection criteria) are included					
• Document on Communicated results (e.g. critical and high risk)					
• Interpretive comments on results, where applicable.					
5.23.3 Report Content Laboratory report contains the following : • The health institution identifier					
• Laboratory Section and Laboratory Number (Specimen Number)					
• Patient identification and patient location on each page					
• Identification of the requester and the location					
• The sample collection and receiving time.					
• The type of sample received					

• The measurement procedure utilized (if appropriate)					
• Examination results reported in SI units, units traceable to SI units, or other applicable units.					
• Biological reference intervals, clinical decision values (if appropriate)					
• Result interpretation (if appropriate)					
• Cautionary or explanatory notes					
• Identification of the person reviewing the results and authorizing the report release.					
• Date and time of release					
• Page number to total number of pages					

10.3.24. Technical / Release of Results

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**		**Rating**		
		Comply (1)	Partially comply 0.5 OFI	Not comply (Zero)	Not applicable
5.24.1 General The authorization privilege for the release of each examination result is stated.					
Clear instructions for the release of results, considering the following: • If sample quality may compromise the result					
• If critical / high risk result encountered					
• If the results are delayed					
• If the results have transcription errors					
• If results are transmitted as an interim report.					
• If results are distributed via telephone or other means					

5.24.2 Automated Selection and Reporting of Results Specific protocols which cover the automatic release are available and meet the following : • Available approved Clear defined criteria and understood by staff					
• Validated criteria are functioning with periodic verification					
• The impact of sample interferences may have upon the examination results is tested.					
• The incorporation of analytical warning messages from instruments					
• Results selected for automated reporting are identified at the point of review and include date and time					
• The Process can be suspended rapidly if required.					

5.24.3 Revised Reports Procedure for amendment of reports is available and ensures the following: • The report is identified as a revision and includes the date and patient's ID in the original report					
• The user is made aware of the revision					
• Record shows time , date of change and staff name responsible for the change					
• The original report entries remain in the record and could be accessed.					
• Incident report is recorded if the change is significant and affects the clinical decision.					

10.3.25. Technical requirements/ Laboratory information management checklist

Laboratory / section name: **Date of audit:** **Name of auditor:**

Clause & Requirement	**Comment, Observations, evidences**		**Rating**		
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.25.1general The procedure for laboratory information management is established					
The laboratory has the access to patient data and information needed to provide the service that ensures confidentiality and security					

Clause & Requirement	Comment, Observations, evidences	Rating			
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
5.25.2Authorities and responsibilities The laboratory defines the authorities, responsibilities and access levels for the laboratory personnel including results entry, modification, releasing and recalling					
5.25.3Information system management LIS has settings for collection, processing, recording, reporting, retrieving of examination data					
• validated by supplier and verified by laboratory					

Clause & Requirement	Comment, Observations, evidences		Rating		
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
• data are documented and protected from unauthorized access or loss					
• operated as to fulfill the manufacturer specification and provided with alternatives when the system is non-computerized					
• maintained properly to ensure the integrity of the data, availability of failure recoding system and corrective actions					

Clause & Requirement	Comment, Observations, evidences		Rating		
		Comply (1)	Partially comply (0.5) OFI	Not comply (Zero) NCR	Not applicable
• managed by informatics department and meets the national and international requirement for data protection					
• maintained with presence of action plan to provide a constant service during system upgrade or failure					

11. Document History and Version Control

Version	Description	Review Date
1	Initial Release	December 2025

12. References:

Title of book/ journal/ articles/ Website	Author	Year of publication	Page
Laboratory biosafety manual 3rd ed. Geneva	WHO	2004	31
https://academic.oup.com/labmed/abstract	Ms.Elsa Quam	2006	347
International Organization for Standardization 15189:2012 (E)	ISO 15189	2012	-
Clinical Laboratory Improvement Amendments (CLIA) Complaints, Department of health & Human Services-USA.	Center for Medicare & Medicaid Services (CMS)	August 2009	-
Supplement to the laboratory quality management system training toolkit, module 16 - documents and records quality manual version 2013	WHO	2013	-
CLIM Center Infectiology Lao -Christophe Mérieuxquaity manual	CLIM	2017	-
German Medical Association Working Group of the German Medical Association Guidelines of the German Medical Association on Quality Assurance in Medical Laboratory Testing	German Medical Association	September 2014	
Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance Complaint Process Fact Sheet.http://health.nv.gov/HCQCC.htm	Bureau of Health Care Quality and Compliance (BHCQC)	2013	-
Complaints and investigation, Bureau of Health Care Quality and Compliance (BHCQC)	Bureau of Health Care Quality and Compliance (BHCQC)		-
Sentinel Event/Adverse Incident/Adverse Occurrence Reporting,Volunteer State Health Plan,		2012	-
Incident Report Form https://www.gov.uk/government/organisations/department-of-health,,	National Patient Safety Agency	2009	-
Advanced Incident Report System https://www.eforms.nrls.nhs.uk/staffreport/,	Dr. Lui Siu Fai,	2009	-

WHO draft report guidelines of Adverse Events Reporting & Learning System, World Health Organization	WHO	2005	-
To err is human: Building a safer healthcare system	IOM	1999	
ISO 9001 ,2012, 2015	**ISO**	**2012,2015**	
Management of continual improvement for facilities and activities: A structured approach. https://www-pub.iaea.org/MTCD/publications/PDF/te_1491_web.pdf	IAEA	April 2006	1-78
Complete guide to corrective action vs. preventive action https://advisera.com/blog/2021/07/19/complete-guide-to-corrective-action-vs-preventive-action/	Mark Hammar	2021	-
Risk-based thinking replacing preventive action in ISO 9001:2015 – The benefits	Ohn Nolan	2015	-
14.3 Problem Solving and Decision Making in Groups https://open.lib.umn.edu/communication/chapter/14-3-problem-solving-and-decision-making-in-groups/	The University of Minnesota Libraries	2009	-
Project Controls: What is it and why is it important? https://projectcontrolsonline.com/definition-and-importance-of-project-controls	Project control online (repository)	18th January 2014	
Laboratories medicine committee report recommendation	Laboratories medicine committee	2012	
Laboratory Biosafety manual 3rd ed. Geneva	WHO	2004	31
Laboratory services and medical supplieshttps://www.msh.org/sites/msh.org/files/mds3-ch47-labservices-mar2012.pdf	Management science for health organization	2012	chapter 47
recommendations from the Royal College of Pathologist (UK), the Institute of Biomedical Sciences (UK) and the Association of Clinical Biochemists (UK) published in their second edition report in the year, with some modifications to suit local circumstances.		1999	

Requirements for the retention of laboratory records and diagnostic material. (Seventh Edition). Australian Government Department of Health	National pathology accreditation advisory council.	2018	
The retention and storage of pathological records and specimens (5th edition) Guidance from The Royal College of Pathologists and the Institute of Biomedical Science April 2015	IBMS	2015	
CAP Internal Auditing Course – Sample Content http://appsuite.cap.org/appsuite/learning/QMED/eStore/Internal_ Auditing_2020_Sample_Content_eStore_062620.pdf	College of American Pathologists	2020	
Tips for Performing Internal Lab Audits https://labmedicineblog.com/2019/06/17/tips-for-performing-internal-lab-audits/	Wojewoda.C et al	June 2019	
RCpath key performance indicators	RCpath	2013	
RCpath Key Insurance indicators 2019	RCpath	2019	
International Federation of Clinical Chemistry and Laboratory Medicine Working Group "Laboratory Errors and Patient Safety"	IFCC	2016	
Performance Indicator Emergency department, vers 1, 1rst edition	MOH, GQAC	2016	
Clin Lab Med, quality indicators for the total testing process, 37 http://dx.doi.org/10.1016/j.cll.2016.09.015	Clin Lab Med	2017	187–205
Defining Calibration & Qualification of Equipment https://learnaboutgmp.com/good-validation-practices/defining-calibration-qualification-of-equipment/	Edward Simpson	2016 Visited 15/7/2021	
COLA centrals Competency Assessment Tracker COLA labs log in at www.COLAcentral.com and select "Lab Operations" under the	COLA		
SLT-competency assessment resources https://www.smartlabtools.com/competency_assessment.html	Smartlabtools Team	Accessed may 2021	
Competency assessment SOPs	WHO	2013	
Nemenqani, Dalal&Tekian, Ara & Park, Yoon Soo.. Competency assessment in laboratory medicine: Standardization and utility for technical staff	Nemenqani. et al	2017	

assessment and recertification in Saudi Arabia. Medical Teacher. 39. 1-12. 10.1080/0142159X.2016.1254751.			
Food and drug administration office of regulatory affairs *ora laboratory manual volume ii*, Document number: ora-lab.5.5, Revision #: 02	FDA	Accessed July /2021	
Procedure for Equipment Calibration and Maintenance – ISO Consultant in Kuwait https://isoconsultantkuwait.com/2019/01/23/procedure-for-equipment-calibration-and-maintenance/ 1/6 ISO Consultant in Kuwait	preteshbiswas	Accessed July /2021	
Facilities Management. https://b38group.com/what-is-ppm-maintenance/	B38 Group Team	Accessed 2020	
SOP Maintenance and monitoring of fridge and storage units	Dr.ElsaWakeman Prof .CatherineThompton	2021	1-10
World Health Organization. (2011). Laboratory quality management system Handbook. Retrieved from https://www.who.int/publications/i/item/9789241548274	WHO	2011	114-124
ISO 15189 standards	**ISO**	**2012**	
Verification of Quantitively analytical methods in medical laboratories. Muhammad *T. Abdel Ghafar, Muhammad I. El-Masry ·· J M*	*Muhammad T* etal	June 2021	
Tietz, Fundamentals to Clinical Chemistry, 5th Edition	Carl A. Burtis , Edward R. Ashwood	5th edition (January 15, 2001)	
Qualitative Assay Validation http://www.clinlabnavigator.com/qualitative-assay-validation.html	Clin lab navigator team	accessed date Oct/ 2021	

Verification and Validation of Procedures in the Clinical Microbiology Laboratory, Cumitech,	Clark etal	2009	*31 A*
Basic Lessons in Laboratory Quality Control Greg Cooper., Inc. Quality Systems Division.	Bio-Rad Laboratories	2008	-
Internal and External Quality Control Management Protocol. BIO-MAN-IPP-023. Version 04. Clinical Biochemistry Department, Sultan Qaboos University Hospital.	Younis al balushi	*2007*	4-23
Internal quality control: planning and implementation strategies. Ann Clin Biochem; 40	James O Westgard	2003	593–611
Quality Control and Proficiency Testing. Ross Molinaro, PhD, MT(ASCP), DABCC, FACB. Emory University Atlanta, GA	Ross Molinaro,	April /2013	-
Efficacy of internal and external quality control in chemical pathology. Clinical laboratories, department of pathology, the aga khan university hospital, stadium road, karachi-5.	Rukhsanaetal	1988	255 – 259
Requirements quality control, external quality assurance and method evaluation. (Sixth edition).	National pathology accreditation advisory council	2018	
External Quality Assessment _ Module 10 _ Content Sheet. WHO,	WHO	2011	*114-124*
Begreber og terminologi [Quality assessment, quality assurance and quality improvement in health care. Concepts and terminology].	Mainz J, Hammershøy EM, Worning AM, Juul S. Kvalitetsvurdering, kvalitetssikring og kvalitetsforbedring i sundhedsvaesenet. Ugeskr Laeger.	1992 Apr	20;154(17):1151-6. Danish. PMID: 1604740.