



The circulation, referral, transfer, and receipt of original slides follows a consistent process that includes records of the location of slides to ensure availability for consultation and legal proceedings.

Evidence of Compliance:

- ✓ Tracking sheet/log that includes identity of slides/blocks, identity of recipient and record of return of slides/blocks

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): [42CFR493.1105(a)(7)(i)(A)].
- 2) 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): [493.1274(f)(2) through (f)(4)].

CYP.07300 Acknowledgment of Receipt

Phase II

There are records, including acknowledgment of receipt, when original diagnostic material is loaned to special programs for the purpose of education and/or proficiency testing.

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): [42CFR493.1105(a)(7)(i)(A)].
- 2) 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): [493.1274(f)(2) through (f)(4)].

GYNECOLOGIC CYTOPATHOLOGY

Content has been added to some requirements in this section for primary HPV screening. Primary HPV screening is a stand-alone HPV test that is performed as an initial cervical cancer screen, with reflex to additional testing as necessary. This is different than HPV/PAP co-testing where both tests are performed together.

Inspector Instructions:

READ  <ul style="list-style-type: none"> • Sampling of gynecologic cytopathology policies and procedures • Written criteria for unsatisfactory specimens • Sampling of patient reports for pathologist review and interpretation of specific screening diagnoses • Sampling of 10% rescreening records • Sampling of records of retrospective review and evidence of amended reports, if applicable • Statistical records including evidence of annual review and investigation when the laboratory falls outside the 5th or 95th percentiles • Records of employee performance monitoring including individual's discrepancies and corrective action 	OBSERVE  <ul style="list-style-type: none"> • Use of Papanicolaou stain • Use of p16/Ki67 dual stain 	ASK  <ul style="list-style-type: none"> • What criteria are used to identify rejected or unsatisfactory specimens? • What is the laboratory's process for follow-up or investigation of significant results? • What is your course of action when you are unable to obtain histological reports or material when reporting gynecologic cases with HSIL?
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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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)].

****REVISED** 12/26/2024****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;111:38-42
- 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.

****REVISED** 12/26/2024****CYP.07465 Pathologist Interpretation****Phase II****All gynecologic slides in the following categories are interpreted by the pathologist.**