*NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed.*

*Controls must be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, change of a critical instrument component, or with software changes, as appropriate. Daily quality control must be run as follows:*

1. *Quantitative tests - two controls at different concentrations at least daily*
2. *Qualitative tests - a negative control and a positive control (when applicable) at least daily*
3. *Tests producing a graded or titered result - a negative control and a control material with graded or titered reactivity, as applicable, at least daily (serially diluted positive controls are not required)*

*Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical or analytical criteria.*

*If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.*

**Evidence of Compliance:**

- ✓ Records of QC results including external and internal control processes **AND**
- ✓ Manufacturer product insert or manual

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 2003(Jan 24):5232 [42CFR493.1256(d)(3)], [42CFR493.1256(d)(6)].
2) Steindel SJ, Tetrault G. Quality control practices for calcium, cholesterol, digoxin, and hemoglobin. A College of American Pathologists Q-Probes study in 505 hospital laboratories. *Arch Pathol Lab Med.* 1998;122:401-408
3) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
4) Ye JJ, *et al*. Performance evaluation and planning for patient/client-based quality control procedures. *Am J Clin Pathol.* 2000;113:240-248
5) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Qualitative, Binary Output Examination Performance;* 3rd ed. CLSI document EP12. Clinical and Laboratory Standards Institute, Wayne, PA; 2023.
6) Clinical and Laboratory Standards Institute. *Laboratory Quality Control Based on Risk Management; Approved Guideline.* CLSI document EP23-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2011.
7) Department of Health and Human Services, Centers for Medicare and Medicaid Services, Brochure #11. CLIA Individualized Quality Control Plan Introduction. July 2013. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure11.pdf
8) Centers for Medicare and Medicaid Services (CMS), Individual Quality Control Plan (IQCP) for Clinical Laboratory Improvement Amendments (CLIA) laboratory nonwaived testing. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-announcement-letter-for-CLIA-CoC-and-PPM-labs.pdf (Accessed June 2014).
9) Department of Health and Human Services, Centers for Medicare and Medicaid Services. S & C: 16-20-CLIA: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. April 8, 2016.

## CHM.13950 Fluorescent Antibody Stain QC — Phase II

**Positive and negative controls are included with each patient run for all fluorescent antibody stains (eg, ANA IFA).**

**Evidence of Compliance:**

- ✓ Records of fluorescent antibody stain QC at defined frequency

REFERENCES

1) Clinical and Laboratory Standards Institute. *Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline.* CLSI Document I/LA23-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2004.

## CHM.14000 Control Range Establishment or Verification — Phase II

**The laboratory establishes or verifies an acceptable control range for each lot of control material.**

*NOTE: For unassayed control materials, the laboratory must establish an acceptable control range by repetitive analysis in runs that include previously tested control material. For assayed control materials, the laboratory must verify control ranges supplied by the manufacturer.*

*Control values supplied by the manufacturer may be used without verification for qualitative (eg, positive or negative) testing.*

**Evidence of Compliance:**

✓ Records for control range establishment or verification of each lot

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures. Approved Guideline.* 3rd ed. CLSI document EP05-A3. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.
2) Clinical and Laboratory Standards Institute. *Statistical Quality Control for Quantitative Measurement Procedures, Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

## CHM.14125 Calibrator Preparation — Phase II

**If the laboratory prepares calibrators and controls in-house, these materials are prepared separately.**

*NOTE: In general, calibrators should not be used as QC materials. If calibrators are used as controls, then different preparations should be used for these two functions.*

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):3708 [42CFR493.1256(d)(9)]

## CHM.14150 Calibrators as Controls — Phase I

**If a calibrator obtained from an outside supplier is used as a control, it is a different lot number from that used to calibrate the method.**

*NOTE: In general, calibrators should not be used as QC materials. However, this practice may be necessary for some methods when a separate control product is not available. In such cases, the calibrator used as a control must be from a different lot number than that used to calibrate the method.*

**Evidence of Compliance:**

✓ QC/calibrator records

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):3708 [42CFR493.1256(d)(9)]

## CHM.14200 Alternative Control Procedures — Phase II

**If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.**

*NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.*

**Evidence of Compliance:**

✓ Records of alternative control procedures