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Guidelines for the adoption of digital pathology in clinical pathology units recommended by the polish society of pathologists

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Abstract

These guidelines provide a clear and practical framework for the effective implementation of digital pathology (DP) in routine anatomical pathology practice. Digital pathology, defined as the digitization of microscope slide into high-resolution whole slide images, is transforming the diagnostic workflow by enabling remote access, improved image analysis, integration with artificial intelligence (AI), and enhanced data management. While digital systems are becoming increasingly integrated into pathology laboratories, the physical archiving of microscope slides remains a legal and procedural requirement in many countries, particularly for histological and cytological materials. As DP continues to evolve globally, the establishment of clear standards, technical requirements, validation procedures, and interoperability guidelines is essential to maintain diagnostic accuracy, patient safety, and system reliability. These recommendations address key technical, organizational, and legal aspects of DP implementation, with an emphasis on ensuring consistent quality and minimizing variability in diagnostic outcomes. The outlined approach supports the safe and effective adoption of DP as an integral element of modern digital healthcare.

Keywords DP, Slide scanning, Anatomical pathology diagnostics, Artificial intelligence in pathology

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Introduction

A key element of DP is the use of whole slide imaging (WSI) scanners that digitally capture microscope slides. These devices generate diagnostic-quality images that are equivalent to those viewed under conventional light microscopy [1].

Digital slides (DS) — digital versions of entire glass slides — form the foundation of virtual microscopy. They may be used for primary diagnostics only after meeting specific technical and validation requirements related to image acquisition and visualization. The head of the pathology laboratory and the reporting pathologist must ensure that diagnoses made using DP are performed under conditions at least equivalent to those of traditional light microscopy, guaranteeing diagnostic accuracy



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and precision. Every pathology laboratory intending to use DP for primary diagnosis must conduct its own validation study.

As technology advances, these recommendations should be regularly updated in conformity with the latest professional standards [2, 3].

Advantages and applications of DP

DP systems, driven by technological progress, now offer image quality and visualization that often surpass traditional light microscopy. To achieve optimal results without relying on resource-intensive scanning methods (such as Z-axis scanning or localized refocusing), histopathological slides must be prepared with high technical precision. In contrast to conventional microscopy, image imperfections cannot be corrected manually, which emphasizes the importance of strict standardization and quality control in slide preparation [4]. A major advantage of DP is the significant reduction in diagnostic turnaround time, resulting in improved efficiency and workflow optimization. The full digitization of the diagnostic process accelerates case review, enhances service quality, and strengthens the trust of both clinicians and patients. An overview of the redesigned diagnostic workflow after digital pathology implementation is shown in Fig. 1. From an economic standpoint, DP promotes better use of laboratory resources and generates long-term cost savings through process optimization and reduced material handling [5]. DP systems also enable advanced visualization modes, such as side-by-side comparison of slides, digital stain overlays, and high-magnification viewing without the need for immersion oil. They facilitate efficient teleconsultations and can be integrated with AI algorithms that provide prognostic and predictive

insights, supporting pathologists in decision-making. Additional benefits include automation of quality control procedures, easier access to image data within integrated healthcare systems, and improved interdisciplinary collaboration. Finally, DP improves ergonomics for pathologists by enabling work with optimized displays and modern input devices, which can enhance comfort and productivity [6, 7].

Key technical considerations for whole slide imaging

For optimal DS quality, paraffin blocks should be sectioned at a thickness of 3 μm . Slides should be properly coverslipped to maintain durability and image clarity. Even distribution of the mounting medium is essential to avoid air bubbles and refraction artifacts that can degrade image quality. In high-throughput laboratories, the use of automatic coverslippers or tape-based systems is recommended. Slides and coverslips vary in size, and material placement often reflects local protocols. Efficient scanner placement—ideally close to staining and coverslipping equipment—reduces unnecessary movement, shortens turnaround time, and minimizes the risk of specimen mix-ups or damage during slide transport. Priority scanning options further support responsiveness in urgent diagnostic cases, improving clinical decision-making and overall resource utilization [4, 8]. To ensure diagnostic accuracy, all relevant tissue on the slide must be captured. Two common causes of omitted fragments include incorrect scan area settings and technical issues such as focus errors, artifacts, or equipment malfunction. Proper scan area designation should be verified during system validation. Typically, scanners generate a low-resolution preview to detect tissue, then capture selected

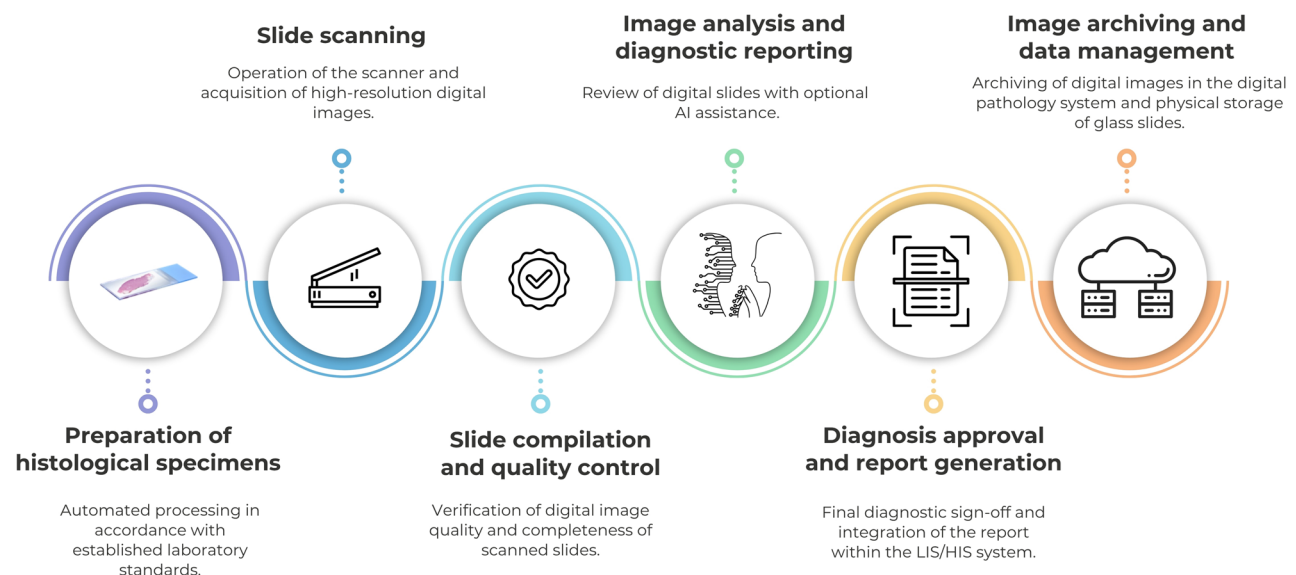


Fig. 1 Redefinition of the diagnostic pathway following digital pathology implementation

regions at higher resolution. If key areas are missed, critical diagnostic material may be excluded. To mitigate this, some scanners use protocols that map the entire slide (excluding the label), reducing the chance of missed tissue. This approach should be preferred, especially for critical cases. Another essential aspect is the standardization of scan parameters and file formats. Open image formats are recommended for long-term data storage, system compatibility, and ease of sharing between institutions. Scanning should ideally be performed during working hours to allow a rapid response to any technical issues. In routine diagnostics, reliance on a single scanner is not recommended due to limited flexibility and the risk of system downtime [6, 9].

Scanner image quality parameters: resolution and colour depth

Scan settings, including the selected image quality profile, should be optimized according to the diagnostic material and the required level of resolution. High-quality images enable precise analysis of cellular and tissue structures, which is particularly important in oncological diagnostics and in detection of subtle histopathological changes. Colour depth refers to the scanner’s ability to capture and accurately reproduce the broad range of colour shades present in the original slide, as observed under a microscope. To ensure diagnostic reliability, scanners must be properly calibrated to minimize colour discrepancies—regardless of whether standard or non-standard staining protocols are used. Ideally, colour representation should remain consistent across different scanners, even within the same institution, to maintain diagnostic continuity throughout the workflow [8]. The resolving power of a scanner defines its ability to render image details with high precision, ensuring faithful reproduction of tissue structures. Both resolution and colour depth are essential

components of scanner performance and should be verified during the Installation Qualification (IQ) phase conducted by the WSI system provider. Furthermore, each warranty and post-warranty inspection should include an Operational Qualification (OQ) to confirm proper system functionality and parameter compliance [10]. A summary of recommended scanner image quality and operational parameters is presented in Table 1.

Image compression and data formats in DP

In virtual microscopy, image compression is not simply an optional means of increasing storage capacity, but a fundamental component of the image processing and visualization workflow. This requirement stems from the vast data volumes generated by WSI systems, which often necessitate the use of lossy compression techniques to enable efficient data handling, transfer, and visualization. Only compressed image files can be transmitted fast enough to ensure smooth and reliable operation of DP systems. However, the degree of compression must be carefully optimized and validated. Compression is typically expressed as the ratio between the original and compressed file size (e.g., 20:1). The process should achieve visually lossless compression - where some image data are technically discarded or simplified, yet the human eye perceives no visible degradation in image quality. At present, open formats such as TIFF remain among the most widely used for storing DP images. These formats ensure long-term data integrity, durability and accessibility. Selecting an appropriate file format is a critical decision, as it affects not only the performance and efficiency of the archiving system but also its long-term security, interoperability, and sustainability.

Digital archiving in DP

Long-term digital data storage is a key factor in maintaining the continuity, traceability, and reliability of virtual diagnostics. The designated system administrator responsible for managing digital archives must ensure data immutability, integrity, and durability over time. To achieve this, structured and scalable storage solutions—such as Network Attached Storage (NAS) systems—are recommended. These systems typically include data protection mechanisms based on redundancy, such as RAID (Redundant Array of Independent Disks) configurations. Server capacity should be scaled according to the anticipated daily scanning volume. Currently, the average file size of a single whole slide image at 40x magnification is approximately 1 GB. Therefore, scanning approximately 300 slides per day would require about 50 TB of storage capacity to maintain a six-month archive. From a practical perspective, long-term archiving of either all or selected digital slides is strongly recommended. A minimum storage period of six months is advised, with

Table 1 Scanner image quality and operational parameters

Parameter	Recommended specification / description
Optical resolution	≤ 0.26 µm/pixel (equivalent to ×40 objective) — ensures diagnostic fidelity and structural detail reproduction.
Colour depth	≥ 24-bit true colour; consistent rendering across scanners after calibration.
Compression	Visually lossless; ratio typically ≤ 20:1 to maintain diagnostic image quality.
Focus control	Automated focusing with optional Z-stack or dynamic refocusing; regular calibration required.
Throughput	Suitable for routine workload (≥ 200–300 slides/day per device, depending on lab size).
Priority queueing	Ability to prioritise urgent or intraoperative cases within batch workflows.
Whole-area mapping	Full-slide capture excluding label area; prevents omission of diagnostic regions.
File format	Open, non-proprietary formats (e.g., TIFF/DICOM) recommended for interoperability and archiving.

an optimal retention time of approximately two years. It is important to note that physical glass slides must still be archived in accordance with national legal requirements—typically 20 years for histological material and 10 years for cytological specimens—as they remain the primary legal and diagnostic reference in digital microscopy. Certain circumstances may require extended digital slide archiving. For example, when physical slides are loaned for consultation or external review, corresponding digital versions should be stored until their return. If a slide is damaged, restrained, or shows signs of fading or discolouration, digital archiving should be extended in accordance with the legal retention requirements applicable to the original specimens. This approach ensures that the original microscopic image can later serve as documentation of the performed examination or as a reference for future diagnostic or legal verification [9, 11].

Beyond secure digital storage, automation and integration of archival systems represent the next step in ensuring data integrity and operational safety. Automated archives—linked to the Laboratory Information System (LIS)—enable continuous monitoring, barcode-based traceability, and controlled access to digital and physical specimens. Such solutions minimize the risk of human error, loss, or accidental deletion, which have been reported in traditional manual archives and may lead to serious diagnostic or legal consequences. Moreover, modern approaches increasingly view pathology archives not as passive repositories but as active biobanks containing valuable biological and diagnostic information. Long-term, or even indefinite, preservation of digital and physical materials is therefore justified both ethically and scientifically. Implementing automated, LIS-integrated archiving systems ensures compliance with legal requirements, supports research and AI model development, and strengthens the overall reliability of DP infrastructure [12–14].

Cloud solutions in DP

In DP, the use of cloud-based solutions must comply with clearly defined security, privacy, and operational standards. All connections should be encrypted using the TLS protocol, and two-factor authentication is strongly recommended to enhance access control. It is acceptable to store identifiers such as examination ID, block ID, or slide ID, provided that these do not allow patient re-identification outside the originating healthcare institution. Data must be stored and processed exclusively within the territory of the European Union, in full compliance with applicable data protection regulations (e.g., GDPR). The selected cloud platform must allow users to export images to a local storage environment and should include functionalities that ensure high system availability and resilience, such as those provided by Kubernetes-based

architectures. When cloud-based systems are used in routine diagnostics, they must support direct integration with scanners to enable automatic image transfer. A reliable, high-bandwidth internet connection is required to ensure smooth image data transfer, with a currently recommended minimum upload speed of 100 Mb/s. In intraoperative consultations, the digital slide should be available for viewing within no more than five minutes after scanning. These technical requirements ensure that cloud-based solutions in DP maintain the performance, security, and efficiency standards required for high-quality diagnostic workflows.

Image quality control

Maintaining consistent image quality in WSI is essential to ensuring the reliability and diagnostic validity of DP. Regular and systematic QC procedures must be implemented to verify that image outputs meet predefined standards and do not compromise diagnostic accuracy. A key component of image quality assurance is the comparison between the compressed digital image and its original, uncompressed version. Compression must be visually lossless, meaning that any data reduction must not affect the visual perception of diagnostically relevant features. The compressed image must permit the same diagnostic conclusions as those drawn from the original full-resolution file. If any irregularities in image quality are detected—such as visual artifacts, colour distortion, or loss of detail—an immediate investigation must be initiated to determine the underlying cause. Potential sources of such issues include scanner calibration errors, inappropriate compression settings, hardware malfunctions, or software-related faults. Identifying and resolving the root cause of the defect is mandatory before the system is returned to clinical operation. Ensuring the stability and fidelity of WSI systems is particularly critical in clinical environments where decisions depend directly on the interpretation of digitized slides. For this reason, QC protocols should be clearly defined, documented, and performed at regular intervals as part of standard operating procedures (SOPs). Only systems that consistently meet diagnostic quality benchmarks should be approved for continued use in routine pathology workflows [5, 15].

Monitor quality for digital slide assessment

The quality of monitors used for the assessment of digital slides (DS) plays a pivotal role in maintaining diagnostic precision in DP. Several technical parameters determine monitor performance, the most critical being matrix size, screen resolution (including pixel size and density), refresh rate, and both absolute and relative colour fidelity. Matrix size is typically defined by the physical diagonal dimension of the screen and its aspect ratio, while smaller pixel sizes and higher pixel densities directly

enhance image sharpness and detail perception. Additional parameters essential for accurate image rendering include colour depth, maximum luminance (brightness), and contrast ratio. These attributes determine how faithfully histopathological structures are visualized. However, due to the natural degradation of display components over time, image performance parameters may deteriorate, potentially affecting diagnostic accuracy. Therefore, regular monitor calibration is strongly recommended to maintain optimal image performance and diagnostic consistency. In the context of DP, monitor selection should prioritize both image fidelity and ergonomic comfort for pathologists. Based on international experience and current guidelines, minimum technical specifications have been established to ensure consistent image quality and performance. A native resolution of at least 2560×1440 pixels is recommended, while 3840×2160 pixels (4 K/ Ultra HD) is preferable for high-precision diagnostic work. Pixel density should exceed 100 pixels per inch (ppi), and a colour depth of at least 10 bits per channel is recommended to ensure a wide and accurate colour gamut. Displays should provide a maximum luminance of at least 300 cd/m² and a contrast ratio of ≥1000:1 to ensure adequate visual clarity under variable ambient lighting conditions. A minimum refresh rate of 60 Hz is required to provide stable, flicker-free viewing—particularly important during prolonged image review sessions. For pathology workstations, a minimum screen diagonal of 27 inches is recommended, with 27–32 inches considered optimal for routine diagnostic use. From a quality-control perspective, the ability to perform precise colour

calibration is essential. Monitors equipped with built-in hardware calibration systems are preferred for their superior precision and long-term consistency. Calibration should be performed at regular intervals as part of routine quality-assurance procedures to maintain diagnostic standards. Finally, from an ergonomic standpoint, pathology workstations should ideally be equipped with at least two monitors to enhance workflow efficiency and reduce visual fatigue. A summary of minimum recommended specifications for displays and workstation performance is provided in Table 2.

End-user computer requirements in DP

The selection of computer hardware for DP should be guided by the minimum technical specifications defined by the diagnostic software provider. It is essential that the performance of the end user’s workstation—whether operated by a consultant pathologist or a trainee—meets or exceeds these specifications to ensure system stability, responsiveness, and diagnostic efficiency. Hardware configuration must be optimized to ensure that the performance of the diagnostic platform is not compromised by insufficient processing power, memory capacity, or graphics performance. In practice, this means that computer components—such as the central processing unit (CPU), graphics processing unit (GPU), random access memory (RAM), and solid-state drive (SSD)—should be specified to support smooth digital slide navigation, image rendering, and analytical tool operation without latency or workflow interruptions.

Technical specifications of scanners and IT infrastructure

Scanners used in DP must meet defined technical requirements to ensure reliable integration into diagnostic workflows. The selection of an appropriate scanner should be guided by the specific operational needs of the pathology laboratory, taking into account the types and sizes of slides processed, including larger formats such as macroblocks. Depending on workload demands, features such as automatic slide loading, batch prioritization, and continuous operation capability may be required to maintain workflow flexibility and efficiency. In terms of image quality, scanner resolving power must enable the acquisition of WSI equivalent in detail to those viewed under a conventional optical microscope with a 40× objective. This corresponds to a recommended spatial resolution of 0.26 µm per pixel or better, which ensures diagnostic precision and fidelity. Equally important is full scanner compatibility with the LIS. Effective implementation of DP systems requires seamless integration between scanner software and the LIS to support secure data exchange, automated case assignment, and traceability. Finally, scanner speed and throughput must be aligned with the anticipated workload of the pathology

Table 2 Minimum specifications for display and workstation performance

Component / parameter	Recommended specification / range
Display resolution	≥ 2560 × 1440 px (preferred 3840 × 2160 px / 4 K Ultra HD).
Pixel density (PPI)	> 100 pixels per inch for detailed tissue visualization.
Colour depth	10-bit per channel for accurate shade differentiation.
Brightness (luminance)	≥ 300 cd/m ² for adequate visibility in varying ambient light.
Contrast ratio	≥ 1000 : 1 for optimal rendering of histological detail.
Refresh rate	≥ 60 Hz to ensure stable and flicker-free viewing.
Screen size	27–32 inches (dual-monitor setup recommended).
Calibration	Hardware-based colour calibration at regular intervals.
Processor (CPU)	Multi-core ≥ i7/Ryzen 7 or equivalent.
Memory (RAM)	≥ 32 GB (64 GB recommended for AI applications).
Storage (SSD)	≥ 1 TB SSD for fast access to WSI files.
Graphics (GPU)	Dedicated GPU ≥ 8 GB VRAM for smooth image rendering.

laboratory. The number and capacity of scanners should be sufficient to process the daily slide volume without delays, thereby maintaining diagnostic turnaround times and overall operational efficiency.

Maintenance and calibration of scanning devices

Microscope slide scanners used in DP must undergo regular technical inspections to ensure sustained accuracy, operational safety, and compliance with applicable standards. Each device should be accompanied by a valid technical passport containing up-to-date inspection certificates confirming that the equipment has undergone scheduled maintenance and complies with all relevant regulatory requirements. Regular calibration and preventive servicing are essential to maintain both the precision of image acquisition and the overall performance and stability of the system. Such procedures facilitate early detection and prevention of deviations in scanning quality, ensuring that diagnostic output remains consistent and reliable throughout the device's operational life. Documented maintenance and calibration protocols constitute an integral component of the quality-assurance system in DP and should be implemented in strict accordance with the manufacturer's recommendations and applicable national or institutional standards.

System integration and data management in DP

Effective implementation of DP depends on system usability from the end-user perspective and requires seamless integration between the LIS, Hospital Information System (HIS), and other interoperable IT platforms. This integration should be based on open data formats and established interoperability standards, including HL7 (Health Level Seven) and DICOM (Digital Imaging and Communications in Medicine). The use of proprietary storage formats or closed image distribution systems creates substantial interoperability challenges and often prevents seamless integration of scanners and software from different vendors. For this reason, a central image archive—typically implemented as a Picture Archiving and Communication System (PACS)—is essential to provide manufacturer-independent access to diagnostic images across the hospital or healthcare network. The adoption of widely accepted standards enables smoother integration and long-term sustainability of IT support by minimizing the need for multiple custom interfaces. It also protects technological investments and contributes to improved diagnostic quality, system scalability, and workflow efficiency. Successful implementation requires a robust technical infrastructure and advanced IT systems capable of managing sensitive diagnostic data securely and compatibly across platforms. Standards such as DICOM and HL7 result from collaborative efforts between professional societies, user communities,

and scientific institutions. Their widespread adoption ensures system flexibility, scalability, and readiness for future technological developments and evolving software solutions. When embedded within standardized and well-integrated environments, WSI enables remote diagnostics, facilitates collaboration among geographically distributed pathologists, and mitigates limitations associated with the physical location of pathology laboratories [7].

Correct assignment of microscope slide specimens to virtual images

Ensuring the consistency and accuracy of DP diagnostics requires reliable, automated linkage between physical microscope slides and their corresponding virtual images. This process is fundamental to diagnostic integrity and directly impacts the reliability of case management and reporting. However, integrating hardware and software components from multiple vendors—such as barcode printers, staining and coverslipping systems, slide scanners, and the LIS—may introduce challenges to maintaining consistent linkage. A frequent source of such errors is reduced barcode readability, which may result from suboptimal slide handling, fixation artifacts, or staining residues that interfere with scanner recognition. In such cases, incorrect or failed barcode readings may lead to mislinked image data, resulting in mismatched patient or specimen information and compromising both diagnostic accuracy and patient safety. To mitigate these risks, laboratories must implement preventive and control measures within the digital workflow. These measures include verifying barcode readability at each stage of the laboratory process and ensuring full compatibility among all devices operating within the DP ecosystem [15, 16].

Approval of hardware and software in DP systems

All hardware and software components used within DP systems must comply with applicable legal and regulatory requirements. Equipment should be certified with a CE IVD mark in accordance with the European Regulation on in Vitro Diagnostic Medical Devices (EU IVDR 2017/746) or, where applicable, approved by the United States Food and Drug Administration (FDA). In addition to regulatory certification, every component of the DP system must undergo validation procedures consistent with the laboratory's internal quality management and assurance framework. Internal validation processes should also be performed to confirm that the selected diagnostic technologies are both safe—meaning their clinical benefits outweigh potential risks—and effective in providing clinically relevant and reproducible diagnostic data.

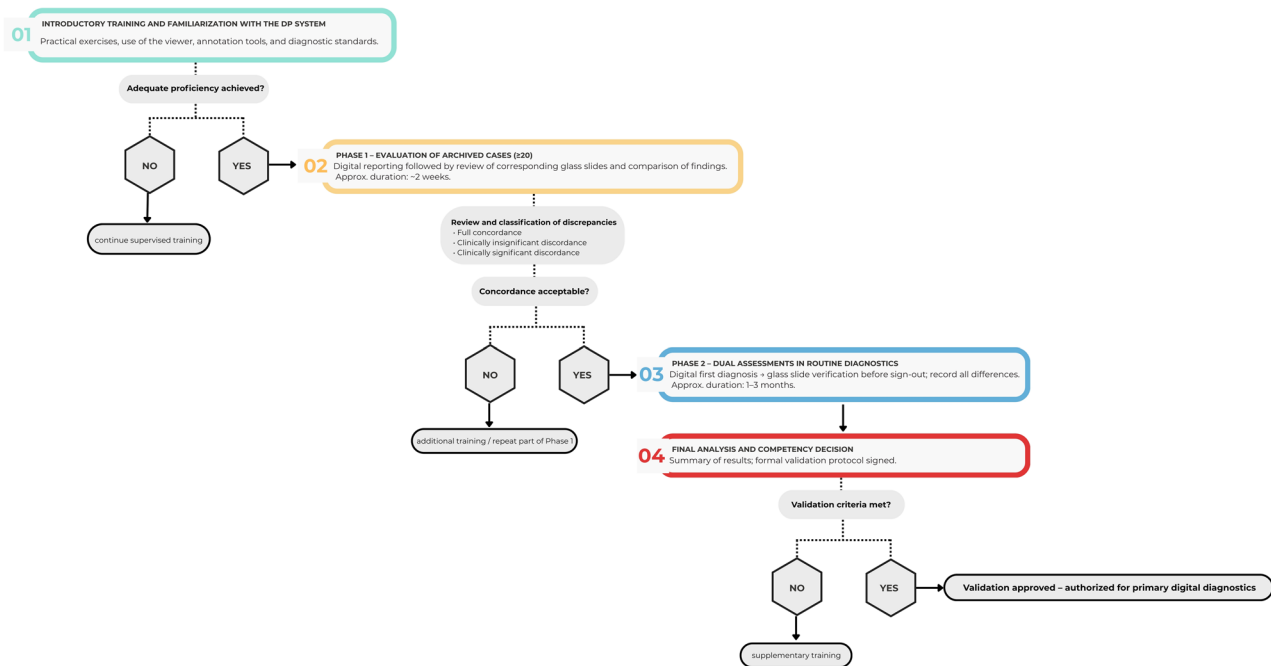


Fig. 2 Recommended validation workflow for pathologists prior to the adoption of primary digital diagnostics

These validation steps form the foundation for ensuring that implemented solutions meet the operational and diagnostic requirements of the pathology laboratory while maintaining full compliance with international standards and best practices.

DP validation

Multiple studies have confirmed that WSI enables histopathological evaluation of diagnostic quality equivalent to that obtained with traditional glass slides under light microscopy. Despite differences in visualization techniques, DP can be implemented without compromising diagnostic accuracy, safety, or reliability—provided that the reporting pathologist is adequately trained and able to use the digital system at a level not inferior to conventional microscopy [15]. Currently, the application of WSI in routine cytopathology remains limited. This limitation primarily results from the variable thickness and uneven cellular distribution typical of conventional cytology smears, which can adversely affect scan quality and image interpretation. However, slides prepared using liquid-based cytology (LBC)—which produces a more uniform cellular layer—are more suitable for digitization and are less affected by these limitations. Digital slides are also increasingly used in postgraduate education, residency programs, and continuous professional development. As technology continues to advance, DP is expected to become a standard diagnostic modality, at which point formal validation procedures such as those described here may no longer be required [7]. Two principal validation frameworks are currently recognized: one developed

by the College of American Pathologists (CAP) and another by the Royal College of Pathologists (RCPath). The CAP model focuses on diagnostic accuracy studies designed to demonstrate the non-inferiority of digital diagnostics compared with conventional methods and incorporates a ‘wash-out period’ to minimize recall bias [2, 17]. The approach recommended in this paper follows the RCPath model, which defines validation as a pathologist-led process focused on identifying potential risks and ensuring the ongoing safety, accuracy, and effectiveness of diagnostic practice. Validation should mirror routine diagnostic practice within the pathology laboratory and focus on representative, real-world case scenarios. At its core, the process involves a direct comparison of diagnoses rendered using glass slides and their corresponding digital images, without the use of AI-assisted tools [3, 5].

Recommended validation procedure (final phase of DP implementation)

Figure 2 provides an overview of the recommended validation workflow for pathologists. Before validation begins, the pathologist must acquire sufficient familiarity with the DP system and its functionalities, preferably under supervision. The process should be embedded within the laboratory’s diagnostic routine and support the pathologist in safely transitioning to a digital diagnostic workflow. The validation process begins with practical training using anonymized archived cases. A representative validation set should comprise at least 20 cases of varying complexity—including small biopsies, larger resections, and diverse staining techniques

(H&E, immunohistochemical, and histochemical). The set should also include diagnostically challenging cases requiring evaluation of features such as dysplasia, micro-metastases, mitotic figures, or subtle staining patterns. Each case should first be assessed digitally, with a complete diagnostic report prepared. This is followed by review of the corresponding glass slides to compare findings and identify any differences. The evaluation should be conducted over a defined but reasonable period (e.g., approximately two weeks), after which all results are reviewed with attention to discrepancies. If the pathologist demonstrates sufficient proficiency and consistent diagnostic accuracy, they may proceed to the next stage. If needed, additional cases may be reviewed under supervision to address any uncertainties. The decision to proceed is made jointly by the pathologist and the head of the pathology laboratory or a designated supervisor, ideally with the involvement of an experienced instructor.

The next stage of validation involves performing dual assessments as part of routine diagnostic practice. The pathologist first evaluates the digital slide and formulates a diagnosis, then reviews the corresponding physical slide before final approval. All relevant slides, including additional stains, should be included in this assessment. The duration and number of evaluated cases may vary depending on the individual's experience and diagnostic scope, but typically span one to three months. During this period, all cases must be documented, particularly those in which differences occur between the digital and traditional assessments. Discrepancies should be categorized as: (1) full concordance, (2) clinically insignificant discordance, or (3) clinically significant discordance. Observations should include any visual differences—such as staining intensity or detail visibility—even if they do not alter the final diagnosis. For each discordant case, the method providing higher diagnostic precision should be identified and documented. All such cases must be discussed with the head of the pathology laboratory and, where possible, with the instructor. Upon completion of the process, a formal validation protocol should be prepared and archived. It must include the diagnostic spectrum covered, the number of evaluated cases (both archived and routine), analysis of discordant results, and a list of participants involved. The final decision should clearly specify whether the pathologist is deemed competent to independently assess digital slides across the full diagnostic spectrum, limited to selected areas (with continued use of glass slides elsewhere), or not yet competent for independent digital evaluation. The protocol must be signed by the head of the pathology laboratory, the instructor (if applicable), and the pathologist.

When a pathologist expands their diagnostic scope (e.g., to new organ systems), an additional validation process is required. This process mirrors the standard

validation but is tailored to the new diagnostic area. All steps must be appropriately documented. In cases of inter-laboratory consultations, consulting pathologists should undergo validation specific to the shared case types. If validated outside the requesting laboratory, the consultant must verify technical compatibility and diagnostic image quality before initiating consultations—ideally through preliminary training and double evaluation of selected cases.

Pathologists previously validated under earlier recommendations are not required to repeat the process if their validated scope aligns with their current practice. However, new diagnostic areas must be validated according to current standards. Significant technical changes—such as the introduction of new scanners, monitors, or software versions—require revalidation, the scope of which should correspond to the extent and nature of the implemented changes.

AI tools in DP

The integration of AI into DP significantly enhances diagnostic workflows by improving diagnostic accuracy, reducing human error, and accelerating case analysis. In practical terms, AI tools are increasingly being deployed in clinical pathology laboratories for tasks such as tumor detection, grading, and biomarker quantification. They assist pathologists in diagnostic decision-making and contribute to the standardization of diagnostic outcomes. AI algorithms are particularly effective in automating complex and time-consuming analytical tasks. They are especially valuable in oncology, where diagnostic precision is critical to therapeutic decision-making. AI tools promote standardization of slide evaluation, particularly in specialized staining techniques such as histochemistry, immunohistochemistry, and in situ hybridization (ISH). They assist in the automatic or semi-automatic quantification of predictive biomarkers, including p53, ER, PR, HER2, PD-L1, and Ki-67. These systems are typically developed and validated using reference digital slides and are implemented following expert review and regulatory approval.

For example, AI-assisted HER2 and PD-L1 scoring in breast and lung cancer has been shown to improve reproducibility and reduce interobserver variability compared with manual evaluation. Similarly, automated Ki-67 quantification in neuroendocrine tumors provides standardized proliferation indices and shorter turnaround times, ensuring improved diagnostic consistency. These findings have been confirmed in real-world validation studies demonstrating the non-inferiority of AI-based assessments compared with conventional human evaluation [18, 19].

The technology underlying AI in pathology includes machine learning (ML) models, deep neural networks

(DNNs), convolutional neural networks (CNNs), fully convolutional networks (FCNs), recurrent neural networks (RNNs), and generative adversarial networks (GANs). Their implementation brings greater objectivity, reproducibility, and efficiency to diagnostic processes across a wide range of pathology applications. Beyond biomarker quantification, AI systems are increasingly used for morphological pattern recognition and prognostic modeling by integrating image-derived features with clinical, molecular, and genomic data. This multidisciplinary approach supports precision diagnostics and personalized medicine, positioning AI as a complementary tool that enhances—rather than replaces—the expertise and judgment of the pathologist.

DP and telepathology in intraoperative examinations

DP and telepathology are increasingly applied in intraoperative consultations, particularly when the pathologist is not physically present at the surgical site. In such cases, diagnoses are rendered remotely using digital slides or real-time microscopic imaging systems. While the general technical and operational requirements of DP systems apply, certain additional specifications are unique to intraoperative applications. Macroscopic sample processing must be conducted by qualified laboratory personnel under the supervision of a pathologist. Ideally, macroscopic handling should be supported by a live video connection that ensures high-quality image transmission and two-way voice communication. If a real-time connection is unavailable, high-resolution photographic documentation may be used as an alternative, provided it is securely transmitted. Clinical data must be shared in full and via secure, encrypted channels, ensuring that the amount and quality of information are equivalent to those available during on-site evaluations. Remote access to microscopic images can be provided via robotic microscopes or digital slide scanners installed at the surgical site. In exceptional circumstances—particularly in resource-limited settings—portable devices such as tablets may be used to support remote intraoperative consultations, provided they have undergone proper validation and maintain image quality consistent with diagnostic standards [15]. Regardless of the method used, image quality must meet standards equivalent to conventional diagnostics.

System reliability is critical in intraoperative settings. Technical failures must be addressed immediately, as delays may impact surgical decisions. Pre-use system checks—including scanners, network connectivity, and remote viewing platforms—should be performed daily to ensure operational readiness. A backup telepathology system is strongly recommended to ensure uninterrupted diagnostic capability and continuity of service in the event of system failure [6, 8, 17, 20].

Acknowledgments

Not applicable.

Conflict of Interest

The authors declare that they have no relevant financial or non-financial interests to disclose.

Authors' contributions

All authors contributed to the preparation of these recommendations and to the drafting and reviewing of the manuscript. Łukasz Szyłberg coordinated the preparation of the manuscript. Łukasz Szyłberg, Justyna Durślewicz, Łukasz Chmura, Witold Rezner, Artur Bartczak, and Andrzej Marszałek participated in the development of the guidelines and reviewed the final version. All authors read and approved the final manuscript.

Funding

The authors did not receive support from any organization for the submitted work.

Data availability

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Received: 19 June 2025 / Accepted: 11 January 2026

Published online: 30 January 2026

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