COSMOS
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42 C.F.R. § 493.1274

Standard: Cytology.

(a) *Cytology slide examination site.* All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) *Staining.* The laboratory must have available and follow written policies and procedures for each of the following, if applicable:

(1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.

(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

(c) *Control procedures.* The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following:

(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under § 493.1469 or § 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section).

(i) The review must be performed by an individual who meets one of the following qualifications:

(A) A technical supervisor qualified under § 493.1449(b) or (k).

(B) A cytology general supervisor qualified under § 493.1469.

(C) A cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2).

(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information.