

## **D5547**

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### ***§493.1269 Standard: Hematology***

**(c) For manual coagulation tests--**

**(c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and**

**(c)(2) Patient specimens and control materials must be tested in duplicate.**

### ***§493.1269 Standard: Hematology***

**(d) The laboratory must document all control procedures performed, as specified in this section.**

**Interpretive Guidelines §493.1269(d)**

Quality control records should include lot numbers, date prepared/opened, expiration dates, the actual measurement(s) taken, reactions and/or observations and demonstrate that controls were tested when shipments of reagents or stains were opened or when the laboratory prepared these materials. However, do not dictate the acceptable format for documentation.