

****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(d)(3)(ii)]
- 2) 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.

CBG.15100 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.15200 Chromatographic Characteristics/Column Performance

Phase II

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

NOTE: Checks should record testing variables such as flow rate of carrier gas and amount of sample injected and indications of error, including split peaks, doublets, and tailing.

Evidence of Compliance:

- ✓ Records of review and approval

CBG.15300 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 of 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
- 3) Clinical and Laboratory Standards Institute (CLSI). *Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures*. 4th ed. CLSI guideline EP10. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

CBG.15400 Column Verification

Phase II

New columns are verified for performance before use.

Evidence of Compliance:

- ✓ Records of column verification

CBG.15500 Instrument Calibration

Phase II



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