D2151
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.855 Standard; Cytology: gynecologic examinations

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.

Interpretive Guidelines §493.855(c)

Any laboratory testing patient specimens for the Human Papillomavirus (HPV) must enroll and successfully participate in a CMS-approved proficiency testing program for HPV beginning in 2008. Laboratories should refer to Subpart H for further information.

The laboratory's CLIA certificate must include the subspecialty of Virology regardless of where the testing is performed.

§493.857 Condition: Immunohematology

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The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

Refer to Subpart I for analytes or tests for which laboratory PT performance is to be evaluated.