	• Sampling of calibration materials (labeling) • Sampling of calibration slides (labeling)
	• What is your course of action if calibration is unacceptable?

ANP.29500 Calibration **Phase II**

The test system is verified/calibrated, as appropriate, to check performance prior to testing.

NOTE: An appropriate process is used to check the optical and mechanical performance of the system. This may be accomplished using the manufacturer's provided material. Manufacturer's instructions must be followed regarding when and how often the verification/calibration is performed.

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): [42CFR493.1255]

ANP.29510 Recalibration **Phase II**

The test system is recalibrated when calibration verification fails to meet the established criteria provided by the manufacturer.

Evidence of Compliance:

✓ Records of recalibration, if calibration or calibration verification has failed

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): [42CFR493.1255(a)(3)]

QUALITY CONTROL

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.

Inspector Instructions:

	• Sampling of QC policies and procedures • Sampling of QC records
	• How do you determine when QC is unacceptable and corrective action is needed?