INFORMATION BRIEF (RAPID REVIEW)

Digital Pathology System: Whole Slide Imaging (WSI)

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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Rapid Review
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DIGITAL PATHOLOGY SYSTEM: WHOLE SLIDE IMAGING

PURPOSE

To provide brief information on the effectiveness, safety, cost-effectiveness and to identify benefit and weakness of the system (Digital Pathology Imaging: Whole Slide Imaging - WSI), following a request from the Pathologist specialist from Hospital Tengku Ampuan Afzan, Kuantan.

BACKGROUND

Pathology, a branch of medical science dedicated to studying and diagnosing diseases, provides crucial diagnostic information to both patients and clinicians. Histopathology is a diagnostic specialty based on the visual assessment of cellular and tissue morphology captured in images. Traditional pathology services examine tissue sections on microscopic glass slides under a microscope. However, the diagnosis relies on the pathologist's expertise and is sometimes apparently subjective. The variation among pathologists is the disadvantage of morphologic diagnosis, therefore, a technology that provides more reliable and consistent diagnosis is required to solve this problem.[1,2] The introduction of digitised imaging has transformed this practice into digital pathology, marking a major shift from conventional microscopy.[3]

Digital Pathology refers to the suite of technologies used to digitise pathology slides and their associated metadata, enabling the storage, interpretation, and analysis of all information generated from a virtual slide. Central to this is Whole-Slide Imaging (WSI), which captures the entire tissue sample to create a comprehensive digital image. Artificial Intelligence (AI) in this context involves intelligent systems—particularly Machine Learning (ML) and Deep Learning (DL); where that process vast amounts of imaging data to recognize patterns, make predictions, and perform quantitative analyses that often surpass human speed and consistency. Early digital image capture relied on microscope-mounted cameras and later smartphones, while the development of WSI in 1999 enabled complete glass slides to be converted into high-resolution virtual slides. Over the past two decades, WSI technology and its use across pathology subspecialties have expanded rapidly. Digital pathology now applies computational methods to whole-slide images and associated metadata, integrating them with clinical information to support accurate and efficient diagnostic interpretation.[1,2,3]

Whole slide imaging (WSI) has gained wider acceptance in routine pathology practice, driven in part by US Food and Drug Administration approval of a WSI system for primary surgical pathology diagnosis. Beyond routine diagnostics, WSI supports the development and application of artificial intelligence and machine learning algorithms for automated and computer-assisted interpretation. The technology also addresses the growing need for telepathology services, which expanded rapidly during the COVID-19 pandemic.[4] Together, these advances enable faster, higher-quality, and more reliable diagnoses through computational histopathology. The integration of digital imaging with advanced digital pathology tools now supports comprehensive reporting across anatomical, clinical, and molecular pathology.[4,5]

TECHNICAL FEATURES

Whole Slide Imaging (WSI) is characterised by four sequential processes:[4]

- image acquisition
- storage
- processing, and
- visualization

The standard digital pathology and deep learning pipeline consists of five key sequential stages:

- **WSI Acquisition**: Tissue samples are fixed in formalin, embedded in paraffin, and sectioned into thin slices (~3-4 mm). These are stained (typically with H&E) and scanned at high resolution to produce gigapixel "tiles" stitched together into a single virtual slide.
- **Storage**: Digital slides generate massive volumes of data, necessitating high-capacity on-premises or cloud storage solutions. Compression algorithms are often used to manage file sizes and storage costs.
- **Pre-processing**: To ensure data quality, images undergo artifact detection, stain normalization (to correct colour variations), and tissue segmentation. The images are then "tiled" into smaller arrays suitable for AI processing.
- **Deep Learning Pipelines**: Data is split into training, validation, and testing sets. Convolutional Neural Networks (NNs) are the primary tools used to identify local patterns through filtering and pooling operations.
- **Applications**: The final trained models are deployed for tasks such as identifying biomarkers, classifying tumours, and conducting quantitative image analysis (QIA).

Image Acquisition and Scanning

Image acquisition is performed by a digital scanner, which is essentially a trinocular microscope robotically controlled for illumination, mechanical stage movement, objectives, and coarse and fine focusing.

1. Scanning Method: WSI scanners capture sequential images either in a tiled or line-scanning manner, which are then assembled or "stitched" to form the Virtual Slide (VS)—an exact replica of the glass slide.
2. Focusing (Z-axis): To replicate the experience of direct microscopy, digital scanners must utilize the z-axis (depth). Scanners differ in their z-focusing methodology, ranging from focusing on every tile to focusing only on selected tiles or focus points. While focusing on every tile yields the highest quality, this is a time-consuming strategy that compromises scanner throughput.
3. Resolution and Magnification: Scanning at times 20X magnification is generally considered suitable for routine surgical pathology and immunohistochemistry slides. However, for cytology slides, studies suggest higher diagnostic accuracy may be achieved z-stack scanning.
4. Throughput Advances: Continuous advances have resulted in high-throughput scanners capable of handling up to 400 slides, with scanning times reduced to as little as 30 seconds to several minutes.
5. Preparation Requirements: Optimal results require careful preparation, including optimizing section thickness, ensuring placement in the centre of the slide away from coverslip edges, and avoiding microtomy or mounting artifacts.

Data Management and Visualization

1. Data Storage: A significant challenge is the requirement for massive data storage capacity. For example, scanning a 1-mm area magnification results in a file size of 48 megabytes. Most WSI systems incorporate image compression algorithms (JPEG, JPEG 2000, LZW) to reduce file size, though this may introduce image artifacts.
2. Archival and Security: When WSI data is linked to patient metadata and clinical information, reliability and security are paramount, necessitating safe archival strategies such as off-site storage, RAID (redundant array of independent disks) storage, or optical storage.
3. Visualization: Viewing and managing virtual slides relies on software installed locally or as part of a network server suite. Advanced image viewers often allow image annotation and export to different file formats. Some WSI systems use a multi-resolution representation (pyramid representation) where the field of view is inversely proportional to the magnification being viewed.

The workflow should include these main steps: (**See Figure 1**)

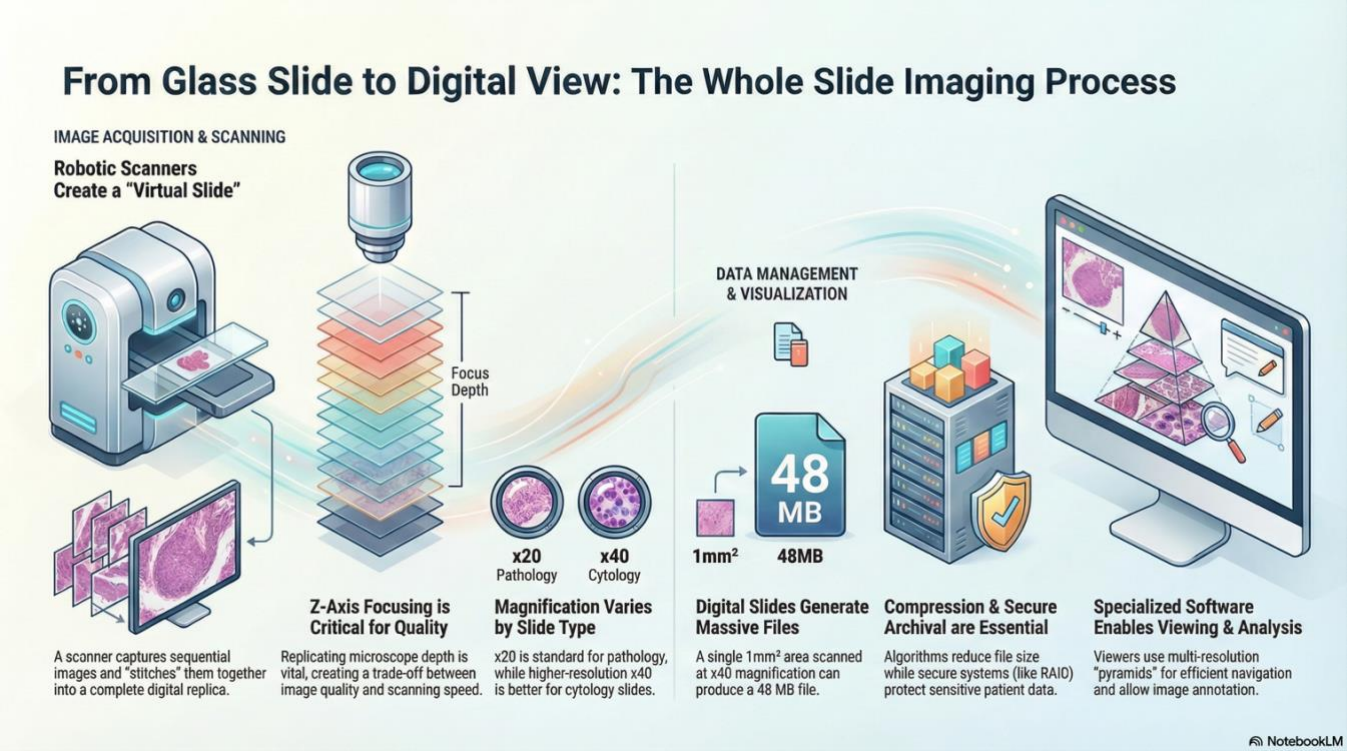

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Figure 1: From Glass Slide to Digital View

Digital Pathology and Telepathology

Whole slide imaging (WSI) systems are advanced optical–electrical microscopes that work similarly to digital cameras, converting tissue sections on glass slides into high-resolution digital images. A typical slide (around 20 × 15 mm) produces extremely large image files, ranging from hundreds of megabytes to several gigabytes. To match the detail seen under a microscope, these images require very high resolution—up to 100,000 × 100,000 pixels—far

exceeding standard computer display resolutions. For practical use, images are usually compressed to reduce file size, often to below 100 MB, making them easier to store, transfer, and review.[6]

Most WSI systems divide images into smaller tiles (e.g., 1024 × 1024 pixels), compressing each tile separately to enable faster loading and smoother viewing. This tiling approach allows rapid reconstruction of the full image during analysis while maintaining performance. However, the level of compression and tile size can influence both image quality and processing speed. Advances in scanning technology have significantly improved image quality, speed, and usability, leading to wider adoption of digital pathology. Several WSI systems have also received regulatory approval, supporting their safe use in clinical practice.[6,7] (**See Table 1)**

Table 1: Summary of Digital Pathology Scanners

Scanner system	Slide volume	Magnification	File format	Scanning speed per slide	FDA approval
Philips Ultra Fast	300 regular slides	×20/×40	RAW or iSyntax Compression	60 s at ×40 equivalent (15 × 15 mm scan area)	Yes
Huron TissueScope LE120	120 regular slides (60 whole-mount slides)	×20/×40	24-bit RGB pyramidal bigTIFF uncompressed, JPEG 2000 compressed, flat TIFF and LZW, compressed TIFF	60 s per slide, 15 × 15 mm at ×20	NA
Hamamatsu NZ S360	360 regular slides	×20/×40	JPEG compressed image + slide information	Approximately 30 s	Yes
Leica Aperio AT2	400 regular slides	×20/×40	SVS	<60 s	Yes
Sakura VisionTek live microscope	4 regular slides	×2.5/×10/×20/×40	JPEG, TIFF, BMP, and PNG	3.0 min for 15 × 15 mm (at 0.275 µm/pixel)	NA
Leica Aperio LV1 live microscope	4 regular slides	×1.25/×5/×20	NA	15 s or less	No
Mikroscan live microscope	2 or 4 regular slides	×2/×4/×10/×20/×40	NA	9 s	NA
GRUNDIUM OCUS microscope scanner	1 regular slide	×40 (NA 0.75)	JPEG, SVS, and TIFF	180 s	NA
Roche Ventana DP 600	240 regular slides (40 trays of 6 single slides)	×20/×40	BIF, TIF, and DICOM	×20: approximately 36 s; ×40: approximately 73 s	No

EVIDENCE SUMMARY

2197 studies were identified through searches PubMed, and Google Scholar using the keywords “digital pathology,” “whole slide images,” “artificial intelligence,” “scanner and “pathology.” The final search was completed on 28 December 2025. A total of five studies, one referring guideline and one cost-implication study were included in this rapid review.

EFFICACY/ EFFECTIVENESS AND SAFETY

Effectiveness

McGenity C (2024) conducted a systematic review (SR) and meta-analysis (MA) to examine the diagnostic accuracy of AI in digital pathology images for any disease. As the integration of digital pathology into clinical workflows accelerates, this study evaluated whether current AI models meet the performance standards required for reliable disease diagnosis across various medical specialties

The SR was conducted following PRISMA guidelines, with searching databases including PubMed, EMBASE, and CENTRAL up to June 2022. The inclusion criteria focused on diagnostic accuracy studies where AI models were applied to WSIs, using histopathological assessment or immunohistochemistry as the reference standard. In this review, 100 studies were identified for the systematic review, with 48 providing sufficient data for meta-analysis and the QUADAS-2 tool was used to evaluate the risk of bias and applicability concerns across the included studies.

Results:
The meta-analysis revealed high overall diagnostic performance, though results varied based on validation methods and the unit of analysis:[8] **(See Figure 2)**

- Models that underwent external validation demonstrated superior performance, with a mean sensitivity of 95% and a mean specificity of 92%. In contrast, those without external validation showed lower accuracy (91% sensitivity and 87% specificity).
- For slide-level analysis, the mean sensitivity was 95% with a specificity of 88% meanwhile, patch-level analysis yielded 91% sensitivity and 90% specificity.
- Multiclass diagnostic tasks showed slightly better performance than binary tasks, resulted with mean sensitivity of 95%.

The authors concluded that while AI in DP shows great potential, there is an urgent need for better transparency, improved reporting standards (such as AI-specific guidelines), and more rigorous study designs to ensure these technologies are safe and effective for clinical use.

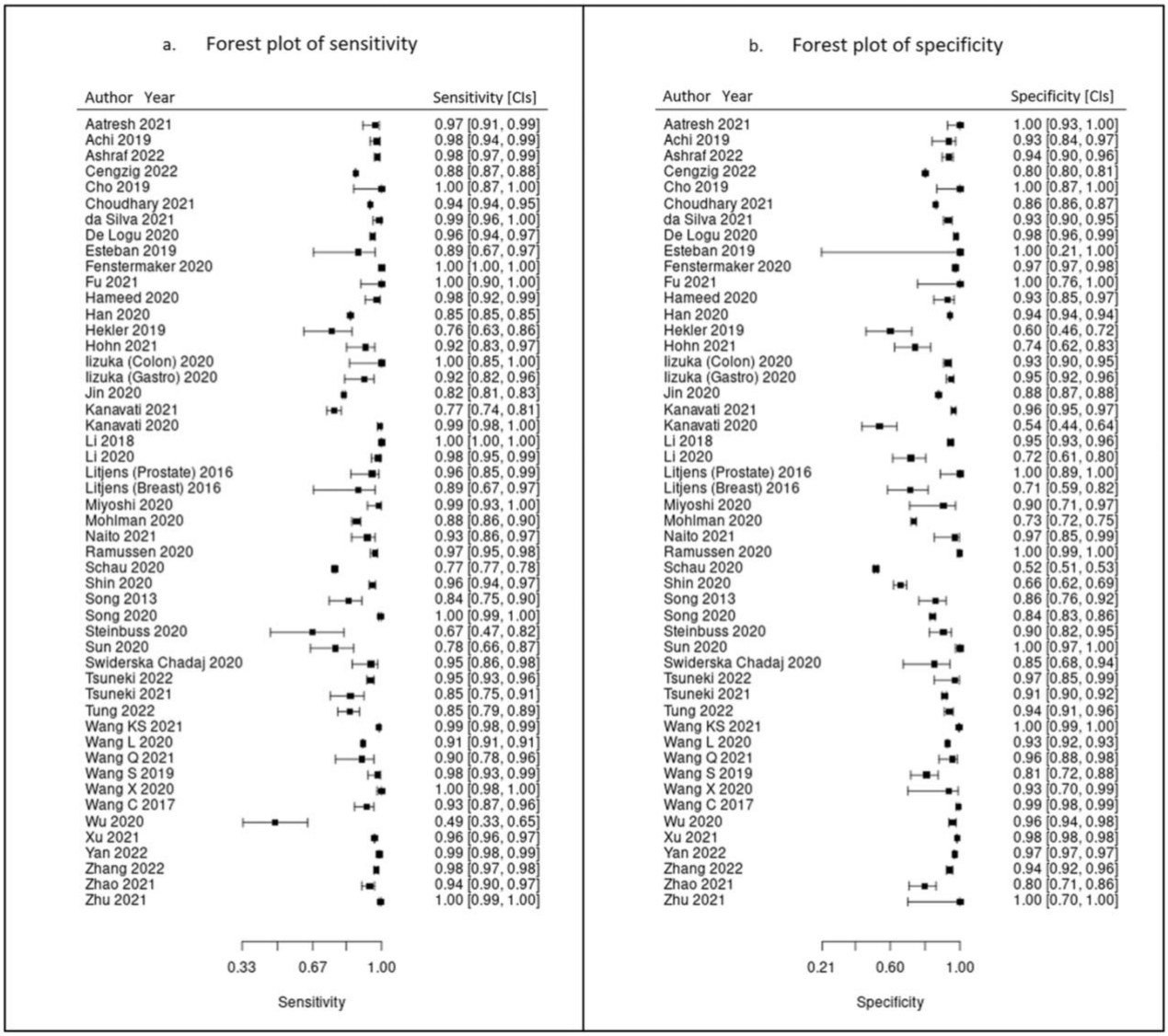

Figure 2: Forest plots of performance across studies included in the meta-analysis.

The systematic review by **Araújo ALD (2019)** evaluated the performance of digital microscopy, particularly whole slide imaging (WSI), for primary diagnosis in human pathology. The study was conducted using a systematic search and included studies that compared digital microscopy with conventional light microscopy using histopathology as the reference standard. The review assessed diagnostic concordance, accuracy, and reliability across different pathology subspecialties, focusing on real-world clinical applications rather than experimental settings.

In terms of effectiveness, the review found that digital microscopy demonstrated high diagnostic concordance with traditional microscopy, generally exceeding 90% agreement across most studies. However, some variability was noted depending on the type of specimen, staining quality, and pathologist experience, with slightly lower agreement in more complex or subtle cases. Most studies assessed intra observer concordance (same pathologist using both methods) and interobserver agreement, using measures such as percentage agreement and kappa (κ) statistics. From this review, demonstrated high diagnostic concordance, with most

studies reporting agreement rates ranging from 90% to 100% between WSI and conventional microscopy. Several studies showed kappa values between 0.80 and 1.00, indicating substantial to almost perfect agreement. Intra observer concordance was generally higher than interobserver agreement, suggesting that variability is more related to individual interpretation rather than the imaging modality itself. Importantly, major diagnostic discrepancies were low, typically reported at <5%, and were often linked to challenging cases such as borderline lesions, subtle cytological features, or poor slide quality rather than limitations of WSI technology. Some studies also reported slightly longer diagnostic time when using WSI, particularly during early adoption, although this difference decreased with user experience.[9] **(See Figure 3)**

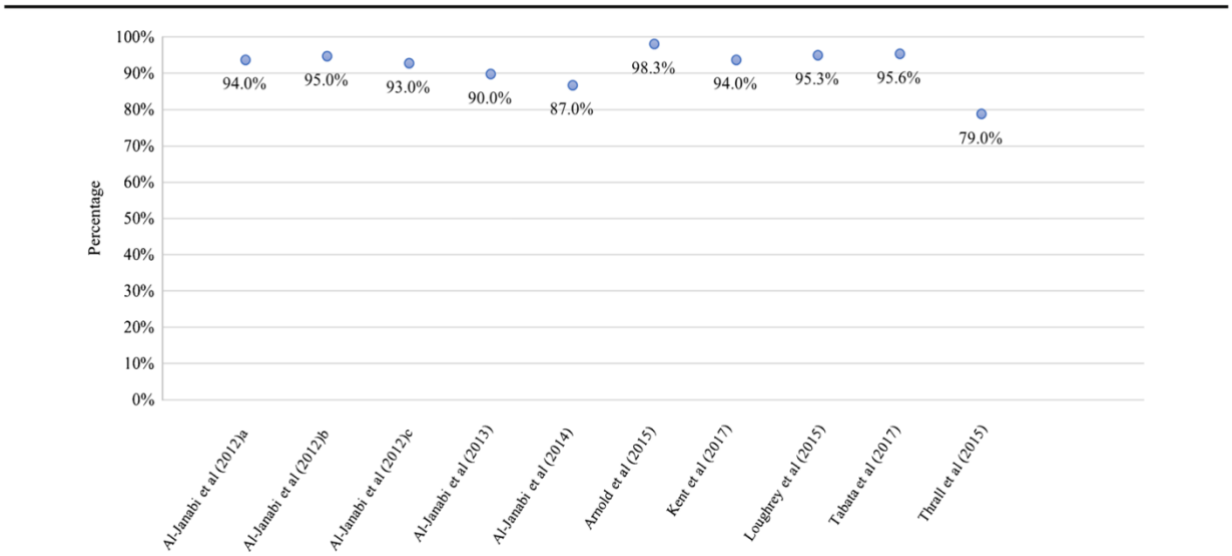

Figure 3: Graphic presentation of intra observer agreement of included studies

Mukhopadhyay S (2018) conducted a study about WSI or digital pathology, involve the high-resolution digital acquisition of entire stained tissue sections, allowing pathologists to navigate and diagnose cases on a computer monitor. This trial was a multicentre, blinded, randomised non-inferiority study aimed to determine if WSI is non-inferior to conventional bright-field microscopy for primary diagnosis in surgical pathology. The study also aimed to validate WSI across a comprehensive range of organ systems and specimen types to support its use in routine clinical workflows. The study were conducted across four institutions, analysed 1,992 cases encompassing 20 organ systems, including both biopsies and resections. The original sign-out diagnosis served as the reference standard. Sixteen board-certified reading pathologists interpreted cases using both microscopy and WSI (the Philips IntelliSite Pathology Solution), separated by a washout period of at least four weeks to mitigate recall bias. A total of 15,925 reads were performed. Diagnostic concordance was evaluated by an independent central adjudication panel of three pathologists who classified differences as concordant, minor discordant, or major discordant (defined as a difference affecting patient management).[10]

Results and Conclusion

The study successfully demonstrated that WSI is non-inferior to microscopy for primary diagnosis. Key findings include:[10]

- Discordance Rates: The major discordance rate with the reference standard was 4.9% for WSI and 4.6% for microscopy.
- Statistical Noninferiority: The difference in major discordance rates was 0.4% (95% CI: -0.30% to 1.01%), which is well within the pre-specified 4% noninferiority margin.
- Operational Efficiency: The mean reading time for WSI was 84 seconds compared to 78 seconds for microscopy, a negligible difference of 6 seconds.
- Organ-Specific Findings: While slightly higher discordance was noted in endocrine (1.8%) and neoplastic kidney (1.5%) pathology, detailed analysis revealed no consistent technical vulnerabilities or systematic inaccuracies attributable to WSI.

In conclusion, WSI is a safe and effective alternative to conventional microscopy for primary surgical pathology diagnosis across diverse clinical settings.

Safety:
McGenity C yielded that despite the high-performance metrics, the study raises significant "safety" and reliability concerns regarding the current state of AI in digital pathology. The risk of bias demonstrated a staggering 99% of the reviewed studies (and 98% of those in the meta-analysis) were found to have at least one area at high or uncertain risk of bias. This suggests that reported diagnostic accuracy may be over-optimistic due to publication bias and heterogeneous study designs, hence the study concluded that these results must be interpreted with caution If real-world performance is poorer than these studies suggest, it could undermine clinical confidence and compromise patient safety.[8]

Regulatory Status: WSI
In the European Union (EU), WSI scanners and related digital pathology software have been regulated under the In Vitro Diagnostic Medical Device Directive, allowing CE marking mainly through manufacturer self-declaration. Since May 2022, the new In Vitro Diagnostic Regulation requires all WSI systems and software to undergo stricter performance, analytical, and clinical evaluations before CE approval, aligning EU oversight more closely with US standards.[3]

In the United States, regulatory control is tighter, with the Food and Drug Administration (FDA) approving WSI systems only after robust clinical evidence. To date, only two WSI platforms have received FDA approval for primary surgical pathology diagnosis, starting with the Philips IntelliSite system in 2017, followed by the Sectra–Leica AT2 DX platform in 2020. These approvals are limited in scope and exclude certain specimen types, such as frozen sections and cytology.[4]

Guidelines:
Telepathology has been validated for second opinion in challenging cases of surgical pathology, cytopathology, and immunohistochemistry with the American Telemedicine Association (ATA) issuing guidelines for the adoption of telepathology in patient care. The ATA Clinical Guidelines for Telepathology (2014) are the main evidence-based reference used globally where it defines the telepathology as remote diagnosis using transmitted pathology images (static, dynamic, WSI, or hybrid systems). These guidelines are considered the foundation for safe and standardised telepathology practice, developed by expert consensus and clinical evidence.

Organizational Training and Learning Curve

Whole slide imaging (WSI) is transforming pathology education by shifting the focus from microscope-handling skills to accurate interpretation and diagnostic reasoning. Unlike traditional teaching, which depends on limited glass slides and physical microscopes, WSI enables the same digital slides to be accessed simultaneously by many learners, supporting standardised training across institutions. It also allows remote teaching, giving trainees in resource-limited areas access to specialised fields such as immunohistochemistry and electron microscopy. In addition, digital slides can be annotated and integrated with clinical and radiological data, providing a more comprehensive and practical learning experience. The use of WSI reduces the need for large teaching facilities and multiple microscopes, making education more scalable and efficient.

For learners, WSI offers flexibility to study at their own pace, compare different cases side by side, and engage in collaborative learning. It is increasingly used in examinations and competency assessments, with organisations such as the American Board of Pathology incorporating virtual slides into computer-based exams. Online repositories and digital slide archives further support continuous learning and easy access to diverse case materials. WSI is also widely used in conferences and scientific publications, improving visualisation and interaction with pathology content. Overall, WSI has enhanced both training and assessment by making pathology education more accessible, interactive, and standardised. [4]

Quality assurance

The integration of high-speed, high-resolution WSI has transformed quality assurance (QA) in pathology. By digitizing slides and making them accessible through Laboratory Information Systems (LIS), practitioners can more effectively conduct teleconsultations, archive materials, and assess inter-observer variance. This digital shift is already being standardized by organizations such as the College of American Pathologists, which now utilises WSI for proficiency testing to supplement traditional glass slides.[11,12]

Artificial Intelligence (AI) serves as a critical diagnostic supplement and a safeguard for patient safety. Given the difficulty of maintaining expertise across all organ systems, AI-driven deep learning tools provide pathologists with continuous feedback and automated diagnostic checks. These algorithms can be applied prospectively or retrospectively to flag potential errors, ensuring high-quality diagnostic outcomes and helping practitioners stay current with evolving diagnostic standards. This synergy between digital imaging and automated analysis creates a robust framework for error prevention, ultimately improving the standard of care in pathology and radiology.[13,14,15]

COST/COST-EFFECTIVENESS

Kumar N (2020) summarise that he implementation of WSI systems involves substantial financial investment, which can be a major barrier, especially for smaller pathology laboratories. Initial procurement costs for scanners alone range from approximately USD 100,000 to USD 1.5 million per unit (≈MYR 397,450 to ≈ MYR 5,961,750.) In addition, there are significant indirect costs, including staff training, technical support, digital storage infrastructure, and regulatory or licensing requirements. The need for telepathology capabilities can further increase overall expenses.

Despite these high upfront and operational costs, some evidence suggests potential long-term economic benefits. A cost–benefit analysis from a large academic centre processing over 1.5 million slides reported projected savings of about USD 1.3 million over five years. However, such findings may not be generalisable, and similar evaluations are needed in smaller laboratories and low-resource settings to determine cost-effectiveness in those contexts.[4]

CONCLUSION

The transition from traditional glass-slide microscopy to WSI and AI represents a paradigm shift in the field of pathology. Based on recent systematic reviews and clinical observations, the synergy between digital workflows and machine learning algorithms provides a robust framework for improving diagnostic accuracy, laboratory efficiency, and, most importantly, patient safety.

Effectiveness

1. **Diagnostic Effectiveness and Performance**

The clinical effectiveness of AI in digital pathology is no longer theoretical but is supported by significant statistical evidence. AI models show high overall diagnostic performance, particularly when subjected to rigorous validation. Key metrics highlight this efficacy:

- Validated Accuracy: Models undergoing external validation reached a mean sensitivity of 95% and a specificity of 92%. This suggests that when AI is trained and tested across diverse datasets, its ability to correctly identify disease is exceptional.
- Slide-Level Proficiency which mirrors the standard diagnostic process yielded high sensitivity (95%), indicating that AI is highly capable of identifying pathology within the context of an entire tissue sample.
- Multiclass Versatility: The finding that AI performs slightly better in multiclass diagnostic tasks than binary ones underscore its potential to assist in complex differential diagnoses, rather than just simple "yes/no" disease detection.

2. **Patient Safety and Error Prevention**

The implementation of AI serves as a critical patient safety mechanism. The primary value of AI in this context is its role as an automated "second opinion." By applying diagnostic algorithms both prospectively (during the initial diagnosis) and retrospectively (during quality reviews), laboratories can create a safety net that catches discrepancies before they impact patient care.

AI tools address the inherent challenge of "staying current" in all organ systems. Because frequency of interaction builds diagnostic confidence, AI can bridge the gap for pathologists who may not encounter specific rare malignancies regularly. By providing intelligent feedback and flagging suspicious areas for manual review, AI minimizes inter- and intra-observer variance, ensuring that a patient's diagnosis remains consistent regardless of which pathologist reviews the slide.

3. **Organizational Impact and Quality Assurance (QA)**

The digitization of pathology via WSI has redefined the standard for Quality Assurance. Having slides readily available through a Laboratory Information System (LIS) enables:

- Seamless Teleconsultation by rapidly sharing digital files for expert opinions without the delay of physical shipping.
- Proficiency Testing by modernizing the evaluation of practitioner skills.
- Automated QA Workflows when transitioning from random, manual "re-reads" of 10% of cases to AI-driven screening of 100% of cases to identify potential errors.

4. **Guidelines**

Despite the clear benefits, the path toward full AI integration requires more rigorous organizational and regulatory oversight. For AI to be safely implemented at scale, the following other factors must be addressed:

- Improved Reporting Standards as there is an urgent need for AI-specific reporting guidelines to ensure transparency in how models are developed and trained.
- Standardized Validation when the organizational policies must mandate external validation to ensure that an algorithm performing well in one laboratory can be trusted in another with different scanning equipment or staining protocols.
- Rigorous Study Design in future research must move beyond "proof of concept" to large-scale, real-world clinical trials that utilize tools like QUADAS-2 to minimize bias and ensure applicability.

In conclusion, based on the review there is fair to good level of study for digital pathology (whole slide imaging) which may be as a transformative force in pathology that enhances the effectiveness of diagnostic workflows and provides a multi-layered safety net for error prevention. However, its success is contingent upon the adoption of digital-first infrastructures (WSI) and a commitment to transparency and rigorous validation standards. By integrating AI as a complement to human expertise, pathology departments can ensure a higher standard of diagnostic precision and improved patient outcomes.

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