Evidence of Compliance:
- ✓ Patient reports or worksheets

CHM.13730 Concentration Techniques **Phase I**

Concentration techniques for quantitative tests are verified.

NOTE: Techniques used to concentrate specimens for analysis must be verified at specified, periodic intervals (not to exceed one year or manufacturer's recommendations).

Evidence of Compliance:
- ✓ Records of concentration technique verification at defined frequency

CHM.13750 Cut-Off Values for Qualitative Tests **Phase II**

For qualitative tests that use a quantitative cut-off value to distinguish positive from negative results, the analytic performance around the cut-off value is verified or established initially, and reverified at least every six months thereafter.

NOTE: This requirement applies to tests that report qualitative results based on a quantitative measurement using a threshold (cut-off value) to discriminate between positive and negative results for clinical interpretation. It does not apply to methods where the laboratory is not able to access the actual numerical value from the instrument.

Appropriate materials for establishment and verification of the cut-off are identical to those recommended for calibration verification. The requirement can be satisfied by the process of calibration or calibration verification using calibrators or calibration verification materials with values near the cut-off. It may also be satisfied by the use of QC materials that are near the cut-off value if those materials are claimed by the method manufacturer to be suitable for verification of the method's calibration process.

Verification of the cut-off should also be performed at changes of lots of analytically critical reagents (unless the laboratory director has determined that such changes do not affect the cut-off); after replacement of major instrument components; after major service to the instrument; and when QC materials reflect an unusual trend or shift or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

For FDA-cleared or approved tests, the clinical appropriateness of the cut-off value is evaluated as part of the clinical validation performed by the manufacturer. For laboratory-developed tests and modified FDA-cleared or approved tests, refer to COM.40640 for validation of clinical claims.

Evidence of Compliance:
- ✓ Records of initial establishment and verification of the cut-off value at defined frequency

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) 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): [42CFR493.1253].

CHM.13810 Neonatal Bilirubin Testing **Phase II**

Neonatal bilirubin results in the range of 5 to 25 mg/dL are accurate and suitable for use with standardized clinical practice interpretive guidelines, with accuracy verified at least annually.

NOTE: Each laboratory must assess the accuracy of its instrument/test system over the range of bilirubin values appropriate for the clinical guidelines (5-25 mg/dL). In many cases, acceptable performance can be verified using proficiency testing materials with assigned reference values.

In other cases, the laboratory can meet the objective by using patient samples to perform correlation studies against 1) a reference method; OR 2) an alternate method that consistently demonstrates good performance in a proficiency testing program (based on the method mean value as compared to the reference value). In all cases, such comparisons should include at least one or two samples annually in the target clinical range of 5-25 mg/dL.

The reference method for total bilirubin is described in Doumas et al, Candidate reference method for determination of total bilirubin in serum: development and validation. Clin Chem, 1985.

Evidence of Compliance:

✓ Written assessment of adequacy for the agreement with target values in the range of the clinical guidelines for clinical purposes, at least annually, by the laboratory director or designee

REFERENCES

1) Lo SF, Doumas BT, Ashwood ER. Bilirubin proficiency testing using specimens containing unconjugated bilirubin and human serum: results of a College of American Pathologists study. *Arch Pathol Lab Med* 2004;128:1219-1223
2) American Academy of Pediatrics Subcommittee on Hyperbilirubinemia. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. *Pediatrics* 2004;114:297-316
3) Doumas BT, Kwok-Cheung PP, Perry BW, et al. Candidate reference method for determination of total bilirubin in serum: development and validation. *Clin Chem* 1985; 31:1779-1789.
4) Lo SF, Doumas BT. The status of bilirubin measurements in U.S. Laboratories: Why is accuracy elusive? *Semin Perinatol* 2011; 35:141-147.
5) Barrington KJ, Sankaran K. Canadian Paediatric Society, Fetus and Newborn Committee. Guidelines for detection, management, and prevention of hyperbilirubinemia in term and late preterm newborn infants. http://www.cps.ca/documents/position/hyperbilirubinemia-newborn. Accessed August 18, 2014.

CONTROLS

Controls are used to ensure that a test system is performing correctly. Traditionally, controls are samples that act as surrogates for patient/client specimens, periodically processed like a patient/client sample to monitor the ongoing performance of the entire analytic process. Under certain circumstances, other types of controls (electronic, procedural, built-in) may be used. (Details are in the checklist requirements in this section, below.)

CONTROLS – WAIVED TESTS

Inspector Instructions:

	• Sampling of quality control policies and procedures • Sampling of QC records
	• How do you determine when QC is unacceptable and when corrective actions are needed?
	• Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action