



- Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory procedure for corrective action

ANP.29520 Daily QC**Phase II**

Control materials at more than one level are run each day of patient testing.

Evidence of Compliance:

- ✓ Records of QC results

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):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.

ANP.29530 QC Handling**Phase II**

The laboratory 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.

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)]

ANP.29540 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)]
- 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)]

ANP.29550 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