If a significant discrepancy, which would affect current patient care, is found during the retrospective review, an amended report is issued.

Evidence of Compliance:

✓ Records of retrospective reviews and amended reports, as necessary

REFERENCES

1) Davey DD. Papanicolaou 5-year retrospective review. *Arch Pathol Lab Med.* 1997;121:296-298
2) Freedman LF. Implications of mandating amended reports following retrospective review of Papanicolaou smears. *Arch Pathol Lab Med.* 1997;121:299-300
3) 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)(3)].

CYP.07543 Correlation of Results — Phase II

Records of attempts to obtain and review follow-up histological reports or material are available within the laboratory when gynecologic cases with high-grade squamous intraepithelial lesion (HSIL) or malignant cytological findings are reported.

NOTE: When the histologic diagnosis is available, correlation to the cytologic findings must be recorded and these records must be readily accessible. The number of cases that have histologic correlation must be recorded.

Evidence of Compliance:

✓ Records of the attempts made to obtain and review histological reports or materials

REFERENCES

1) Joste NE, *et al.* Cytologic/histologic correlation for quality control in cervicovaginal cytology: experience with 1,582 paired cases. *Am J Clin Pathol.* 1995:103:32-34
2) Tritz DM, *et al.* Etiologies for non-correlating cervical cytologies and biopsies. *Am J Clin Pathol.* 1995;103:594-597
3) Jones BA, *et al.* Q-Probes - cervical biopsy-cytology correlation: a College of American Pathologists Q-Probes study of 22439 correlations in 348 laboratories. *Arch Pathol Lab Med.* 1996;120:523-531
4) Zhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017.
5) Wright, DC, *et al*. 2001 Consensus guidelines for the management of women with cervical cytological abnormalities. *JAMA.* 2002;287:2120-2129
6) Clary KM, *et al*. Cytohistologic discrepancies. A means to improve pathology practice and patient outcomes. *Am J Clin Pathol.* 2002;117:567-573
7) Renshaw A, Granter SR. Appropriate follow-up interval for biopsy confirmation of squamous intraepithelial lesions diagnosed on cervical smear cytology. *Am J Clin Pathol.* 1997;108:275-279
8) 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)(2)].

CYP.07556 Additional Reports — Phase II

When a follow-up histological report or material is not available within the laboratory, there are records of attempts to obtain follow-up histological information for correlative review when gynecologic cases with significantly abnormal (high-grade SIL) or malignant cytological findings are reported.

Evidence of Compliance:

✓ Records of attempts to obtain the information (eg, follow-up correspondence, telephone calls, or requests included in the report)

REFERENCES

1) Jones BA, *et al.* Q-Probes - cervical biopsy-cytology correlation: a College of American Pathologists Q-Probes study of 22439 correlations in 348 laboratories. *Arch Pathol Lab Med.* 1996;120:523-531
2) Clary KM, *et al*. Cytohistologic discrepancies. A means to improve pathology practice and patient outcomes. *Am J Clin Pathol.* 2002;117:567-573
3) Wright, DC, *et al*. 2001 Consensus guidelines for the management of women with cervical cytological abnormalities. *JAMA.* 2002;287:2120-2129

CYP.07569 Correlation of Results - Gynecologic Cytopathology — Phase II

Gynecologic cytopathology findings are correlated with clinical information, when available.

NOTE: Methods of clinical correlation must be defined. Examples of clinical correlation methods include: focused rescreening of cases based on clinical history, history of bleeding, or previous abnormality; correlation of glandular cells with hysterectomy status, age of patient, and last menstrual period; review of previous or current biopsy material.

Evidence of Compliance:

✓ Records of clinical correlation (eg, policies, problem logs with resolution, or notes in reports)

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)(2)].
2) Joste NE, *et al.* Cytologic/histologic correlation for quality control in cervicovaginal cytology. Experience with 1,582 paired cases. *Am J Clin Pathol.* 1995;103:32-34
3) Jones BA, Novis DA. Follow-up of abnormal gynecologic cytology. A College of American Pathologists Q-Probes study of 16 132 cases from 306 laboratories. *Arch Pathol Lab Med.* 2000;124:665-671
4) Wright, DC, *et al*. 2001 Consensus guidelines for the management of women with cervical cytological abnormalities. *JAMA.* 2002;287:2120-2129
5) Clary KM, *et al*. Cytohistologic discrepancies. A means to improve pathology practice and patient outcomes. *Am J Clin Pathol.* 2002;117:567-573

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

CYP.07582 Cervical Cancer Screening Test - False Negative Notification **Phase I**

There is a mechanism to educate providers that cervical cancer screening tests, including primary HPV and Pap tests, are screening tests with inherent false negative results.

NOTE: The preferred mechanism is an educational note on all negative Pap test reports and all primary HPV screening tests. Other mechanisms include sending periodic educational information to providers, conference presentations, specimen collection manual, etc.

REFERENCES

1) Robb JA. The Pap smear is a cancer screening test: why not put the screening error rate in the report? *Diagn Cytopathol.* 1993;9:485-486.
2) Mitchell, H. Report disclaimers and informed expectations about Papanicolaou smears; an Australian view. *Arch Pathol Lab Med.* 1997;121:327-330.
3) Ge Y, Mody RR, Olsen RJ, et al. HPV status in women with high-grade dysplasia on cervical biopsy and preceding negative HPV tests. *J Am Soc Cytopathol.* 2019;8(3):149-156. doi:10.1016/j.jasc.2019.01.001.

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CYP.07600 Statistical Records - Gynecologic Cytopathology **Phase II**

For gynecologic cytopathology cases (not including those reflexed from primary HPV screening), statistical records are maintained and evaluated at least annually, and include the following:

- **Total number of gynecologic cytology cases examined**
- **Number of cases reported by diagnosis for each specimen type (including the number reported as unsatisfactory for diagnostic interpretation)**
- **Number of cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison**
- **Number of cases where cytology and histology are discrepant**
- **Number of cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms**
- **Number of negative cases rescreened before sign-out**
- **Number of positive and negative p16/Ki67 dual stains performed.**

NOTE: The data must be evaluated by the laboratory director or designee and included in the annual cytopathology statistical report. Inclusion of AGC data is optional. Separate statistics for conventional and each type of liquid-based preparations are required.

If a p16/Ki67 dual stain is used as a follow-up to an HPV positive co-test with a negative Pap test, statistics should be maintained separate from p16/Ki67 dual stain results derived from a positive primary HPV screening test.