

QUALITY CONTROL PROCEDURES

PURPOSE

For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. The laboratory must establish the number, type, and frequency of testing control materials used, if applicable, the performance specifications verified or established by the laboratory. The control procedures must detect immediate errors that occur due to test system failure, adverse environmental conditions, operator performance and monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

POLICY

To ensure the accuracy and precision of the analytic process, procedures will be maintained that define the number, frequency, and control product to be used for each test system. The results will be evaluated using Westgard rules to detect immediate errors and for performance over time. Internal controls or electronic controls will be used as specified by the manufacturer, and in compliance with CLIA regulations.

- Control results “out of control” will initiate corrective action and its documentation on the quality control log. Controls will be retested and must be acceptable before reporting any patient results.
- A technical supervisor will review the quality control records at least monthly for appropriate action and system performance over time. If patterns are discovered appropriate actions will be taken.

For microscopic tests where commercial controls are unavailable such as Wet Mount, Fecal WBC, quality control is monitored by the following, but not limited to: (1) Microscopic maintenance (2) Proficiency Testing (3) Blind Sample Testing (4) Staff Competency Assessment (5) MTS Staff Competency – Micrographs.

Documentation:

- Quality Control data and Levy Jennings print outs.
- Corrective action documentation.
- Record of Supervisor review
- Internal control documentation
- Electronic control documentation

