HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Quality Management Plan		
Applies To:	All Laboratory Staff		
Preparation Date:	August 06, 2024	**Index No:**	LB-IPP-258
Approval Date:	August 20, 2024	**Version :**	NEW
Effective Date:	September 20 2024	**Replacement No.:**	
Review Date:	September 20, 2027	**No. of Pages:**	05

1. PURPOSE:

1.1 To use as a guideline for the evaluation and implementation of the quality system and standards for the laboratory, it provides a simple approach to meet each of the requirements.

1.2 To identify opportunities for improvement of laboratory processes and patient outcomes, monitor the quality and appropriateness of laboratory services, and resolve identified problems.

2. DEFINITONS:

2.1 **Quality control** refers to laboratories' internal procedures for day-to-day monitoring of instruments, and work processes, detecting problems, and making corrections prior to the delivery of test results or Services.

2.2 **Quality assurance/assessment QA** monitors the totality of components or characteristics that affect Quality and customer satisfaction. Characteristics such as turnaround time, patient preparation, recording, interpretation, and specimen collection. This can be monitored at a basic level internally and externally. Proficiency testing is an external mechanism for QA.

2.3 **Quality management** systems QMS refers to a systematic approach to achieving quality objectives. QMS constitutes a coordinated and comprehensive effort to meet quality objectives using management systems and standards.

2.4 **Quality cost management (QCM)** includes all activities involved in QMS, QA, and QC, along with related economic aspects (i.e., "Cost of quality"). QCM promotes the integration of quality processes throughout an organization subject to the constraints of the organization's financial resources.

2.5 **Quality & Patient Safety (QPS)** -is intended to sustain high quality by focusing on long-term success through customer satisfaction. TQM holds quality as the driving factor behind leadership, design, planning, and improvement. Variations of quality are artifacts of poorly designed systems, rather than the fault of one or more individuals.

2.6 **KPI -**Key Performance Indicator

3. POLICY:

3.1 The laboratory shall strive to provide the clients of the MCH Hafer Albatin with the highest quality of service using state of the art technology in a cost-effective manner while providing a safe work environment for laboratory staff.

3.2 To achieve Quality Management goals, MCH Hafer Albatin laboratory shall:

3.2.1 Understand the needs and expectations of our customers, including MCH Hafer Albatin, and Hospital Laboratory staff, and measure satisfaction with the services provided.

3.2.2 Improve resource utilization to further enhance cost-effectiveness

3.2.3 Maintain open communication and working relationships with other departments. Implement teamwork and collaboration as strategies for Quality Management.

3.3 Continue to sustain high standards and compliance with the College of American Pathologists (CAP), American Association of Blood Banks (AABB), and Central Board for Accreditation of Health Care Institutions (CBAHI) requirements.

3.4 Quality essentials shall include:

3.4.1 **Organization**: The laboratory has a Quality system that ensures compliance with accreditation requirements. Quality planning and evaluating the effectiveness and efficiency of the Quality System is through scheduled leadership reviews. The manager is firmly committed to supporting all activities, participation, and implementation of the Quality System. The sections support the Quality system and contribute data for Quality reports. An authorized written procedure (SOP) giving instructions for performing operations not necessarily specific to a given process, product, or material (e.g. Equipment operation, maintenance, and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Standard operating procedures are described in a detailed form the activities performed in the laboratory, Provide uniformity, consistency, and reliability in each of the activities performed in the laboratory, Reduce systematic errors, and Provide training and guidance for new staff. (SOP) should be maintained in a central file, Copies distributed to locations, and supervisors review SOPs for completeness and content.

3.4.2 **Personnel:** Staff is the most valuable resource in the laboratory. Policies and Procedures are developed for Orientation and Training, Competency, and Continuing Education. Job descriptions with qualifications are maintained for each job function. The laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel to ensure that duties are assigned according to the capability of staff.

3.4.3 **Equipment**: It is the Policy of the laboratory that all equipment purchased meets the needs of the laboratory. All equipment is to be tested, maintained, and calibrated according to the manufacturer's guidelines. Each section will maintain problem logs and equipment logs. The information in the logs should be reviewed and analyzed periodically to identify trends and recurrent problems. For each piece of equipment establish a routine maintenance plan, establish required function checks and develop a list of spare parts.

3.4.4 **Purchasing and Inventory**: Defined and documented policies and procedures to select and purchase external equipment and supplies. Verify purchased equipment and supplies before use, develop an inventory control system for supplies including quality records and evaluate external services and suppliers and maintain a record of evaluation and approval. Procedures for external services and supplies shall be clearly defined by using percentages or scoring the evaluation system to ensure the evaluation outcome such as its quality, service, and cost. Recorded data and information from the physician's request for service and Laboratory retrospective data shall be included in the evaluation criterion. Purchased equipment and consumable supplies such as laboratory chemicals and reagents that affect the quality of examinations shall be verified prior to laboratory usage and shall be recorded for external services and supply evaluation.

3.4.5 **Process Control:** The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. The laboratory shall identify procedures to determine the uncertainty of results, where relevant and possible. Significant sources that contribute to uncertainty shall be considered such as sampling. Corrective action shall be implemented when control criteria are not fulfilled to correct any defect. The laboratory shall participate in inter-laboratory comparisons such as those organized by external quality assessment. The laboratory shall monitor the results of external quality assessment to find any determinant causing the control criteria to be unfulfilled.

3.4.6 **Documents and Records**: The laboratory shall establish and implement procedures for the collection and Storage of quality and technical records. Quality and technical records shall be legible and understandable. All records shall be stored and maintained to prevent deterioration and to be readily retrievable. These records may include request forms, results and reports, instrument printouts, examination procedures, laboratory workbooks or sheets, calibration records, conversions factors, quality control records, complaints and action taken records, external quality assessment records, quality improvement records, instrument

maintenance records, certificates of supplies, package inserts, incident/accident records and action taken, Staff training and competency records. All levels of documents shall be accessed by an authorized staff that is responsible for the actions included.

3.4.7 **Advisory Services:** Provide advice on the choice of examination and use of services by professional staff, and conduct regular meetings with professional and clinical staff for consultation on scientific matters. Examination results shall be interpreted appropriately. The laboratory shall provide the scientific consultation for the service requested such as choice of examination method, use of the services, repeat, and sample selection.

3.4.8 **Corrective Action** The laboratory shall have procedures for corrective action including an investigation process to determine the underlying cause or causes of the problem. Staff responsible for corrective action shall be assigned. Corrective and preventive action shall be taken to prevent the recurrence of the problem. Corrective action and the result of the investigation shall be recorded. The corrective actions shall be audited and submitted for management reviews.

3.4.9 **Preventive Action:** Develop, implement, and monitor an action plan to reduce nonconformities, Including initiation of action and application of controls. Preventive action shall be developed to reduce the likelihood of nonconformities or the risk of a problem that affects laboratory quality and technical standards. The person/authority responsible for analyzing the risk of nonconformity shall be specified and problems shall be analyzed and included in preventive action to identify opportunities for improvement. The preventive action shall include the review of the operational procedures, analysis of data, including trend and risk analyses, and External quality assurance such as quality assurance and development program.

3.4.10 **Continual Improvement:** The laboratory management shall define the time interval for the review of the laboratory's operational and technical procedures. The laboratory shall have an action plan for continual improvement and development, and a management training program.

3.4.11 **Management Review:** The laboratory management shall have time intervals for the laboratory's quality management system review. Such a review shall be conducted at least once every 12 months. The information for the management review shall be indicated in a timetable to the laboratory manager; its details shall be communicated to quality and technical management.

3.4.12 **Customer Satisfaction**: A Staff suggestion/comment questionnaire is available to all laboratory staff. Submissions are made to the Quality Management Coordinator and discussed during Quality Management and Laboratory Utilization Committee meetings for appropriate action and feedback to the submitting individual if applicable. Customer satisfaction surveys are distributed that target specific customer groups determine the quality of service provided by the laboratory and identify areas that require improvement.

3.4.13 **Facilities and Safety:** The Laboratory Safety Program provides a thorough understanding of safety procedures, to Define responsibilities for the safety program and to ensure a safe environment for all Department of Pathology and Laboratory Medicine personnel, visitors, volunteers, and trainees

4. PROCEDURE:

4.1 Each laboratory section will submit an annual quality assessment to the QM coordinator. The assessment will include the identification of problem areas and opportunities for improvement.

4.2 A comprehensive list of improvement opportunities and outstanding issues will be compiled from the sectional assessments and data obtained from the activities described in the previous section of this policy.

4.3 The laboratory director will review the list and establish the QM priorities for the ensuing year

4.4 The scope of the issue/project will determine the action and reporting to Quality Improvement & the Patient Safety Committee for asking its approval of performing the project & updating the committee for any progress.

4.5 The laboratory has a quality improvement project. The FOCUS-PDCA methodology will be utilized for performance improvement projects (see attached FOCUS-PDCA worksheet,).
4.6 Evaluation
4.7 The annual quality assessment submitted by each section includes information on all sectional quality related activities. Documentation of the effectiveness of Quality Management projects/activities is included in the report.
4.8 The appraisal of the effectiveness of the quality system is through the monthly internal audit process with all sections of the QM staff.
4.9 The lab director and Quality Management department will perform an annual assessment of the Quality Management Plan.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**
- 5.1.1 Laboratory quality indicator monitoring
- 5.1.2 List of Laboratory KPIs
- 5.1.3 Application for Quality Improvement Project Request Form
- 5.1.4 Sample of Laboratory Performance Improvement Project

6. RESPONSIBILITIES:

6.1 Laboratory Director
6.2 Quality Management Coordinator
6.3 Laboratory Staff

7. APPENDICES:

7.1

8. REFERENCES:

8.1 CBAHI Standards, 3rd edition
8.2 College of American Pathologists – General Laboratory Checklist. Revised December 2004
8.3 Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition, 26 October 2010.
8.4 Laboratory Quality Management system, "CLSI Hand Book", WHO, 2011
8.5 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA.

9. APPROVALS:

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