COLLEGE of AMERICAN PATHOLOGISTS

Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology: 2021 Guideline Update

Statements and Strengths of Recommendations

SUMMARY OF RECOMMENDATIONS

Guideline Statement	Strength of Recommendation
1. The validation process should include a sample set of at least 60 cases for one application, or use case, (eg, H&E stained sections of fixed tissue, frozen sections, hematology) that reflect the spectrum and complexity of specimen types and diagnoses likely to be encountered during routine practice. The validation should include another 20 cases to cover additional applications such as immunohistochemistry or other special stains if these applications are relevant to an intended use and were not included in the 60 cases mentioned above.	Strong Recommendation
2. The validation study should establish diagnostic concordance between digital and glass slides for the same observer (ie, intraobserver variability). If concordance is less than 95%, laboratories should investigate and attempt to remedy the cause.	Strong Recommendation
3. A washout period of at least two weeks should occur between viewing digital and glass slides.	Strong Recommendation

Evans A, Brown RW, Bui MM, et al. Validating whole slide imaging systems for diagnostic purposes in pathology: guideline update from the College of American Pathologists in Collaboration with the American Society for Clinical Pathology and the Association for Pathology Informatics. *Arch Pathol Lab Med*. 2021;146(4):440-450. doi: 10.5858/arpa.2020-0723-CP