COLLEGE of AMERICAN PATHOLOGISTS

Validating Whole Slide Imaging (WSI) for Diagnostic Purposes in Pathology Guideline

Summary of Recommendations

Guideline Statement	Strength of Recommendation
1. All pathology laboratories implementing WSI technology for clinical diagnostic purposes should carry out their own validation studies.	Expert Consensus Opinion
2. Validation should be appropriate for and applicable to the intended clinical use and clinical setting of the application in which WSI will be employed. Validation of WSI systems should involve specimen preparation types relevant to intended use (eg, formalin-fixed paraffin-embedded tissue, frozen tissue, immunohistochemical stains, cytology slides, hematology blood smears). *Note: If a new intended use for WSI is contemplated, and this new use differs materially from the previously validated use, a separate validation for the new use should be performed.*	Recommendation
3. The validation study should closely emulate the real-world clinical environment in which the technology will be used.	Recommendation
4. The validation study should encompass the entire WSI system. *Note: It is not necessary to validate separately each individual component (eg, computer hardware, monitor, network, scanner) of the system nor the individual steps of the digital imaging process.*	Recommendation
5. Revalidation is required whenever a significant change is made to any component of the WSI system.	Expert Consensus Opinion
6. A pathologist(s) adequately trained to use the WSI system must be involved in the validation process.	Recommendation
7. The validation process should include a sample set of at least 60 cases for one application (eg, H&E stained sections of fixed tissue, frozen sections, cytology, hematology) that reflects the spectrum and complexity of specimen types and diagnoses likely to be encountered during routine practice. *Note: The validation process should include another 20 cases for each additional application (eg, immunohistochemistry, special stains).*	Recommendation
8. The validation study should establish diagnostic concordance between digital and glass slides for the same observer (ie, intraobserver variability).	Suggestion
9. Digital and glass slides can be evaluated in random or nonrandom order (as to which is examined first and second) during the validation process.	Recommendation
10. A washout period of at least 2 weeks should occur between viewing digital and glass slides.	Recommendation
11. The validation process should confirm that all of the material present on a glass slide to be scanned is included in the digital image.	Expert Consensus Opinion
12. Documentation should be maintained recording the method, measurements, and final approval of validation for the WSI system to be used in the clinical laboratory.	Expert Consensus Opinion

Source: Pantanowitz L, Sinard JH, Henricks WH, et al. Validating whole slide imaging for diagnostic purposes in pathology: Guideline from the College of American Pathologists (CAP) Pathology and Laboratory Quality Center. *Arch Pathol Lab Med.* doi: 10.5858/arpa. 2013-0093-CP. Effective date: May 1, 2013.