Evidence of Compliance:

- ✓ Records of communication of cold ischemia (if applicable) and fixation guidelines to clinical services **AND**
- ✓ Records of action taken when cold ischemia (if applicable) and fixation times are consistently outside of required parameters or are not available to the laboratory

REFERENCES

1) Wolff AC, Somerfield MR, Dowsett M, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update. *Arch Pathol Lab Med.* Published online June 7, 2023. doi: 10.5858/arpa.2023-0905-SA.
2) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11)1346-63.
3) Allison KH, Hammond EH, Dowsett M, et al. Estrogen and Progesterone Receptor Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Guideline Update *Arch Pathol Lab Med.* 2020; 144(5):545-63.

ON-SITE MICROSCOPIC REVIEW

On-site review of actual case (slide) material and corresponding reports is an important element of the inspection process. This is NOT a comprehensive rescreening of slides or evaluation of competency, but rather an action to facilitate the Inspector's evaluation of the laboratory's overall procedures.

Laboratories that do not file slides on-site (for example, some "read-only" laboratories) must retain a sample of slides on-site for review by the inspector on all days when the laboratory is subject to its regular on-site inspection. The sample must, at minimum, include all slides accessioned over a continuous two-week period within the previous two years. The laboratory must be able to produce any slide upon the request of an inspector during the required retention period for gynecologic and non-gynecologic slides (including fine needle aspiration slides).

Inspector Instructions:

- Review a randomly selected representative sample of 10-15 cases using the table below to guide selection:

Gynecologic Cases	**Non-Gynecologic Cases (including FNAs)**
Unsatisfactory	Negative for malignancy / Reactive
Negative for intraepithelial lesion or malignancy (NILM) / Repair	Atypical or suspicious with qualifiers / Suspicious for malignancy / Positive for malignancy
Atypical squamous cells	
LSIL (encompassing HPV)	
HSIL / Carcinoma	
p16/Ki67 dual stain	

Cases should be selected by the laboratory pathologist and/or cytopathology supervisor in a random manner defined by the inspecting Team Leader (eg, the first 1-3 negative and abnormal cases in each specimen category from a certain date or week). The following are core elements of the on-site review:

- Evaluate slides for quality of technical preparation and specimen adequacy
- Determine if significant cells have been identified
- Compare slides with the diagnostic report for completeness and clarity of diagnostic terminology
- Determine if the information provided with the requisition and included in the diagnostic report is complete and appropriate

	If, during the on-site review, there is believed to be a significant diagnostic discrepancy, this should be discussed by the pathologist team leader with the laboratory director. Interpretations may be considered discrepant if there is a significant diagnostic difference in interpretation. An example of this would be an interpretation of Negative for Intraepithelial Lesion/Malignancy, vs. an interpretation of LSIL or greater. Cases considered to be "ASC/AGC" (either by the inspector or inspectee) should not be included in the analysis to determine significant discrepancies, because of the current lack of interlaboratory reproducibility of these interpretations.

CYP.04900 Cellular/Nuclear Detail **Phase II**

Cellular and nuclear detail are sufficient for proper interpretation.

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

CYP.05000 On-Site Slide Review **Phase II**

The findings from the on-site slide review are free of any issues or any significant diagnostic discrepancies as defined in the Inspector Instructions.

NOTE: If p16/Ki67 dual stain is performed, slides should be included in the on-site slide review.

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

	• How does your laboratory perform ongoing monitoring of screening instrumentation? What corrective action is taken when tolerance limits are exceeded? • How do you identify slides that have not successfully been processed by the automated screening instrument?
	• Follow a slide through automated staining, cover-slipping and automated screening. Determine if practice matches procedure.

CYP.05292 Unsuccessful Slide Processing **Phase II**

The laboratory has a process to identify and handle slides that are not successfully processed by the automated screening instrument.

NOTE: Laboratories must clearly identify slides that fail screening by an automated instrument and ensure that these slides are completely rescreened by another method. In most instances, manual rescreening will be used.

Evidence of Compliance:

✓ Records of slide rescreening