The laboratory evaluates mass spectrometry assays for possible ion suppression or enhancement in patient samples during routine testing.

NOTE: Ion suppression (or less frequently, ion enhancement) is a recognized analytical anomaly in mass spectrometry assays. Such suppression can lead to false negative results or poor quantitative analyses (especially near assay limit of quantitation). While difficult to predict and observe from specimen to specimen, certain precautions should be used to try to detect ion suppression or enhancement.

Routine monitoring of the signal intensity of internal standard(s) is an effective way to recognize signal suppression/enhancement in a single patient sample, due to unexpected interfering components of the matrix. Internal standards to be used are those that cover the areas of the elution profile where matrix effects are most pronounced, and that the suitability of these internal standards has been determined (ie, with acceptance limits) during assay development and validation. Internal standard abundance acceptance criteria may be based on signal to noise ratio or may be compared to internal standard abundance in QC samples. As an example, for isotopically-labeled internal standards, if there is poor recovery of the internal standard, a signal to noise ratio greater than 3:1 should still suffice for acceptance of the specimen in question. If recovery of the isotopically-labeled internal standard is considered poor, then an alternate analysis should be considered (eg, the method of standard addition). For analogue-type internal standards, internal standard recovery may be used as a guide for identification of ion suppression/enhancement, although another option, such as the method of standard addition, would be a reasonable alternative. It should be noted that even isotopically-labeled internal standards do not always readily identify ion suppression or enhancement.

Evidence of Compliance:

✓ Records of monitoring of internal standards **OR** records of alternative methods used

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Liquid Chromatography-Mass Spectrometry Methods.* 2nd ed. CLSI document C62. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

COLORIMETERS, SPECTROPHOTOMETERS, AND FLUORIMETERS

Inspector Instructions:

READ	• Sampling of colorimeter/spectrophotometer policies and procedures
ASK	• How does your laboratory verify calibration curves?

CBG.17700 Absorbance/Linearity **Phase II**

Absorbance and/or fluorescence linearity is checked and recorded at least annually or as often as specified by the manufacturer, with filters or standard solutions.

Evidence of Compliance:

✓ Records of absorbance and linearity checks at required frequency

CBG.17800 Spectrophotometer Checks **Phase II**

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:

READ	• Sampling of electrophoresis policies and procedures • Sampling of electrophoresis QC logs
OBSERVE	• 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