CONTROL PROCEDURES FOR HEMATOLOGY

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. Another important change in the final CLIA regulations reduces the frequency of QC required for automated hematology instruments from every eight hours of testing to each day of testing.

Routine Hematology

In general, for routine hematology:

- 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 the QC requirements that apply to automated hematology, see the general requirements for control procedures (quality control) that are given in *CLIAFacts16E: Analytic Phase: Control Procedures*. There are also additional, specific hematology control requirements for:

- Manual cell counts
- Coagulation

Manual Cell Counts

For manual cell counts performed using a hemocytometer:

- One control must be tested each eight hours of operation
- Patient specimens and controls must be tested in duplicate
- The laboratory must document all control procedures performed

Non-manual Coagulation Test Systems

For all non-manual coagulation test systems, the laboratory must:

- Test two levels of controls each eight hours of operation and each time a reagent is changed
- Document all control procedures performed

Manual Coagulation Tests

For manual coagulation tests:

- Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed
- Patient specimens and control materials must be tested in duplicate
- The laboratory must document all control procedures performed