

**§493.801(b) Standard: Testing of proficiency testing samples**

**(b)(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.**

**Interpretive Guidelines §493.801(b)(5)**

Review records to ensure that the analyst or analysts performing the testing and the director or his/her designee have signed the statement attesting that PT samples were tested in the same manner as patient specimens. For moderate complexity testing, in accordance with §493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447. The signature of the director or technical consultant/supervisor need not be obtained prior to reporting PT results to the PT provider.

**(b)(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.**

**Interpretive Guidelines §493.801(b)(6)**

**Primary** means the test system(s), assay(s) or examination(s) routinely used for patient testing at the time of the PT testing event.