



**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.

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

**CBG.17100 Mass Spectrometer Tuning**

**Phase II**



**The mass spectrometers are tuned as defined based on the particular platform in use, assay performance requirements, and specimen types tested.**

*NOTE: Instruments must be tuned at least as frequently as recommended by the manufacturer. Acceptable tolerance limits for tune parameters must be defined, and tuning records retained.*

*Tandem mass spectrometers require tuning at the time of maintenance that requires shutdown of the vacuum.*

**Evidence of Compliance:**

- ✓ Records of tuning

**\*\*NEW\*\* 08/24/2023**

**CBG.17150 Validation, Monitoring, and Annual Verification of MS Data Analysis Tools**

**Phase II**



**The laboratory validates data analysis tools used for compound identification and quantification when first installed and after any modifications, as applicable, and verifies performance at least annually.**

*NOTE: Data analysis tools may be used for various processes, such as integration of targeted and untargeted peaks, evaluating acceptability of calibration and control performance, stability of baseline, calculation of ion mass ratios, discrimination of positive and negative results, and assessing risk of carryover. Data analysis tools (eg, software or code-based rules, algorithms, machine learning) used for automated data analysis must be verified using defined acceptability criteria. Version control of custom data analysis tools is required. Reassessment of lower limit of quantification (LLOQ) and other decision points may be used to ensure that a shift has not occurred due to instrument performance or another factor impacting assay performance.*

*Customized data analysis tools, and modifications to that software, should be appropriately documented and records should allow for tracking to identify persons that have added or modified that software. The purpose of the computer program, the way it functions, and its interaction with other programs must be clearly stated. The level of detail should be adequate to support troubleshooting, system modifications, or additional programming.*

**Evidence of Compliance:**

- ✓ Records of validation and revalidation after modifications **AND**
- ✓ Records of monitoring for changes to software update tools and other change impacting performance

**REFERENCES**

- 1) Vincente FB, Lin DC, Haymond S. Automation of chromatographic peak review and order to result data transfer in a clinical mass spectrometry laboratory. *Clin Chim Acta*. 2019;498(11):84-9.

**CBG.17300 Identification Criteria - Single Stage Mass Spectrometry**

**Phase II**



**The identification criteria for single stage mass spectrometry (ie, GC/MS, LC/MS) are in compliance with recommendations.**

*NOTE: One acceptable criterion for compound identification by GC/MS using ion ratios is that the unknown result must have ion ratios within a predefined tolerance limit. This limit should be supported by either literature references or through experimental means. Such ion ratio tolerance limits may differ based on the technique applied (eg, GC/MS versus LC/MS) as well as the analyte(s) being determined (eg, compounds with mainly ions of low abundance); thus, a defined limit to cover all methods and analytes cannot be given.*

*Identification using ion ratios typically requires the use of at least two ion ratios. However, one ion ratio of two characteristic ions may be acceptable if there are only a few characteristic ratios AND if there are other identifying characteristics, eg, retention time. The internal standard's identification should be monitored with at least one ion ratio. An acceptable criterion for compound identification using total spectra is that the unknown result must have a "spectral*