CBG.15700 Gas Leakage **Phase I**

Gas lines and connections are checked for leaks every time tubing or a connection has been manipulated.

Evidence of Compliance:
- ✓ Records of gas line checks

CBG.15800 Reagent Grade **Phase II**

Reagents, solvents and gases are of appropriate grade.

CBG.15900 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

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.

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

Inspector Instructions:

READ	• Sampling of HPLC policies and procedures • Sampling of control, calibration/standards records • Sampling of column verification records
ASK	• How does your laboratory evaluate potential carryover? • How have you determined the limit of detection and the AMR?

CBG.16000 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.

Quality control materials in the appropriate concentration range may be used for calibration verification, providing that the linear response is verified by periodic multipoint calibration verification and AMR verification.

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]

CBG.16100 Quality Control - HPLC **Phase II**

Appropriate controls are extracted and run through the entire procedure.

NOTE: Controls used in HPLC 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 appropriate. 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]

CBG.16200 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.16300 Chromatographic Characteristics/Column Performance **Phase II**

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

Evidence of Compliance:
- ✓ Records of review and approval

CBG.16400 Column Verification **Phase II**

New columns are verified for performance before use.

Evidence of Compliance:
- ✓ Records of column verification

CBG.16500 Reagent Grade **Phase II**

Reagents and solvents are of appropriate grade.

CBG.16600 Instrument Calibration **Phase II**