D5543

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1269 Standard: Hematology

(a) For manual cell counts performed using a hemocytometer--

(a)(1) One control material must be tested each 8 hours of operation; and

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

Interpretive Guidelines §493.1269(a)

When condition-level deficiencies in Hematology are identified in any or all phases of testing, use D5024.

For all manual cell counts performed using a hemocytometer (e.g., synovial fluids, CSF, semen) the laboratory may meet the requirement for duplicate testing by counting two chambers from one dilution.

"Hours of operation" is defined as each shift of 8 consecutive hours the laboratory is in operation, including "on-call" shifts. When documenting standards/controls results, the laboratory must identify the shifts in which controls are tested with patients.

If the manufacturer of an instrument that performs automated differentials does not give criteria for when to perform a manual differential, the laboratory must establish criteria indicating when to perform a manual differential including instructions for reporting the results. Use D5423.

Control requirements for automated instruments that perform hemoglobin, hematocrit, red and white cell counts and differentials are found at §493.1256(d)(3)(i). Use D5447. The calibration verification exception for automated cell counters is found at D5439.