21-Quality Management Plan

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ANNUAL REVIEW:

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SUPERSEDES: Procedure titled _____

Purpose:

The purpose of this Quality Management Plan is to establish a framework for ensuring the accuracy, reliability, and quality of clinical laboratory testing. The Quality Management Plan has been developed to comply with the regulatory requirements of the Centres for Medicare and Medicaid Services (CMS), the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and other relevant accrediting agencies. The goal of this Quality

Management Plan is to implement a systematic approach to quality management that enables the laboratory to provide accurate and reliable test results to patients and healthcare providers.

The Quality Management Plan defines the policies, procedures, and processes that are necessary to achieve the laboratory's quality objectives. It describes the management structure, roles, and responsibilities of laboratory personnel, as well as the resources needed to implement and maintain a robust quality management system. The Quality Management Plan outlines the laboratory's quality control and quality assurance programs, including procedures for monitoring and evaluating the accuracy and precision of test results, and for identifying and addressing any errors or non-conformities.

The Quality Management Plan provides a means for laboratory patients and clients to have confidence that the laboratory's analytical data is accurate and reliable.

Scope:

The scope of this Quality Management Plan encompasses all activities related to clinical laboratory testing performed by the laboratory, including specimen collection, processing, analysis, and reporting of results. The Quality Management Plan applies to all laboratory personnel, equipment, facilities, and processes that are involved in the testing of human specimens for medical purposes.

Abbreviation

CAP – College of American Pathologist
CLIA- Clinical Laboratory Improvement Amendments
CMS-Centers for Medicare and Medicaid Services
COLA - The Commission on Office Laboratory Accreditation
MMCCCL- Meharry Medical College Clinical Consolidated Laboratory
PPE-personal protective equipment
QMP-Quality Management Plan

Definitions:

CMS- Centers for Medicare and Medicaid Services- Government agency responsible for enforcing CLIA.

Health and Safety:

ALWAYS use appropriate PPE whenever in the lab. This includes but is not limited to lab coats, gloves, face shields, goggles, shoe covers, and masks.

Policy:

The laboratory provides both quantitative and qualitative testing in compliance with the Quality Management Plan, CMS, CLIA, CAP, and other regulatory requirements. These activities are performed to meet the needs of the patients and clients. The Laboratory Director has final responsibility for the laboratory, while the Director of Quality or Laboratory Manager/Supervisor ensures that the quality plan is implemented and followed.

Meharry Medical College Clinical Consolidated Laboratory (MMCCCL) policies ensure that lab employees are able to carry out their duties without undue influence or pressure from internal or external sources. Complaints regarding lab services can be brought forward by staff, patients, or clients, and can be reported to the appropriate State Agency. Employees are informed about the protocol for reporting concerns that could impact the safety or quality of patient testing, and are encouraged to report concerns promptly. The lab investigates concerns and takes corrective actions as necessary, without reprisal against employees.

Objectives:

To support the quality policy and meet its objectives, laboratory management plans, documents, implements, and reviews quality objectives. The Director of Quality or Laboratory Manager/Supervisor is responsible for maintaining quality objectives, which are reviewed regularly and updated as needed.

The quality control plan policy outlines several objectives to ensure accurate and reliable laboratory testing in compliance with regulatory requirements and standards.

These objectives include

1. Hire qualified personnel for the job, providing training and education to laboratory staff on quality control practices.

2. Regularly monitoring and evaluating the performance of testing methods and equipment.

3. Investigating any errors or discrepancies in test results.

4. Maintaining complete documentation of all laboratory procedures and results.

In addition to these objectives, the laboratory aims to continuously improve its processes and procedures through ongoing review, evaluation, and implementation of best practices and new technologies. The laboratory also places a high priority on communication with clients and patients to ensure their satisfaction with services and address any concerns or complaints in a timely and effective manner.

Finally, the laboratory is committed to promoting ethical standards among staff, including confidentiality and data privacy requirements, as well as adherence to safety regulations and guidelines. By meeting these objectives, the laboratory can provide high-quality testing services that meet the needs of patients and clients while complying with regulatory requirements.

Procedures:

1. Service Agreements

a. Requests for testing services are received through a written or electronic test request submitted by a licensed medical professional. This document serves to define the patient's requirements and the responsibilities of the laboratory in fulfilling those requirements. MMCCCL uses the CliniSys LIS previously known as Sunquest and its online Client Portal software to order tests, and send requisitions to the laboratory.

2. Subcontracting of Testing

a. When testing activities are to be subcontracted, steps are taken to ensure that subcontracting activities are handled appropriately.

b. Subcontracting of testing will be undertaken with competent subcontractors whose quality systems meet the requirements of CLIA. Physicians will be notified of the need to use subcontracted services and physician approval obtained where necessary. Appropriate records of subcontractors and evidence of their compliance with the quality plan requirements will be maintained.

3. Purchasing Services and Supplies

a. Suppliers are selected based on their ability to supply external services, equipment, reagents, and consumable supplies in accordance with the lab's requirements.

4. Advisory Services

a. Advisory services are provided when it becomes necessary to either clarify the request for testing, clinical indications and limitations of examination procedures, advising on individual clinical cases, professional judgements on the interpretation of the results of examinations, consulting on scientific and logistic matters such as instances of daily of sample(s) to meet acceptance criteria, or to monitor the performance of testing activities. Turnaround time (TAT) for each test is to be determined and significant delays in analysis (greater than 24 hours over the posted turnaround time) and reporting will be communicated to the physician.

5. Complaints

a. Complaints received from employees, clinicians, and patients are managed through the Corrective Action Process. This process provides the means for recording the details of the complaint, the results of the subsequent investigation, the actions to be taken to correct, the circumstances that resulted in the complaint, and the assessment of the effectiveness of the corrective action taken. Refer to the Corrective and Preventive Actions SOP.

6. Control of Nonconformances

a. Quality control is exercised over instances where any aspect is found to be nonconforming to laboratory standards. Steps are to be taken to evaluate the significance of the nonconformance. A determination of the level of correction is to be made and the appropriate corrective actions are carried out. Physicians are notified as required. Records of non-conformities are maintained. Notification to CLIA and /or CAP, where appropriate, will be made as required in the event that the organization is under investigation by a government entity or oversight agency. Notifications will be made to CLIA and/CAP/COLA upon changes in testing, ownership, lab location, or directorship of the organization within the requisite time period. In the event of an unexpected change, notification to CLIA and/or change. See the SOP entitled "Corrective and Preventive

Actions will be made no later than two (2) business days after the unexpected event

b. Corrective Action Process

A Corrective Action Process will be implemented for the resolution and prevention of nonconformities. A Corrective Action investigation will be initiated upon a nonconformity (or a “Near Miss”) and will remain open until such time that all corrective actions have been implemented and a review of their effectiveness is completed. Refer to “Corrective and Preventive Actions” for an explanation of the entire process and the Corrective Action Report Form.

c. Preventive Action Process

Preventive actions are taken to address potential sources of nonconformities. The Preventive action process provides for the development of plans and controls to ensure those actions are effective in eliminating sources of nonconformities. These are most commonly developed in light of a “Near Miss" where a nonconforming incident ALMOST happens but is caught at the last minute. These and other Preventive actions are to be recorded on the Corrective and Preventive Action Report Form, along with corrective actions.

7. Continual Improvement

There are ongoing efforts to enhance the efficacy of the Quality Management Plan, covering the pre-examination, examination, and post-examination processes. Quality reviews will be used to compare the laboratory's actual performance in its evaluation activities and corrective and preventive measures with its stated policy objectives.

8. Control of Records

a. Confidentiality of hardcopy and electronic patient information, including patient reports, is protected throughout the pre analytical, analytical, and post analytical phases of the testing process in accordance with federal and state laws. The laboratory retains records of quality reports in an appropriate place that prevents unauthorized access or deterioration. These records are stored such that they are readily available for review in a timely fashion. The Laboratory Information System (LIS) maintains test requests, testing records, and test reports for each patient. Retention times are as follows.

Specimen Requisitions 7 Years

Maintenance Forms Life of Instrument + two (2) Years

Quality Control Records 2 years

Personnel Records las far as still working + 2 years

Discontinued SOPs/FORMs 2 years

Patient Test Records 2 Years

Reports 10 years

b. Should the laboratory cease operation, all records will be retained and available for the times listed above, the Medical Director will ensure safety and security of all materials. When mistakes are identified in hardcopy records, the mistake is crossed out but left legible. The corrected value is entered to the side with the initials of the person making the change and date the correction was made.

9. Evaluations and audits

a. Internal quality audits are conducted to verify that operations continue to comply with the requirements of CLIA. The scope of the audits encompasses the preanalytic, analytic, and post-analytic aspects of laboratory operations in order to ensure internal and external customers that operations continue to be in compliance with the lab's policies and procedures, and to identify areas for improvement**. Quality indicators** used at MMCCCL are:

i. Specimen Label/Req Mismatch

ii. Specimen Label Missing information

iii. No Specimen Label

iv. Specimen Req Missing information

v. Incorrect Sample Type

vi. Incorrect Tube Type

vii. Incorrect Swab Type

viii. Specimen Not Received

ix. Specimen Damaged in Transport

x. Specimen not properly stored before analysis

xi. Specimen transported at incorrect temperature

xii. Specimen has excessive transportation time

xiii. Specimen Gross Contamination

xiv. Insufficient Volume (QNS)

xv. Erroneous Data Entry

xvi. Missed Test

xvii. QC unacceptable

xviii. Excessive TAT

xix. Incorrect Laboratory Results

10. Technical Requirements for Personnel

a. MMCCCL strives to quantify and control major factors affecting the data coming from the lab in order to meet the requirements of the Quality Management Plan, and to ensure the accuracy and reliability of results. These major factors include but are not limited to: operator difference, environmental factors, testing and calibration methodologies, equipment differences, traceability and handling of calibration related materials, etc.

b. The laboratory personnel who handle the test samples/specimens, perform testing, analyze results, and provide approvals are qualified to do so based on meeting the job requirements outlined by CLIA. In addition, they must complete mandatory on-the-job orientation and training, demonstrate the skills necessary to perform testing in a high complexity lab, and meet any prerequisite physical requirements.

c. The laboratory maintains job descriptions, diplomas, transcripts, certifications/licenses, and training documents for all laboratory staff. Competency is evaluated at the beginning of the employee's tenure in the lab (before they begin testing independently), at six (6) months, and then

annually thereafter. All training and competency records will be maintained for the length of the employee's time and for additional two years.

d. Authorization to perform specific test methods and tasks is subject to the Laboratory Director's determination of successful on-the-job training, in conjunction with achievement of the requisite requirements specified in the applicable job description.

11. Accommodation and Environmental Conditions

a. The lab's environmental conditions are monitored and controlled by the laboratory staff.

b. Testing instruments and standards are maintained at the appropriate conditions. Electrical power is conditioned and protected from surges and fluctuations for analytical equipment.

c. Electrical grounding is verified upon introduction of new equipment and periodically.

d. Good laboratory practices are observed relative to standard personal hygiene, ambient dust, and other possible sources of contamination.

e. The laboratory is constructed, arranged, and maintained to minimize risk of contamination.

f. To the extent possible, specific areas are designated for various tasks to minimize accidental spills, mix ups, or contamination.

g. Testing supplies are maintained in a secure location.

h. Cabinets and safety equipment are available and maintained within the testing areas.

i. Employees are required to utilize universal precautions when handling patient specimens, and they complete safety training annually.

12. Equipment and Materials

a. The proper equipment to complete testing methodologies is maintained. Calibration is done on all instruments according to the manufacturer's instructions and recommendations. The results of these calibrations are reviewed and verified by the laboratory staff. New calibrations are to be performed, when necessary, based on the manufacturer's direction.

b. Reagents and consumables are received and stored in a manner that prevents damage or deterioration.

c. Lot to Lot verification is completed on all reagents, and records are maintained for each consumable used in testing.

13. Pre-examination Processes

a. Work instructions (SOPs) detail the appropriate steps for the transport, receipt, handling, protection, and storage of specimens. Specimen integrity is maintained throughout the laboratory processes to protect the interests of the laboratory and the patient.

b. Upon arrival at the laboratory, specimens are assigned unique accession numbers. Appropriate records are maintained in the Laboratory Information System. Appropriate control is maintained to ensure that test result data is protected and patient confidentiality is maintained. Access to the LIS is restricted for data entry, collection, storage, and processing. Only approved personnel may utilize the LIS; read-only access is granted to physicians to facilitate the viewing of testing results via the patient portal.

14. Testing Methods and Method Validation.

a. Standard Operating Procedures (SOPs) are maintained for all test methods covered by the scope of the lab. The instructions provide guidance, detailed procedures, maintenance requirements, and instruct on the proper use of instruments and equipment used in testing.

b. The Laboratory personnel have ready access to these SOPs. Deviations from these established methods may occur only if the deviation has been documented, the basis of the deviation has been investigated, and authorization from the Lab Director must be obtained.

c. Prior to patient testing, key performance specifications are verified and documented for each non-waived test method. In the event that a change to a methodology is needed, or a new testing methodology is identified as being required, MMCCCL will perform appropriate testing validations for the new or modified tests. The validation records include the procedure used for the validation, the results, and a determination regarding fitness and acceptability of the testing method.

15. Assuring the Quality of Test Results

a. The validity of tests performed by the laboratory is monitored. This monitoring ensures that data is collected in such a way that trends are detectable. Corrective action is implemented when instances of nonconforming testing are identified. The appropriate calibrations and quality control frequencies are established based on manufacturer's guidelines and current research. Regular reviews of the data are performed. Test results are reviewed and approved for release via the LIS and are transmitted only after they are approved for release. Patient confidentiality is maintained throughout each phase of testing, including preanalytical activities, analytical activities, and post-analytical activities.

b. The laboratory is enrolled in proficiency testing (PT) programs for each test where such programs are available. If no such PT program is available, CLIA approved methods of maintaining and proving proficiency such as split sample, or alternative PT programs will be used to assess the validity of the entire path of workflow in the lab. PT will be reviewed by the Lab Director or designee, and corrective actions issued for any nonconforming results.

16. Post-examination Processes

a. Regular reviews of the data are performed.

b. Test results are reviewed and approved for the release via the LIS.

c. SOPs detail the appropriate steps for storage, retention, or disposal of samples/specimens where these activities are applicable.

17. Reporting results

a. The test results are maintained in an electronic database (CliniSys). Patients and physicians may view the results in this database with read-only access via the online patient/client portal. Physicians are provided with the necessary information related to the test results, including patient name and unique identification number, laboratory name and address, test report date, test performed, test result, units of measurement/interpretation, any information regarding the condition of the specimens that do no meet the laboratory's standards for acceptability. Pertinent reference intervals or normal values are made available in LIS associated with patients report and when requested, to the authorized requesting patient.

18. Release of Results

a. Test results are only released by authorized persons. In the event that a test result indicates an imminent life-threatening condition, or a panic or critical value is detected, the lab will immediately notify the authorized entity requesting the test. Test reports or records of the information on the test reports are maintained in a manner that permits accurate traceability, ready identification, and rapid accessibility. When errors are in the reported test results are detected, appropriate corrective action will be initiated per the nonconforming product process. Revised reports are labeled as revisions. Patients are notified of revisions. Original reports and records with any amendments, changes, or alterations are retained.

19. Laboratory Information Management

a. The LIS safeguards patient confidentiality and tracks specimen identification throughout the laboratory process and access to the LIS is controlled.

ANNUAL QUALITY ASSESSMENT CALENDAR

JANUARY QC IT SYSTEM HIPAA compliance ~~IQCP Annual Review~~ *For All Moderately Complex tests, we use minimum of 2 QC	**FEBRUARY** QC SPEC COLLECTION/ IDENTIFICATION Verification of ~~correct INR and PT reference range~~ *We do not do PT, PTT INR	**MARCH** QC EQUIPMENT MAINTENANCE & CALIBRATION Specimen integrity of received specimens	**APRIL** QC PT COMPLAINTS
MAY QC TEST REPORTS for Completeness REFERENCE LAB (TAT, ISSUES)	**JUNE** QC PERSONNEL TRAINING AND COMPETENCY Alert value reporting	**JULY** QC Written request all tests All necessary information on test requests	**AUGUST** QC PT SAFETY AUDIT

SEPTEMBER QC EQUIPMENT MAINTENANCE & CALIBRATION	**OCTOBER** QC COMPLAINTS New analytes with complete verification and ordering of PT	**NOVEMBER** QC POLICIES & PROCEDURES -Complete -Signed -Followed	**DECEMBER** QC PT RECORD RETENTION & Chemical and Bio Waste Disposal

References:

College of American Pathologists. “Retention of Laboratory Records and Materials.” Revised March 2010. www.cap.org

College of American Pathologist, CAP lab general checklist 2023

CAP all common checklist 2023
COLA accreditation manual 2022