Hematology	
Former Standard and Guidance	***Proposed Standard and Guidance***
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. (HM S2 revised and effective July 14, 2014)	**Deleted**
Cellular Hematology	
Hematology Standard 2 (HM S2) For manual cellular hematology procedures, one level of quality control material shall be run during each eight hours of operation. If a laboratory's primary cellular hematology procedures are manual methods, a minimum of two levels of quality control material are required during each eight hours of operation. **Guidance –** For manual white, red (including reticulocytes) and platelet cell counts, one level of assayed material, or one procedural control, during each eight hours of operation is required. Procedural control is defined as duplicate dilutions of either an assayed control or previously assayed patient specimen. These may be assayed by the same individual or by different people and the results compared to previously defined acceptable limits for differences between duplicates. White blood cell and platelet counts may be compared with a value estimated from a blood smear.	**Hematology Standard of Practice 1 (HM S1): Quality Control Requirements** Unless an individualized quality control plan (IQCP) is implemented according to Quality Control Standards of Practice 2, 3 and 4, for manual cellular hematology procedures, the laboratory must: a) test one (1) level of quality control material during each eight (8) hours of operation; b) test specimens and quality controls in duplicate (e.g., counting two (2) hemocytometer chambers from one (1) dilution); and c) ensure that precision for duplicate specimens meet laboratory defined performance specifications. **Guidance –** For manual white, red (including reticulocytes) and platelet cell counts, one level of assayed material, or one procedural control, during each eight hours of operation is required. Procedural control is defined as duplicate dilutions of either an assayed control or previously assayed patient specimen. These may be assayed by the same individual or by different people
Hematology Standard 3 (HM S3) When cell counts are performed manually using a	

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hemocytometer: a) testing shall be performed in duplicate (e.g., counting two hemocytometer chambers from one dilution); and, b) acceptable precision limits for duplicate specimens shall be defined.	and the results compared to laboratory defined performance specifications for acceptable differences between duplicates. White blood cell and platelet counts may be compared with a value estimated from a blood smear.
Hematology Standard 4 (HM S4) For automated coagulation procedures, a minimum of two levels of quality control material shall be run: a) each eight hours of operation unless a quality control protocol has been validated as required in Quality Control Sustaining Standard of Practice 2 (QC Design S2) or Quality Control Sustaining Standard of Practice 1 (QC Design S1). b) each time a change in reagent occurs. **Guidance –** The quality control material should include a normal and at least one abnormal level in the expected range of patient samples.	**Hematology Standard of Practice 2 (HM S2): Automated Coagulation Quality Control** Unless an individualized quality control plan (IQCP) is implemented according to Quality Control Standards of Practice 2, 3 and 4, for automated coagulation procedures, the laboratory must test two (1) levels of quality control materials: a) each eight (8) hours of operation; and b) each time a change in reagent occurs. **Guidance –** The quality control material should include a normal and at least one abnormal level in the expected reference range of patient population.
Hematology Standard 5 (HM S5) For manual coagulation tests: a) each individual performing tests must test a minimum of two levels of quality control material: i. prior to testing patient results; ii. each time a change in reagents occurs; and,	**Hematology Standard of Practice 3 (HM S3): Manual Coagulation Quality Control** Unless an individualized quality control plan (IQCP) is implemented according to Quality Control Standards of Practice 2, 3 and 4, for manual coagulation tests: a) each individual performing tests must test a minimum of two (2) levels of quality control materials: i. prior to testing patient specimens;

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b) patient and control specimens shall be tested in duplicate.	ii. each time a change in reagents occurs; and b) patient and control samples must be tested in duplicate.