



**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*. 2<sup>nd</sup> 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"> <li>• Sampling of MS policies and procedures</li> <li>• Sampling of calibration and tuning records</li> <li>• Identification criteria compliance</li> </ul>
	<ul style="list-style-type: none"> <li>• How does your laboratory identify possible ion-suppression or enhancement?</li> </ul>

#### 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.

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#### CBG.17100 Mass Spectrometer Tuning

Phase II