D5621

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§493.1274 Standard: Cytology

(c)(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).

Interpretive Guidelines §493.1274(c)(1)

The 10 percent rescreen of negative cases is not required for a one-person laboratory consisting of a technical supervisor or a laboratory which only employs pathologists

qualified as technical supervisors. However, these laboratories must establish and follow a program to detect errors. This program must include, but is not limited to, cytologic/histologic correlations, retrospective review of negative cases, documentation of initial and rescreening results, and statistics [(c)(2)-(5) of this section].

The laboratory must review all slides from each case selected for rescreen.

(c)(1)(i) The review must be performed by an individual who meets one of the following qualifications:

(c)(1)(i)(A) A technical supervisor qualified under §§493.1449(b) or (k).

(c)(1)(i)(B) A cytology general supervisor qualified under §493.1469.

(c)(1)(i)(C) A cytotechnologist qualified under §493.1483 who has the experience specified in §493.1469(b)(2).

Interpretive **Guidelines §493.1274(c)(1)(i)**

The laboratory must document which individual(s) are qualified to conduct the 10 percent rescreen. Slides reviewed as part of the 10 percent rescreen must be included in the workload limit of the cytology general supervisor or the cytotechnologist performing the review. Use D5639.

(c)(1)(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.

Interpretive **Guidelines §493.1274(c)(1)(ii)**

The laboratory must have a procedure to determine which slides are rescreened. This procedure should ensure that individuals screening the slides do not know which slides will be chosen for rescreen.

The laboratory must establish criteria to ensure that random negative gynecological cases selected for rescreening include, when possible, cases from patients that are identified as having a higher than average probability for developing cervical cancer.

(c)(1)(iii) The review of those cases selected must be completed before reporting patient results.