

D5217

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§493.1236 Standard: Evaluation of proficiency testing performance

(c)(1) Any test or procedure it performs that is not included in subpart I of this part.

Interpretive Guidelines §493.1236(c)(1)

Refer to subpart I, Proficiency Testing Programs for Nonwaived Testing. Subpart I includes those specialties, subspecialties, analytes and tests that are considered regulated tests. For those tests not listed in subpart I (not regulated), the laboratory must verify the accuracy of the test or procedure twice annually, including the accuracy of calculated results, if applicable.

For those tests not listed under Subpart I, the laboratory may enroll in a PT program to verify the accuracy of their test or procedure. However, under no circumstances may these PT samples be referred (or results communicated) to another laboratory for any reason prior to the PT testing event cut-off date. The PT referral consequences (loss of certificate and bar on owner/operator) apply equally to all PT testing samples and results. (See D2013).