

§493.807 Condition: Reinstatement of laboratories performing nonwaived testing

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

Interpretive Guidelines §493.807

The surveyor may review Report #155 of the PT monitoring system to determine whether the laboratory has performed two consecutive PT events successfully. These data are identified as "non-routine" scores in the system. The PT program supplying the reinstatement samples will grade the events and enter the scores in the system.

***PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR
LABORATORIES PERFORMING TESTS OF MODERATE
COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH
COMPLEXITY, OR ANY COMBINATION OF THESE TESTS***

§493.821 Condition: Microbiology

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.