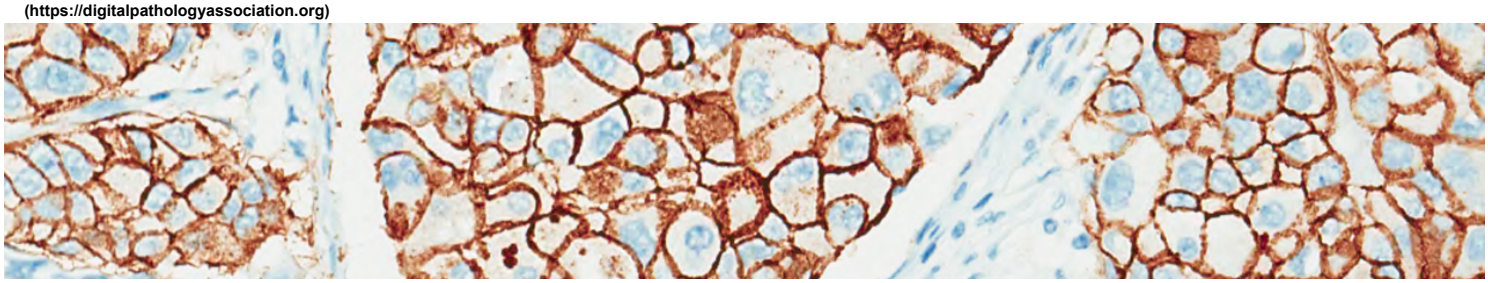
search MEMBER LOGIN (https://digitalpathologyassociation.org/login?member_group=members&redirect_to_profile_flag=1) NON-MEMBER LOGIN (https://digitalpathologyassociation.org/login?member_group=non-members&redirect_to_profile_flag=1)

JOIN TODAY (https://digitalpathologyassociation.org/register)

DIGITAL PATHOLOGY DPA ASSOCIATION

(https://digitalpathologyassociation.org)



FAQs

Resources (https://digitalpathologyassociation.org/resources)

- COVID-19 (https://digitalpathologyassociation.org/covid-19-updates-resources)
- About Digital Pathology (https://digitalpathologyassociation.org/about-digital-pathology)
- FAQs (https://digitalpathologyassociation.org/faq)
- Blog (https://digitalpathologyassociation.org/blog_1)
- Blog Submission Form (https://digitalpathologyassociation.org/dpa-blog-submission)
- CAPA Online Education (https://digitalpathologyassociation.org/2020-capa-webinar-schedule)
- Twitter Chats (https://digitalpathologyassociation.org/twitter-chat)
- DPA White Papers (https://digitalpathologyassociation.org/white-papers_2)
- Past Webinar Presentations (https://digitalpathologyassociation.org/past-webinar-presentations)
- The Alliance (https://digitalpathologyassociation.org/dpa-mdic-fda-alliance-meeting)
- Member Publications (https://digitalpathologyassociation.org/member-publications_1)
- Industry Publications (https://digitalpathologyassociation.org/industry-publications)
- DP Certificate Program (https://digitalpathologyassociation.org/digital-pathology-certificate-program)
- Healthcare (https://digitalpathologyassociation.org/healthcare-background)
- Life Sciences (https://digitalpathologyassociation.org/life-sciences-background)
- FDA Guidance for WSI (https://digitalpathologyassociation.org/fda-guidance-for-whole-slide-imaging)
- WSI Repository (https://digitalpathologyassociation.org/whole-slide-imaging-repository)
- Vendor Directory (https://digitalpathologyassociation.org/vendor-list)
- Glossary of Terms (https://digitalpathologyassociation.org/glossary-of-terms_1)
- Press Releases (https://digitalpathologyassociation.org/press-releases)
- Other Resources (https://digitalpathologyassociation.org/other-resources)

Digital Pathology FAQ

1. **What is digital pathology?**
   Digital pathology broadly refers to a discipline in which digital tools are used to advance the practice of pathology, to educate trainees, or to promote discovery. These tools include digital imaging technologies (e.g. whole-slide imaging (http://www.archivesofpathology.org/doi/10.5858/arpa.2018-0343-RA)), telepathology, and data science methods such as data mining, digital image analysis (http://www.jpathinformatics.org/article.asp?issn=2153-3539;year=2019;volume=10;issue=1;spage=9;epage=9;aulast=Aeffner;type=0), and artificial intelligence (https://onlinelibrary.wiley.com/doi/full/10.1002/path.5331).

2. **In what ways can digital pathology benefit patients?**
   - Consultation from off-site pathologists with a shorter turnaround time
   - Telepathology for frozen section to benefit patients undergoing operative procedures
   - International collaboration, consults, and helping under-served areas
   - Improved organization, reduced possibility of missing slides
   - Digital images as part of a patient's medical record
   - Measurement and counting, including quantitative and automated analysis
   - Work flow automation
   - Efficient slide archival

3. **Do I need to validate my digital pathology system for clinical use?**
   It is recommended by the College of American Pathologists (CAP) (http://www.cap.org/), a CLIA accredited organization, that all institutions or practices considering the implementation of digital pathology for clinical diagnostic purposes must carry out their own validation. For more information please refer to the Regulatory page (/healthcare-regulatory-information).

4. **Do I need to perform a validation if I am only doing the professional component (PC) of the diagnosis?**
   It is recommended by the College of American Pathologists (CAP) (http://www.cap.org/), a CLIA accredited organization, that all institutions or practices considering the implementation of digital pathology for clinical diagnostic purposes must carry out their own validation. However, it is up to the institution or practice who has implemented the digital pathology system to determine the scope of the validation study; specifically what will and will not be included as an intended use. Refer to the institution performing the technical component (TC) for information on their validation of the digital pathology system and whether or not it is validated for the professional component (PC) of a primary or secondary diagnosis.

5. **What CPT codes can apply to digital pathology?**
   Reference chart below:

CPT CODE(S)	DESCRIPTION	DIGITAL PATHOLOGY APPLICATION
88300-88309	Accession, examination, and reporting of gross and microscopic	
88321	Consultation and report on referred slides prepared elsewhere	Second opinion consultations preformed on whole slide images
88323	Consultation and report on referred material requiring preparation of slides	Second opinion consultations on whole slide images
88329, 88331, 88332	Pathology consultation during surgery, frozen section	Frozen section consultation preformed via live telepathology or on whole slide images
88360, 88361	Morphometric analysis, tumor immunohistochemistry (eg. Her-2/neu, ER/PR), quantitative or semiquantitative, each antibody, manual or using computer assisted technology	Computer-assisted analysis of IHC (ie Her2)**
88365, 88367, 88368	In situ hybridization (eg. FISH), morphometric analysis (quantitative or semi-quantitative), manual or using computer assisted technology for each probe	Manual or computer assisted analysis of FISH

*** Some manufacturers have obtained 510(k) clearances for manual and/or quantitative analysis of Immunohistochemistry and/or FISH. Please refer to the 510(k) clearance list (https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances) and the Regulatory page (https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.proofpoint.com%2Fv2%2Furl%3Fu%3Dhttps-3A__nam04.safelinks.protection.outlook.com_-3Furl-3Dhttps-253A-252F-252Furldefense.proofpoint.com-252Fv2-252Furl-253Fu-253Dhttps-2D3A-5F-5Fdigitalpathologyassociation.org-5Fhealthcare-2D2Dregulatory-2D2Dinformation-2526d-253DDwMFaQ-2526c-253DQ1ICj3vG2xbuf44-5FonkKqw-2526r-253DMRgWcB-5FRO9EWkbjSVPLHI7I3rXea-2DkU-2DlyGDxsiQ6cM-2526m-253DXs613s3uJ513losQD2-5F6qBPdSaqGzFwuJLGqhWBm6hU-2526s-253DEerqYz4WKbZsY565xGp-5FleNnDWYCnwShZ5u6e5Oz14Q-2526e-253D-26data-3D01-257C01-257CGarcc14-2540LabCorp.com-

257C4ee3cee6e62f449272cd08d7b0a504c1-257C7b3bf3a5ce934afbabec7bf49544d250-257C1-26sdata-3DwfoWNbNkCZ61qbAvbUjbzaVop-252FdyOgnM7LwmlR8Esf4-253D-26reserved-3D0%26d%3DDwMFaQ%26c%3DQ1ICj3vG2xbuf44_onkKqw%26r%3DMRgWcB_RO9EWkbjSVPLHI7I3rXea-kU-lyGDxsiQ6cM%26m%3D48ikjq6BXDM4luV1gEkHrWqmVV1QpBfdsEz6xEOzsN0%26s%3D40sOQ7OQHJsgp1pCGznx1MoL0EsWrcXgQHBVSd for more information.

Whole-slide Imaging FAQ

1. **What is whole-slide imaging and what components are needed?**
   Whole-slide imaging is the high-resolution digital capture of glass slides to generate "virtual slides." It consists of a microscope designed to scan one or more slides in an automated fashion (the whole-slide scanner) and accompanying image viewing software that allows users to navigate a slide in a manner similar to Google Maps. It may optionally include an image management platform that provides controlled access and organization, educational tools, and image analysis software for computer-assisted measurement.

2. **In what format are virtual slides stored and how can I view them?**
   Virtual slides are usually stored in a proprietary format which can be viewed by the image viewing software provided by the vendor. However, some viewers are vendor-neutral and can support multiple image formats. Some of these are freely available.

3. **Is viewing a whole-slide image on a computer monitor inferior to viewing a glass slide under a microscope?**
   There has been a great deal of debate about the differences in the experience of viewing a slide digitally or under a microscope. However, a recent multi-institutional validation study reported whole slide imaging to be non-inferior to glass slide microscopy [link]. The College of American Pathologists has provided validation guidelines for institutes planning to use whole-slide imaging [link].

4. **Is whole-slide imaging FDA approved for primary diagnosis?**
   Yes, one Whole Slide Imaging device for primary diagnostic use can be legally marketed in the US, please click here (https://www.accessdata.fda.gov/cdrh_docs/pdf16/DEN160056.pdf). Please refer to the regulatory page (/healthcare-regulatory-information) for more information.

5. **Is Fluorescence imaging supported?**
   Some whole-slide scanners support fluorescence imaging in addition to brightfifield viewing.

6. **Does whole-slide imaging support z-stacking?**
   Many whole-slide scanners can optionally capture multiple focal planes of the same glass slide arranged in a z-stack. Often, users can select the number of focal planes to capture and the plane spacing (or total range). Z-stacks can usually be incorporated into a single file. However, two main challenges presently exist: 1) the file sizes produced can be quite large and 2) the image viewer must support z-stacking. Computational methods have been developed to collapse z-stacks into a single plane representing the "in focus" region, which may mitigate these challenges but would no longer allow the user to traverse the z-stack in its entirety.

7. **What is the file size of a whole slide image and how should files be managed?**
   Most scanners support resolutions of 0.5 microns/pixel (effective viewing magnification: 20X) or 0.25 microns per pixel (effective viewing magnification: 40X). Following image compression, the image files produced may exceed 1 GB in size each. Some whole-slide scanning vendors allow the user to modify the compression quality factor, enabling users to manage the tradeoff between image quality and file size. Users have the option of storing images in the cloud, on local servers, or on local workstations.

8. **Should I compress whole-slide images?**
   Virtual slides are rarely stored in their raw form. Usually, they are compressed (lossy or losslessly) by the whole-slide scanner during capture. Lossless compression refers to an image compression method in which no information is lost. This method may reduce raw file sizes by a factor of 4 or more. Lossy compression typically achieves lower file sizes (a reduction by a factor of 20-30 is common) but may reduce image quality. Users should decide the amount of image compression they can tolerate to optimally balance the tradeoff between file size and image quality.

9. **Is cloud (SaaS) storage secure and fast for digital pathology?**
   Yes, cloud technology or Storage as a Service (SaaS) is growing in popularity and offers some significant benefits for primary storage and for replication of data. Cloud based storage can lower storage costs, maintain or improve security and data integrity including HIPPA compliance, improve exibility, and expand capacity when capacity resources are strained. More information on cloud replication of data is provided in the DPA white paper "Archival and Retrieval in Digital Pathology Systems."

   (/_data/files/Archival_and_Retrieval_in_Digital_pathology_Systems_final.pdf)
10. **Is digital pathology HIPAA compliant?**
    HIPAA compliance should be checked and assured with providers of digital pathology solutions. Most vendors have arrangements for encryption of patient identifying data like dates, medical or pathology numbers, labels, and restricting access. Some platforms also support deidentification procedures.

11. **What is DICOM?**
    DICOM (Digital Imaging and Communications in Medicine) is the international standard to transmit, store, retrieve, print, process, and display

medical imaging information. DICOM makes medical imaging data interoperable by enabling integration of image acquisition devices, archive solutions and workstations across different vendors. In radiology, the DICOM standard is universally used. DICOM has been deployed in hundreds of thousands of medical imaging devices worldwide, with hundreds of billions of DICOM images archived to date.

12. **Are WSI DICOM compatible?**
    Yes. DICOM's Working Group 26 (WG-26) was established in 2005 to develop and extend the DICOM medical imaging standard for pathology and whole slide imaging (WSI). Since then, WG-26 has made two major contributions to the DICOM standard by finalizing the specimen & pathology supplement (2008) and the whole slide imaging supplement (2010). Together, these supplements allow whole slide images containing multi-resolution, pyramidal, z-stacked and multi-spectral pixel data, as well as the related clinical, patient and specimen preparation steps (e.g. fixation, embedding, staining, etc.) to be handled in a standard, open and interoperable fashion.

13. **How long does it take to scan a glass slide?**
    Scan time is determined by how much tissue is on the slide, the magnification to be acquired (20X or 40X), and how many focal planes are to be acquired (z-stack size). In general, most modern scanners can acquire a 15mm x 15mm region at 40X in about 4-8 minutes. This does not take into account the time it takes to transfer the file from the scanner to its ultimate destination (e.g. a network server).

14. **Can whole slide images be integrated with my Laboratory Information System (LIS) or a snapshot put into my pathology report?**
    Four integration options commonly exist: 1) Direct delivery of selected image regions (snapshots) to the patient record in the LIS or EHR; 2) Cataloging of the whole-slide image in the LIS or EHR, so that users can navigate to an image management or PACS system from within the patient record to view the whole-slide image in its entirety; 3) The electronic delivery of whole-slide image-derived data, such as IHC scoring; 4) Document delivery in which an imaging report is issued and attached to the patient record.

15. **Who should perform scanning? Is there a CLIA complexity associated with scanning images?**
    Unlike chemistry and other analyzers, the scanner is not considered a high complexity instrument by CLIA and CAP. But the instrument does take skill to maintain and operate. Someone in the lab— usually a histotechnologist— can assume the role of "scanning tech" and be appropriately trained. Vendors usually have a training course, but techs can also attend the DPA-NSH whole-slide imaging course (/digital-pathology-certificate-program). The course, consisting of 22 hours of training, is not mandatory but shows a level of professionalism appropriate for this important function. At the completion of the course, the tech (or pathologist) will receive a certificate. There is a discount for DPA and NSH members.

16. **Are slide scanners calibrated to insure the integrity of the image data?**
    All digital pathology systems have a calibration process to insure the scanner produces consistent, high quality whole slide images. However the calibration technique and process will be different for each manufacturer. Therefore, discuss the calibration process with your digital pathology provider.

17. **Do I have to calibrate images when used with image analysis software?**
    If your image analysis software is compatible with proprietary whole slide image formats then no calibration is needed. However, if you are working with an unsupported format or with a static "snapshot" from a whole slide image, then yes you will have to manually calibrate the image for accurate image analysis results.

18. **How does digital pathology benefit drug development?**
    Digital Pathology streamlines the drug development process through discovery, preclinical, and clinical trials by enabling pathologists to more efficiently illustrate, communicate, and collaborate on crucial findings in tissue based toxicity and efficacy studies. A few benefits of digital pathology include high throughput scanning of glass slides, quantitative analysis of whole slide images, immediate web based consultations with expert pathologists, and secure archival of pathology data.

19. **Are digital pathology systems GLP and CFR compliant?**
    No, but you can create a validation plan to establish a GLP and CFR compliant environment to work with your digital pathology system. Please refer to the life science Regulatory page (/life-sciences-regulatory-information) for additional information or the DPA white paper "Validation of a Digital Pathology System in the Regulated Non-clinical Environment."

    (/_data/files/DPA_White_Paper_Final_-_2011-11-17.pdf)

20. **Do I need to validate my digital pathology system for use in a GLP study or for clinical trials?**
    Yes, please refer to the life science Regulatory page (/life-sciences-regulatory-information) for additional information or the DPA white paper "Validation of a Digital Pathology System in the Regulated Non-clinical Environment."

    (/_data/files/DPA_White_Paper_Final_-_2011-11-17.pdf)

21. **How much does whole-slide scanning cost?**
    Costs can vary considerably depending on the features needed and slide capacity of the scanner. Typically, a whole-slide scanner costs between $50,000 and $300,000, ranging from a single slide capacity to several hundred slides. Scanners come packaged with an image viewer, but many include more sophisticated viewing tools, image management platforms, or image analysis software. Some users opt to purchase software solutions separately, which can add to the total cost of the scanner but can provide additional function or a more seamless integration into existing information systems. Additional cost considerations include IT infrastructure (e.g. storage, data management) and personnel to manage and operate the device.

FOLLOW US (http://www.facebook.com/digitalpathologyassociation) (https://twitter.com/dpatweet) (http://www.linkedin.com/company/2896225?trk=cws-btn-overview-0-0)

DISCLAIMER () | SITEMAP (https://digitalpathologyassociation.org/sitemap)