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 external controls must be run as follows:

- *For quantitative tests, two controls at two different concentrations must be run daily or with each batch of samples/reagents, unless a different requirement is specifically required by this checklist. Analytes selected are based on availability of materials.*
- *For qualitative tests, a negative control and a positive control (when available) must be run daily or with each batch.*

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

Evidence of Compliance:

✓ Records of QC results

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) (i, ii)], [42CFR493.1256(d)(6)].
2) 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.
3) Ye JJ, *et al*. Performance evaluation and planning for patient/client-based quality control procedures. *Am J Clin Pathol.* 2000;113:240-248
4) 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.

CBG.12900 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.

CBG.13000 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)]

CBG.13100 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.