

D6116

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§493.1451 Standard: Technical supervisor responsibilities

(b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

Interpretive Guidelines §493.1451(b)(3)

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. The laboratory must also be in compliance with all the CLIA regulations governing the preanalytic, analytic, and postanalytic phases of testing including proficiency testing and personnel requirements.