*method or with another laboratory, the testing of previously tested specimens in duplicate, testing of specimens in duplicate, or other defined processes approved by the laboratory director.*

**Evidence of Compliance:**
- ✓ Records of alternative control procedures

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): [42CFR493.1256(h)].

**FDT.02060 Weekly QC Review** **Phase II**

**Quality control data are reviewed and assessed at least weekly by the laboratory director or designee to detect instrument malfunction or analytical system trends.**

**Evidence of Compliance:**
- ✓ Records of QC review with follow-up for outliers, trends, or omissions

**FDT.02080 Monthly QC Review** **Phase II**

**Quality control data are reviewed and assessed at least monthly by the laboratory director, including QC and blind QC records or summarized QC data to detect trends, and review of corrective actions taken by laboratory personnel.**

*NOTE: The laboratory director must be responsible for the overall QC program, which must include review at least monthly of QC analysis, QC evaluation and corrective actions taken, including appropriate records by laboratory personnel. The review of the quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.*

*The QC data for tests performed less frequently than once per month should 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

**FDT.02150 Confirmation Assay Precision** **Phase II**

**The laboratory monitors the precision of each confirmation assay around the commonly accepted cut-offs.**

*NOTE: This may be accomplished by using the cut-off control to determine the assay's precision at the cut-off value.*

**Evidence of Compliance:**
- ✓ Records of precision monitoring

**FDT.02166 Error Detection** **Phase II**

**The laboratory has processes to detect significant clerical and analytical errors before reporting the results.**

*NOTE: The detection of errors (eg, wrong donor identification information, wrong client information, failure to report critical chain-of-custody errors, wrong tests performed, etc.) may have forensic implications, as may analytical errors. A documented procedure must be present that describes the laboratory's system to detect and prevent these clerical and analytical errors.*

*One common method is review of results by a qualified person (technologist, supervisor, pathologist, section director) before release from the laboratory, but there is no requirement for*