	• What is your process for correlating gynecologic cytopathology findings with clinical information? • How do you educate providers that the Pap test and primary HPV are screening tests with false negative results? • What is the process for performance monitoring of cytotechnologists?
DISCOVER	• Follow a slide through automated staining, cover-slipping and automated screening. Determine if practice matches procedure. • Review records or specimen log for unsatisfactory specimens. Determine if the quality of the specimens follows defined criteria. • Review a sampling of rescreening records. Determine if the rescreening was performed by a qualified individual, results are not reported until the rescreen is complete and a minimum of 10% of cases for each screener are rescreened.

CYP.07439 Papanicolaou Stain **Phase II**

The Papanicolaou stain is used for gynecologic specimens.

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(b)(1)].

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CYP.07452 Unsatisfactory Specimens - Gynecologic Cytopathology **Phase II**

The laboratory has written criteria for identification and reporting of unsatisfactory gynecologic specimens and slide preparations including p16/Ki67 dual stain.

NOTE: Cytopathology reports must clearly specify when a specimen and/or slide preparation is unsatisfactory for evaluation and state the reason in the cytopathology report. The criteria for categorizing a specimen and/or slide preparation as unsatisfactory (eg, scant cellularity, obscuring blood, obscuring inflammation, or quantity insufficient for reflex testing from primary HPV screening) must be defined by the laboratory. Unsatisfactory cases must not be reported as negative or normal. Gynecologic specimens with atypical cells are always "satisfactory," although the report may include comments on the quality of the preparation.

Adequacy criteria are consistent with manufacturer instructions; however, any p16/Ki67 dual stain with positive cell(s) is reported as adequate.

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(e)(4)].
2) Davey DD, *et al.* Terminology and specimen adequacy in cervicovaginal cytology. *Arch Pathol Lab Med.* 1992;116:903-907
3) Ransdell JS, *et al.* Clinicopathologic correlation of the unsatisfactory Papanicolaou smear. *Cancer Cytopathol.* 1997;81:139-143
4) Renshaw AA, *et al.* Accuracy and reproducibility of estimating the adequacy of the squamous component of cervicovaginal smears. *Am J Clin Pathol.* 1999:11:38-42
5) Selvaggi SM. Is it time to revisit the classification system for cervicovaginal cytology? *Arch Pathol Lab Med.* 1999;123:993-994
6) Davey DD, *et al.* Atypical cells and specimen adequacy. Current laboratory practices of participants in the College of American Pathologists interlaboratory comparison program in cervicovaginal cytology. *Arch Pathol Lab Med.* 2000;124:203-211
7) Zhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017.
8) Solomon D, *et al*. The 2001 Bethesda system. Terminology for reporting results of cervical cytology. *JAMA.* 2002;287:2114-2119
9) Solomon D, Nayar, R, *eds*. The Bethesda system for reporting cervical/vaginal cytologic diagnoses: Definitions, criteria, and explanatory notes for terminology and specimen adequacy. New York, NY: Springer-Verlag; 2nd edition, 2004
10) Clinical and Laboratory Standards Institute. *Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline*; 3rd ed. CLSI document GP15-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2008.

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CYP.07465 Pathologist Interpretation **Phase II**

All gynecologic slides in the following categories are interpreted by the pathologist.

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

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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