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

supervisory review of all reported data for single analyte tests that do not include interpretation. All tests that include an interpretation must be reviewed by the section director or qualified designee before release from the laboratory. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results must provide for timely correction of errors, ie, before results become available for decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the ordering physician or referring laboratory, as applicable.

Each procedure must include a listing of common situations that may cause analytically inaccurate results, together with a defined protocol for dealing with such analytic errors or interferences. This may require alternate testing methods; in some situations, it may not be possible to report results for some or all of the tests requested.

The intent of this requirement is NOT to require verification of all results outside the reference (normal) range.

Evidence of Compliance:

- ✓ Records of review of results **OR** records of consistent implementation of the error detection processes **AND**
- ✓ Records of timely corrective action of identified errors

FDT.02182 QC Data **Phase II**

Results of quantitative controls are conveniently recorded or plotted and analyzed routinely to detect trends in instrument or process failure.

FDT.02715 QC Corrective Action **Phase II**

The laboratory performs and records corrective action when control results exceed defined acceptability limits.

NOTE: The actions taken must be consistent with the laboratory's quality control program (GEN.30000). Test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in test results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if donor samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected test results.

Evidence of Compliance:

- ✓ Records of corrective action for unacceptable control results

PROCEDURE MANUAL

Inspector Instructions:

- Representative sample of procedures for completeness, organization (can retrieve information easily) and laboratory director review. Current practice must match contents of policies and procedures.