

**D2009**

**(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)**

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

**(b)(1)The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory’s routine methods.**

**Interpretive Guidelines §493.801(b)(1)**

This requirement is NOT to be interpreted as prohibiting more than one testing individual from performing PT if the laboratory routinely performs patient testing using more than one “individual”. PT samples are to be tested in the same manner as patient specimens. IF patient specimens are tested using procedures that require more than one individual to perform, PT must be performed in the same manner.

Review records to ensure that the analyst or analysts performing the testing and the director or his/her designee have signed a 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.