

GAS CHROMATOGRAPHY (GC)

Inspector Instructions:

	<ul style="list-style-type: none"> Sampling of GC policies and procedures Sampling of control, calibration/standards records Sampling of column verification records
	<ul style="list-style-type: none"> How does your laboratory evaluate potential carryover? How have you determined the limit of detection and the AMR?

CBG.14900 Calibration and Calibration Verification

Phase II



Appropriate calibration or calibration verification is performed on each day of patient testing or following the manufacturer's instructions.

NOTE: For qualitative assays, an appropriate calibrator should be run at normal and abnormal levels. For quantitative assays, a multipoint calibration may be required if the measurement has a non-linear response. For some assays, a level near the assay's limit of detection (LOD) or at critical decision point(s) is needed. For measurement systems that have a linear response verified by periodic multipoint calibration verification and AMR verification protocols, a calibration procedure that uses a single calibrator at an appropriate concentration is acceptable. Analyses based on a single point calibration must be controlled by appropriate quality control samples. In addition, inclusion of a negative control (reagent blank) is good laboratory practice.

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]
- 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.15000 Daily QC - GC

Phase II

Appropriate controls are extracted and run through the entire procedure on each day of patient testing.

NOTE: Controls used in GC 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 inappropriate. 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(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.