

some cases from high-risk patients, based upon criteria established by the laboratory director, as well as random negative cases. Alternative procedures for 10% rescreening could include, but are not limited to a rapid rescreening of all cases or rapid prescreening of all cases with targeted rescreening of discrepant cases. Slides must be rescreened or prescreened in their entirety, including slides processed by imaging instruments that select a limited number of microscopic fields for examination.

Evidence of Compliance:

- ✓ Defined method to be used for rescreening or prescreening and the criteria for case selection
AND
- ✓ Records of rescreened or prescreened cases with comparison to final comprehensive screening results

CYP.07491 Result Reporting Phase II



The results of gynecologic cases selected for rescreening are not reported until the rescreen is complete.

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1274(o)(1)]

CYP.07504 Rescreener Qualifications Phase II

The rescreening of negative gynecologic cases is performed by an individual qualified as a cytopathology supervisor (see CYP.08100).

Evidence of Compliance:

- ✓ Records of section director/technical supervisor or supervisor/general supervisor qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field for each individual performing rescreening

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR493.1274(c)(1)].

CYP.07517 Retrospective Review Phase II



All available (either on site or in storage) previously negative slides received within the past five years are reviewed whenever a new high-grade squamous intraepithelial lesion (moderate or severe dysplasia, carcinoma in situ, CIN II or III) or malignant cervical/vaginal cytology is reported.

NOTE: Previously negative slides (read manually or automated) from the index patient must be rescreened or reviewed by an individual qualified as a cytology supervisor (see CYP.08100). Laboratory policy should specify which cases require pathologist review.

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register*. 2003(Jan 24):5232 [42CFR493.1274(c)(3)]
- 2) Jones BA. Rescreening in gynecologic cytology. Rescreening of 3762 previous cases for current high-grade squamous intraepithelial lesions and carcinoma - a College of American Pathologists Q-Probes study of 312 institutions. *Arch Pathol Lab Med*. 1995;119:1097-1103
- 3) Jones BA. Rescreening in gynecologic cytology. Rescreening of 8096 previous cases for current low-grade and indeterminate-grade squamous intraepithelial lesion diagnoses - a College of American Pathologists Q-Probes study of 323 laboratories. *Arch Pathol Lab Med*. 1996;120:519-522
- 4) Davey DD. Papanicolaou smear five year retrospective review: what's required by the Clinical Laboratory Improvement Amendments of 1988? *Arch Pathol Lab Med*. 1997;121:296-298
- 5) Clary KM, et al. Cytohistologic discrepancies. A means to improve pathology practice and patient outcomes. *Am J Clin Pathol*. 2002;117:567-573

CYP.07530 Retrospective Review Requiring Amendment Phase II