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	• 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	• Use of Papanicolaou stain • Use of p16/Ki67 dual stain
ASK	• 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?