



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:

	<ul style="list-style-type: none"> • Sampling of MS policies and procedures • Sampling of calibration and tuning records • Identification criteria compliance
	<ul style="list-style-type: none"> • 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