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.