

CONTROL PROCEDURES FOR CHEMISTRY

In 2003, the final CLIA regulations were published and included changes designed to streamline the quality control (QC) process. There is no longer a distinction between high complexity and moderate complexity with regard to quality control.

Routine Chemistry

In general, for routine chemistry:

- You must follow the manufacturer's instructions for performing QC, but at a minimum test two levels of controls each day the test is performed
- You must perform QC before resuming testing and reporting results when:
 - there is a complete change of reagents
 - major preventive maintenance is performed
 - any critical change occurs that may influence test performance

For QC requirements that apply to routine chemistry, see the general requirements for control procedures (quality control) that are given in *CLIA Facts 16E: Analytic Phase: Control Procedures*.

Blood Gas Analysis

There are additional, specific control requirements for blood gas analysis. The lab must perform the following:

1. Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.
2. Test one control each eight hours of testing using a combination of controls that include both low and high values on each day of testing.
3. Test one control each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.
4. Document all control procedures performed.

