Practice Guideline

PGL- 004

Acceptable materials for evaluation or quality performance

This practice guideline was developed to inform Medical Laboratory Technologists (MLT) of recommended practices for the evaluation of quality performance when conducting calibration, correlation, validation, or verification studies in the workplace.

Collection or testing of patient samples, a member of laboratory staff, or oneself for these purposes poses several risks and ethical challenges[1,2]. Whenever possible, anonymous, or commercially available materials should be used.

Where no anonymous or commercially available material is readily available, the MLT involved should:

- Follow the standard operating procedure that outlines the use of patient, staff, or samples from one-self for the purposes of evaluating test methods, instrument validation studies, reference intervals, specimen container acceptance studies, correlation studies or any similar studies.
- If no standard operating procedure is currently available, it is recommended they request that the manager provide written instructions to be followed by all staff for these circumstances.
- Follow the process outlined in the standard operation procedure or the written instructions on what action is required when a personally identified human biological specimen is found to have unreported abnormal results.
- Whenever identified human biological specimens are used, the MLT should submit a notification form if available, or notify their manager in writing of the date, time, and details for documentation. The MLT should keep a copy of this communication for their record.

Laboratories may refer to relevant guidelines from CLSI, ISO, CAP, or CPSS laboratory quality assurance program.

1. *SSMLT Code of Ethics- SSMLT Regulatory Bylaws- Appendix A*
2. *SSMLT Standards of Practice*

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