D5215

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1236 Standard: Evaluation of proficiency testing performance

(b)(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

Interpretive Guidelines §493.1236(b)(2)

The laboratory must have a mechanism for routine review of its proficiency testing results that are evaluated by its PT providers. This includes a review of its actual PT results against the PT provider's participant summary results for the particular PT event and when any of the following occur:

- The PT program assigned an artificial score of 100% (e.g., results not evaluated or scored);
- A zero score for nonparticipation; if the laboratory did not test the specimen, it must document what other means were used to assess the accuracy of the test for the PT event that was missed; or
- The PT provider notifies the laboratory that its results were not evaluated (given a score of "0") due to missing the return deadline.

Probes §493.1236(b)(2)

Has the laboratory reviewed its test menu to determine if it tests any analyte(s) that are not listed in subpart I?

§493.1236(c) At least twice annually, the laboratory must verify the accuracy of the following: