	• 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
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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
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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.