1. **Malignant or suspicious for malignancy**
2. **Low and high-grade squamous intraepithelial lesions**
3. **Atypical squamous cells**
4. **Atypical glandular cells**
5. **Reactive or repair**
6. **Gynecologic slides with p16/Ki67 dual stain**

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):7169 [42CFR493. 1274(e)(1)(i) through (e)(1)(v), and (e)(2)]
2) Raab SS, *et al.* Interobserver variability of a Papanicolaou smear diagnosis of atypical glandular cells of undetermined significance. *Am J Clin Pathol.* 1998;110:653-659
3) Selvaggi SM. Is it time to revisit the classification system for cervicovaginal cytology? Arch Pathol Lab Med. 1999;123:993-994

*****REVISED** 12/26/2024***

CYP.07478 10% Rescreen **Phase II**

At least 10% of each cytotechnologist's gynecologic cases, including cases reflexed from primary HPV cases, that have been interpreted to be negative are rescreened.

NOTE: The 10% rescreening is a CLIA requirement, and only applicable to US laboratories and other laboratories subject to those regulations. An individual who qualifies as a cytotechnologist supervisor and who performs initial screening must also have a minimum of 10% of his or her cases that are initially interpreted as negative subjected to rescreening. This rescreening must include some cases from high-risk patients, based upon criteria established by the laboratory director, as well as random negative cases. Cases screened by MDs or DOs who are certified in Anatomic Pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or who possess qualifications that are equivalent to those required for the above certifications are not subject to this rescreening requirement. If FDA-approved automated instruments are used for quality control rescreening case selection, the laboratory must ensure that the methods used meet the requirements of CLIA, and that manufacturer and FDA recommendations for quality control are followed.

Slides must be rescreened in their entirety, including slides processed by imaging instruments that select a limited number of microscopic fields for examination by the cytotechnologist.

Evidence of Compliance:

- ✓ Defined qualifications of the individual to perform rescreening and the criteria for case selection **AND**
- ✓ Records of rescreened cases with comparison to original screening results

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):7169 [42CFR493.1274(c)(1)]
2) Krieger P, *et al.* Guest editorial: random rescreening of cytology smears: a practical and effective component of quality assurance programs in both large and small cytology laboratories. *Acta Cytol.* 1994;38:291-298
3) Krieger P, *et al.* A practical guide to Papanicolaou smear rescreens. How many slides must be reevaluated to make a statistically valid assessment of screening performance? *Cancer Cytopathol.* 1998;84:130-137
4) Renshaw AA, *et al.* Performance characteristics of rapid (30-second) prescreening. Implications for calculating the false-negative rate and comparison with other quality assurance techniques. *Am J Clin Pathol.* 1999;111:517-522
5) Intersociety Working Group for Cytology Technologies. Proposed method for evaluating secondary screening (rescreening) instruments for gynecologic cytology. *Am J Clin Pathol.* 1999;111:590-593
6) Raab SS, *et al.* Cost effectiveness of rescreening cervicovaginal smears. *Am J Clin Pathol.* 1999;111:601-609

CYP.07480 Rescreening or Prescreening Negative Cases **Phase II**

For laboratories not subject to US regulations, the competency of each screener of gynecologic cytopathology specimens is assessed by either a pre-screening or rescreening process.

NOTE: Laboratories not subject to US regulations may follow the US requirement or may use an alternative procedure. Laboratories subject to US regulations are required to rescreen 10% of each cytotechnologist's gynecologic cases that have been interpreted to be negative, including

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(c)(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