CBG.13700 QC Confirmation of Acceptability **Phase II**

Personnel review control results for acceptability before reporting patient/client results.

Evidence of Compliance:
- ✓ Records of control result approval

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):7166 [42CFR493.1256(f)]
2) 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):3708 [42CFR493.1256(d)(6)]

CBG.13800 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

Evidence of Compliance:
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

METHODS, INSTRUMENT SYSTEMS, AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

- If problems are identified during the review of the methods, instrument systems, and equipment or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions
- Select a representative assay and follow the entire process from specimen receipt to final result reporting

ENZYME ASSAYS

Inspector Instructions:

- Sampling of enzyme assay policies and procedures
- Sampling of control, calibration curve records
- Sampling of patient reports for completeness

CBG.14100 Control for Interference **Phase II**

Appropriate blanks are included in each run.

NOTE: Blanks are used to control for interference from two sources: background activity related to the reagents and non-enzymatic conversion of substrate to product.

CBG.14200 Calibration Curve **Phase II**

Standards are used to create a calibration curve for each run unless the calibration has been validated to remain stable over a defined period of time.

Evidence of Compliance:
- ✓ Records for calibration of each run or at the defined interval **AND**
- ✓ Records for validation of calibration stability if calibration is not performed with each run

CBG.14300 QC - Enzyme Assays **Phase II**

Controls are analyzed with each run.

NOTE: Ideally at least one affected control and one normal control sample are analyzed with each run. However, samples from affected patients may not always be available, and the use of inactivated samples (ie, samples that have been heated or treated in some other way to inactivate the enzyme of interest) is an acceptable alternative.

CBG.14400 Reference Intervals **Phase II**

Reference intervals for normal, disease, and if appropriate, carrier reference intervals are defined for each assay.

NOTE: Reference intervals must be established by the laboratory based on its own analysis of samples from multiple individuals, when appropriate. For rare diseases, it may not be possible for the laboratory to establish its own disease ("affected") reference interval. In this case, it is permissible to use reference intervals from the literature or other laboratories performing the test, as long as these are based on the same analytic method.

Evidence of Compliance:
- ✓ Records of establishment of reference intervals **OR**
- ✓ Literature to support reference intervals

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition.* CLSI Document EP28-A3c. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.

CBG.14500 Report Content **Phase II**

Laboratory reports include an interpretation of the result that reflects the presence or absence of the disease (or carrier state), possible limitations of the test, and, if appropriate, recommendations for additional testing.