

Spectrophotometer (including ELISA plate readers) wavelength calibration, absorbance, and linearity are checked at least annually or as often as specified by the manufacturer, with appropriate solutions, filters or emission line source lamps, and the results recorded.

NOTE: Some spectrophotometer designs, eg, diode array, have no moving parts that can alter wavelength accuracy and do not require routine verification. The manufacturer's instructions must be followed.

Evidence of Compliance:

- ✓ Records of spectrophotometer checks at required frequency

CBG.17900 Stray Light

Phase II

Stray light is checked at least annually with extinction filters or appropriate solutions, if required by the instrument manufacturer.

Evidence of Compliance:

- ✓ Records of stray light checks, as applicable

CBG.18000 Calibration Curves

Phase II



For procedures using calibration curves, all the curves are rerun at defined intervals and/or verified after servicing or recalibration of instruments.

NOTE: Calibration curves must be run following manufacturer's instructions, at minimum, and as defined in laboratory procedure.

Evidence of Compliance:

- ✓ Records of calibration curve rerun and/or verification at defined frequency

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]

ELECTROPHORESIS

Inspector Instructions:

<p>READ</p>	<ul style="list-style-type: none"> • Sampling of electrophoresis policies and procedures • Sampling of electrophoresis QC logs
<p>OBSERVE</p>	<ul style="list-style-type: none"> • Electrophoretic patterns (appropriate separations)

CBG.18025 Daily QC - Electrophoresis

Phase II

Suitable control samples are run and reviewed with each batch of patient samples for all electrophoresis procedures for which controls are available.

Evidence of Compliance:

- ✓ Records of electrophoresis QC