1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1046 [42CFR493.1282(b)(2)]

FLO.24250 QC Handling **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing procedure must be controlled.

Evidence of Compliance:

✓ Records reflecting that QC is run by the same personnel performing patient testing

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7166 [42CFR493.1256(d)(8)]

FLO.24300 QC Confirmation of Acceptability **Phase II**

Personnel review control results for acceptability before reporting patient/client results.

Evidence of Compliance:

✓ Records of control result approval

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7166 [42CFR493.1256(f)]

FLO.24475 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

Evidence of Compliance:

✓ Records of QC review **AND**

✓ Records of corrective action taken when acceptability criteria are not met

INSTRUMENTS AND EQUIPMENT

FLOW CYTOMETERS

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

READ	• Sampling of optical alignment/laser output checks • Sampling of procedures for optical alignment, calibration, color compensation, and laser checks • Sampling of calibration records with fluorochrome standards
ASK	• How does your laboratory monitor instrument reproducibility? • How does your laboratory ensure each fluorochrome is appropriately calibrated? • How does your laboratory determine appropriate color compensation settings? • How is carryover mitigated for rare event assays and paucicellular specimens?

FLO.25150 Optical Alignment — Phase II

The laboratory monitors optical alignment (where applicable) and instrument reproducibility at least daily, or after each time the flow cytometer is restarted.

NOTE: Verifying reproducibility of instrument performance is an essential element of quality assurance within the laboratory. Instrument performance must be monitored under the same conditions used to run test samples.

Evidence of Compliance:

✓ Records for monitoring optical alignment (where applicable) and instrument reproducibility

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition*. CLSI document H43-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2007.

FLO.30250 Fluorochrome Standards — Phase II

Appropriate standards for each fluorochrome (*eg,* fluorescent beads) are run each day that the instrument is used as part of the quality control to verify instrument performance, and the results are recorded and reviewed.

NOTE: These steps are necessary to optimize the flow system and the optics of the instrument.

Evidence of Compliance:

✓ Records of results, with corrective action when quality control beads fail

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline—Second Edition*. CLSI document H42-A2 (ISBN 1-56238-640-9). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007

FLO.30255 Voltage Settings — Phase II

The laboratory optimizes the voltages for each specific assay.

NOTE: Voltage settings for each PMT must be optimized in order to maximize the resolution (signal-to-noise ratio) and place the antigen-negative and antigen-positive populations visibly "on -scale" for analysis. This is particularly important for dimly expressed antigens as well as visualization of antigen-negative populations. Appropriate voltage settings must be determined during validation of the specific assay; however, timing and frequency of monitoring on-going performance is at the discretion of the laboratory director.

Evidence of Compliance:

✓ Records demonstrating voltage optimization

REFERENCES