

6. Good Laboratory Practice

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ANNUAL REVIEW:

REVIEWED	<u>Sanford N. Bailey, M.D</u>	<u>July-15-2025</u>
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SUPERSEDES: Procedure titled _____

Purpose

This procedure defines the responsibilities and describes the process used for general laboratory practices.

Scope

Applies to the testing areas, personal and activities of the laboratory.

Abbreviations

MMCCCL- Meharry Medical College Clinical Consolidated Laboratory

NIST = National Institute of Standards and Testing

SOP- Standard Operating Procedure

Policy

To ensure the safety of testing personnel and the quality of results at MMCCCL in accordance with good laboratory practice, as described below, will be used at all times.

Procedure

1. Daily Verification Activities

- a. Lab Personnel Verify that the temperature and relative humidity of the lab are within the acceptable range/ In the event conditions are outside of the acceptable ranges, take the appropriate action as per the Control of Nonconformances SOP.
- b. Verify that storage equipment is operating within the acceptable range. Refer to the Environmental Control SOP. In the event conditions are outside of the acceptable ranges, take the appropriate action as per the Control of Nonconformances SOP.

2. Verification and Equipment Calibration Activities

- a. Perform calibration checks on auto pipettes as required. Thermometers and hygrometers (NIST traceable) should be checked and replaced on expiration.
- b. At the required frequency, engage external services to perform calibration and certification on equipment. Verify that calibration is traceable to the International Systems of Units. Perform required reagent verifications for new lots of reagents.
- c. Refer to/comply with cleaning, calibration and maintenance procedures in specific method/equipment manufacturer work instructions. Record maintenance activities on the appropriate Maintenance Log form.
- d. Ensure integrity and consistency while analysing, documenting, or reporting data.

e. Maintain records to provide traceability of calibration/test samples, calibration/test equipment, data, and reports. In addition, maintain records to provide traceability of personnel performing these activities.

3. Safety Considerations

a. Observe safety requirements when handling hazardous materials and specimens.

b. Reagents, calibrators, controls, solutions, and chemicals are properly labeled, as applicable and appropriate, with the following elements:

1. Contents/ quantity/ concentration/ titer

2. Storage requirements

3. Date opened or prepared

4. Expiration date

c. Label new reagent bottles with a “Received date” and initials as soon as they are received in the laboratory. When opening unused solvents, reagents, standards, note the date opened and initials on the container or accompanying documentation. When transferring these items to other containers for storage, label the container with the date, preparer’s initials, and any required hazard labels.

d. Before using previously opened solvents, reagents, standards, verify that the expiration date of these items has not been exceeded. In the event that reagents do not have a manufacturer’s expiration date, an expiration date will be assigned based on known stability, frequency of use, storage conditions, and risk of deterioration. For unopened containers, follow the manufacturer’s instructions for expiration.

e. Ensure that separation of specimens and standards is maintained.

f. Take appropriate measures to prevent mixing calibration/test materials.

g. Store specimens, standards, and solvents in the appropriate designated locations only.

h. Dispose of excess specimens in the sanitary landfill waste container by collecting the specimens in heavy duty plastic bags with absorbent pads placed in each bag. Dispose of waste solvents and waste reagents in the designated waste

solvent drums. Hazardous chemical waste is to be disposed of in designated hazardous waste containers.

i. Observe the lab's Hazards Communication Plan.

j. Molecular testing should be performed in a unidirectional manner in which there is separation of the pre-analytical and analytical work space.

4. General Activities

a. Observe personal sanitation precautions to avoid contamination of calibration/test materials and calibration/test systems.

b. Do not consume food and drink or apply cosmetics in laboratory/non designated areas.

c. Lock doors to the lab at the end of business each day. If all lab personnel are absent from the laboratory during the working day, lock doors while personnel are absent, if possible.

d. Shutdown or lock test-related and personal computers at the end of each business day.

e. Ensure that a general housekeeping maintenance program is conducted and effective, whether conducted wholly or partially by outside contractors or by lab personnel

References

CAP all common checklist 2023
COLA accreditation manual 2022