

D2064

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

§493.831 Standard; Virology

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

Interpretive Guidelines §493.831(e)

Any laboratory testing patient specimens for the Human Papillomavirus (HPV) must

enroll and successfully participate in a CMS-approved proficiency testing program for HPV. Laboratories should refer to Subpart H for further information. For example: A Cytology laboratory that performs HPV testing must have a CLIA certificate that includes the subspecialty of Virology.

§493.833 Condition: Diagnostic immunology

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The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.