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.