Evidence of Compliance:
- ✓ Records of calibration/calibration verification

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]

CBG.16100 Quality Control - HPLC **Phase II**

Appropriate controls are extracted and run through the entire procedure.

NOTE: Controls used in HPLC procedures must evaluate as much of the complete testing process as is technically feasible. The control process includes any pre-treatment, pre-purification or extraction steps, unless non-pretreated control material is appropriate. For qualitative assays, the negative and positive controls should be at concentrations that meaningfully confirm performance below and above the decision threshold for the analyte. For quantitative assays, appropriate controls must include at least one normal sample, and at least one sample reflecting a disease range. For some assays, an additional control concentration may be useful to confirm performance near the assay's LOD, LOQ** or cut-off, if appropriate, or at a concentration consistent with highly abnormal levels that test the AMR.*

**LOD - limit of detection*

***LOQ - limit of quantitation*

Evidence of Compliance:
- ✓ QC records at defined frequency

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]

CBG.16200 Sample Run Order **Phase II**

A record of sample run order is maintained for review.

NOTE: Run list must include blanks, standards, controls and patients included in each run and be stored with the results of each batch run.

CBG.16300 Chromatographic Characteristics/Column Performance **Phase II**

Chromatographic characteristics and column performance are reviewed and approved for each run before results are released.

Evidence of Compliance:
- ✓ Records of review and approval

CBG.16400 Column Verification **Phase II**

New columns are verified for performance before use.

Evidence of Compliance:
- ✓ Records of column verification

CBG.16500 Reagent Grade **Phase II**

Reagents and solvents are of appropriate grade.

CBG.16600 Instrument Calibration **Phase II**

The laboratory calibrates HPLC equipment and reviews calibration records for acceptability.

CBG.16700 Carryover Detection **Phase II**

The laboratory has a process to detect and evaluate potential carryover.

NOTE: No matter what type of injection is used, the process must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis.

Evidence of Compliance:

- ✓ Records for reassessment of samples with potential carryover

REFERENCES

1) Clinical and Laboratory Standards Institute. *Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline.* 2nd ed. CLSI Document C43-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.
2) Society of Forensic Toxicologists/American Academy of Forensic Sciences. *Forensic Toxicology Laboratory Guidelines.* 2002; 8.2.8:13

CBG.16900 Limit of Detection/AMR **Phase II**

The limit of detection (sensitivity) and the AMR for quantitative methods have been determined for each procedure.

Evidence of Compliance:

- ✓ Records of limit of detection and AMR determination

MASS SPECTROMETRY (MS)

Inspector Instructions:

READ	• Sampling of MS policies and procedures • Sampling of calibration and tuning records • Identification criteria compliance
ASK	• How does your laboratory identify possible ion-suppression or enhancement?

CBG.17000 Instrument Calibration **Phase II**

The laboratory calibrates the mass spectrometer and reviews calibration records for acceptability.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Quantitative Measurement of Peptides and Proteins by Mass Spectrometry.* CLSI guideline C64. 1st ed. Clinical and Laboratory Standards Institute, Wayne, PA; 2021.
2) Clinical and Laboratory Standards Institute (CLSI). *Liquid Chromatography-Mass Spectrometry Methods.* 2nd ed. CLSI document C62. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.

*****REVISED** 08/24/2023***

CBG.17100 Mass Spectrometer Tuning **Phase II**