§493.1256 Standard: Control procedures

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

Interpretive Guidelines 493.1256(d)(3)(i)

For monitoring the abnormal range, the laboratory must select controls that correlate with the patient values either in terms of specimen matrix or range to be evaluated. A laboratory must not use control materials outside the patient reportable range. Control samples not containing the analytes or substances to be controlled are not acceptable as control material.

Routine Chemistry:

For monitoring the abnormal range, the laboratory should select control materials that correlate with the patient values both in terms of specimen matrix and range to be evaluated. For example, an elevated serum-based bilirubin control should be employed when measuring neonatal bilirubins; a low-level protein control or cerebrospinal fluid control should be used for monitoring cerebrospinal fluid protein.

Hematology:

For instruments which perform hemoglobin, hematocrit, red and white blood cell counts, platelets and/or differentials, acceptable controls are 2 levels of assayed materials, OR 1 level of assayed material and 1 patient specimen that was verified in the same batch of specimens with the assayed control material. The laboratory must establish criteria for an acceptable range of performance as required at D5481.

EXCEPTION:

Unless otherwise required by the test system's manufacturer or the laboratory's performance specifications, for instruments that perform white blood cell differentials directly from blood films (smears), a commercial control or patient specimen

(differential) that has been verified through repetitive testing is an acceptable control and satisfies the requirements of §493.1256(d), as appropriate.