D5469

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§493.1256 Standard: Control procedures

(d)(10) Establish or verify the criteria for acceptability of all control materials.

(d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

Interpretive Guidelines §493.1256(d)(10)

Acceptable ranges must be verified (assayed) or established (unassayed) by the laboratory for control materials and any calibrators that are used in lieu of control materials.

For procedures in which a spiked sample is used as a control, an acceptable range must be established for the amount of recovery of the spiked sample, either in percentage or actual concentration.

If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits.

When patient specimens are used to meet the control requirements, data must be evaluated in accordance with §493.1256(d)(10)(iii).

There are no specific guidelines for the number of times a material must be tested to establish statistical limits. In general, twenty replicate tests should be considered the minimum for determining a standard deviation.

Probes §493.1256(d)(10)

What statistics does the laboratory have to demonstrate the number of assays and the period of time in which the laboratory repetitively tested control materials to verify or establish control limits?

How does the laboratory evaluate control results to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytical system?

If more than one test system is in use for a test procedure, did the laboratory evaluate the data for each test method in the establishment of control limits?