

# Covid-19 and the rise of Digital Pathology



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We would like to share with you the questions raised during the Q&A from the original webcast. Dr. Eric Glassy and Dr. Matthew Hanna have responded to these questions.

## **How do you evaluate the penetration of digital pathology Globally?**

EG – One has to evaluate the social media and the amount of scientific literature being published all over the world performing digital sign off. MH – DP is probably much advanced in European countries who had less barriers in the implementation than USA. DP has a global footprint that has been capitalized during the pandemic with the increase in need.

## **What level of backup is considered adequate/sufficient for digital slides?**

EG – The backup strategy for digital slides is essentially the same as for any hospital-grade system. The scanner manufacturer can help with the details, but I would follow the same guidelines you use for your laboratory information system. Assuming the glass slides are still available, scans can be repeated, but the work of annotation, image analysis, etc. would be challenging to resurrect. You are working in a regulated environment. This is patient data and should be handled appropriately. A ransomware attack may make the files inaccessible. Plan for redundancy. It is best practice to have a “backup of the backup.” This is traditionally tape’s role in the enterprise—and usually stored in a secure offsite facility.

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### **Where do you save the images of the slides - on clouds or hardware?**

EG – Image storage is up to you. Most scanner manufacturers provide onsite storage hardware solutions, but the whole world seems to be moving to the Cloud. Your hospital IT department would have a say in what is best but remember that pathologists want a fast response when viewing whole slide images. Long distances between the viewer and the server can impact response times.

In addition, consider your use cases, slide volume, and need to access images quickly. Many facilities with large case volumes have “hot storage” for recent scans and then less expensive “cold storage” for older images that do not need to be readily available. Your scanner manufacturer can assist you in creating a storage plan that fits your needs.

Finally, consider how long the whole slide images must be saved. By CAP guidelines, glass slides must be stored for 10 years. There is no such requirement for digital slides, even if used for primary diagnosis, as long as the glass slides used to make the scans are accessible. If the tissue on the glass slide is not available because it was used for molecular studies, the digital image must be stored for 10 years. These are the current CAP checklist requirements, but the Digital and Computational Pathology Committee of the CAP may revise them in the near future.

### **Are you FDA approved, or are you self-validated?**

EG – At my laboratory, I do not have an FDA-cleared scanner and performed validation following the College of American Pathologists guidelines. But even if you use an FDA-cleared system, you absolutely must do appropriate validation.

### **What are the cost implications/cost effectiveness of routine digital pathology?**

EG – Many laboratories, particularly in Europe, have gone completely digital. Others have taken more of a niche approach and adopted whole slide images for selected use cases, such as frozen sections, image analysis, tumor board conferences, and primary diagnosis on general surgical pathology cases (not cytology and hematology).

The transition from glass to digital comes with a cost, and you will have to balance those costs with the benefits that a fully digital workflow provides. The costs of digital are more than just the scanner, the monitor and slide storage. Software algorithms, service agreements, and IT infrastructure are all part of the equation. People need to be trained, both pathologists and techs. So, there are direct costs and indirect costs to consider.

Dr. Hanna described his digital workflow and its advantages. For a detailed discussion, I would also refer you to a journal article by Dr. Hanna: Implementation of Digital Pathology Offers Clinical and Operational Increase in Efficiency and Cost Savings. Arch Pathol Lab Med. 2019;143:1545–1555; doi: 10.5858/arpa.2018-0514-OA. Another source of information is the Digital Pathology Association website, where you will find several white papers about adopting digital pathology (<https://meridian.allenpress.com/aplm/article/143/2/222/64743/A-Practical-Guide-to-Whole-Slide-Imaging-A-White>).

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### **It took you ten years to scale to 2.5k slides per day, but how long would it take you to scale to that many per day from scratch?**

MH – Since the technology has matured, you can probably do it quicker than the last 10 years. There are much higher throughput instruments out there, the vendors have matured in their offerings,

For those starting fresh you may have an easier and much streamlined approach because there is plenty of literature on lessons learned and business profiles from creating digital pathology to guide you through gaining leadership support and such.

### **Were different pathologists evaluating glass and digital slides or same pathologist over different times? Were discordances evaluated further? Which was more accurate, digital or glass?**

MH – All of the pathologists reviewed their slides digital 1st and then came back to the department for a glass slide microscopy review within a few days. The same pathologist reviewed the digital and glass slides, this was looking at intra observer concordance. The ultimate clinically reported diagnosis was used as the ground truth, any discordance between the ground truth and other reported diagnoses were adjudicated accordingly as a major or minor discordance. There was 100% major diagnostic concordance between the digital and glass slide diagnosis.

### **Did you include lymph node and bone marrow (hematopathology cases) in your scanning?**

MH – This validation included FFPE specimens from surgical pathology cases, including lymph node specimens. Cellular tissue preparation specimens were not included such as cytology or bone marrow smears, or touch preparations. We are separately validating those specimens with non-FFPE tissue preparations.

### **Can you discuss use of whole slide imaging for frozen section diagnosis and second opinion?**

MH – There is various whole slide scanning hardware that can be used for frozen section or second opinion. These include live hybrid robotic scanners or real time streaming of a video capture from a microscope. The live hybrid robotic scanners allow pathologists to remotely control the microscope as if they were sitting at it live, whereas the real time streaming of an image requires a skilled operator to show relevant fields of interest.

Alternatively, with high throughput scanners scanning at faster speeds, barcoded frozen section slides could be scanned and available in the laboratory information system using a high throughput scanner. Second opinion can also relate to consultation cases, where patient slides can be scanned and reviewed on a whole slide image viewer for diagnostic rendering of a second opinion.

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### **Do you scan mostly prospective or retrospective cases? For how long do you keep them, and for what reason(s)?**

MH – Early implementations were retrospective scanning, cases that were reviewed conventionally and selected slides were marked later for digitization. We are shifting more to prospective scanning, having less of a need to mark individual slides for retrospective scanning. At MSK we keep all the scanned slides within LIS indefinitely. Ready access to patient prior digital images, review of prior biopsies, to show value of digital pathology to the pathologist.

### **How do you store (cloud, local servers) and for how long do you save the digital images? What are the backup processes for these images?**

MH – So far, we have kept every scanned image link to the laboratory information system. the institutional data center has its own policies and procedures for disaster recovery and backup policies.

### **Regarding the scan slides, do you store than digitally over a period of time or not?**

MH - There are different states mandates depending on where your lab practices, in genera it is required to keep them 10-20 years. CAP does require glass slides to be kept for 10 years.

### **How long is your institute is intending to keep the saved scans?**

MH – Indefinitely

### **What is the name of the digital education portal? Are you building this and the consultation portal yourself or using a vendor product?**

MH – The Department of Pathology is licensing a web based platform from PathPresenter as an institutional digital education portal.

### **As far as input devices do you have recommendations or solutions for issues with "conventional" mouse?**

MH- There are a lot of potential software improvements that are in development that can facilitate the use of traditional computer mouse. There is also a slew of mouse complements or replacements as input devices can be a more intuitive way to navigate digital images.

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### **What is the approximate cost of implementation and how do you expect this methodology to be economically feasible?**

MH – The cost of implementation will differ based on the use cases of that specific institution. Factors that affect the cost of implementation include the number of scanners/volume of slides needed to be scanned, storage requirements, personnel, to mention a few. Looking at short-term versus long-term costs and return on investment over time will help each laboratory or organization map out the respective value digital pathology can bring to them.

### **What is the cost implications or cost effectiveness of routine digital pathology?**

MMH, EG - The effective blueprint is likely different depending on the laboratory uses cases, and what you are using digital pathology for, but from a primary diagnosis use of digital pathology from a routine stand point, there have been several studies published showing a decrease in transportation costs, reduce cost of slide storage at an alternative location, ready access to digital slides and virtual control slides can also bring in additional savings.