CAP releases a new evidence-based guideline

Validating Whole Slide Imaging for Diagnostic Purposes in Pathology

This clinical guideline, now available in *Archives of Pathology & Laboratory Medicine*, is the first-of-its kind and marks a significant step forward in demonstrating the value of this emerging technology for diagnostic use.

The document serves as a practical guide for pathologists and laboratories to confirm the accuracy and concordance of their own whole slide imaging (WSI) systems for diagnostic work while ensuring the digital tool is being used properly for its intended clinical purpose in an effort to deliver optimal patient care.

Twelve practical recommendations are outlined in the guideline, including the following key items:

- Validation of the entire WSI system, involving pathologists trained to use the system, should be performed in a manner which emulates the laboratory's actual clinical environment.
- It is recommended that such a validation study include at least 60 routine cases per application, assessing intraobserver diagnostic concordance between digitized and glass slides viewed at least two weeks apart.
- It is important that the validation process confirms that all material present on a glass slide to be scanned is included in the digital image.

Currently, the US Food and Drug Administration does not approve WSI systems for primary diagnosis. In that context, this CAP guideline gives current recommendations while preparing its members for wider adoption of digital imaging technology in the future. Pathologists practicing abroad can begin to implement the guideline immediately in concordance with their country's regulatory guidelines for using WSI in making primary diagnoses.