



**Control materials are run concurrently with patient specimens to ensure appropriate functionality of the digital image system.**

*NOTE: Controls are samples that act as surrogates for patient/client specimens. They are periodically processed like a patient/client sample to monitor the ongoing performance of the analytic process. Controls should check test performance at relevant decision points for the digital image analysis system.*

*For qualitative tests, a positive and a negative control may be sufficient. For quantitative or semiquantitative tests, controls at more than one level should be used.*

**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)]
- 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.

**BAP.05425 QC Handling**

**Phase II**



**The biorepository tests control specimens in the same manner and by the same personnel as patient/client samples.**

*NOTE: Personnel who routinely perform patient/client 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 process 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)]; 2) *ibid*, 2003(Jan 24):3708[42CFR493.1256(d)(7-8)]

**BAP.05430 QC Confirmation of Acceptability**

**Phase II**

**Personnel review control results for acceptability before reporting results.**

*NOTE: Control results must be reviewed 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)]
- 2) 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)(6)]

**BAP.05435 Monthly QC Review**

**Phase II**

**The biorepository 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.*