

Digitization of Pathology Is Making Steady Progress

► **New technology and innovations contribute more capabilities to digitized pathology systems**

►► ***CEO SUMMARY: Pathology digitization incorporates a greater scope of work-changing technologies than telepathology. It incorporates information technology, new diagnostic knowledge, and other engineering innovations to help pathologists move past glass and paper. Existing digital pathology systems are already helping pathologists reduce their travel from site to site by enabling them to view digitized images from a central location.***

ONGOING ADVANCES IN DIGITIZATION AND PATHOLOGY INFORMATICS are providing pathologists with new tools that hold the potential to change the way pathologists work.

Pathology digitization was one of the trends identified and described in THE DARK REPORT's biannual list of anatomic pathology macro trends. (See TDR, February 11, 2008.) Because digitization holds the promise of moving pathology away from paper, it is an important trend and one that complements the efforts across healthcare to move to fully electronic medical records (EMRs).

► **Changing Work Practices**

In a more direct way, newly approved digital technology is already changing the way some pathologists work. Rather than having to be in the same room with specimens, this technology allows pathologists to work remotely. Further, in medical schools, the shift to digital images and away from glass slides means that newly-graduating pathologists enter the practice of pathology already comfortable and proficient with digital pathology images.

These developments have significant implications for the pathology profession, which is predicted to soon face a shortage of pathologists. That's because viewing digital images eliminates travel and saves shipping costs. "A pathologist who spends his morning at one hospital and then goes across town to read slides at another facility may not have to make that drive anymore," said Ole Eichhorn, Chief Technology Officer of **Aperio Technologies Inc.**, a company in Vista, California, that specializes in digital pathology.

"For example, this represents a dramatic change for pathologists who serve hospitals in rural areas," he observed. "Circuit-riding pathologists in rural areas—who literally spend every day of the week in a different location—don't have to do that anymore. Digitization of pathology images means they can perform the same work from a central location. By eliminating the time spent traveling, it makes the pathologist much more productive."

One of the features of new digital pathology technology is that digital images are stored on a server and can be viewed on a computer screen miles away.

“The system is designed to work much like Google maps in that you can pan and zoom over a large image,” explained Eichhorn. “Just as you don’t have to download the entire dataset of Google maps to find the nearest pizzeria, the same thing happens with a digitized pathology image. The pathologist doesn’t need to see the whole image at high resolution. Rather, he/she pans through at lower resolution, zooming in to see features of interest, then zooming back out to continue studying the image.

“We don’t view this technology as replacing eyeballs with automation,” Eichhorn continued. “These digital images allow pathologists to find the things that are important more quickly, then use software tools to precisely quantify what they find. Thus, instead of estimating that something on the specimen is expressed at 70%, a pathologist would now be able to report that something is expressed at 68.234%, for example.

“It’s doubtful that the day will come when computers replace pathologists,” he added. “Instead, this new digital technology allows pathologists to quantify results more accurately, thus providing more specificity in the results reported to the referring physician.

► Increasing Productivity

“Another benefit is that pathologists have always worked in the same physical location with their specimens,” stated Eichhorn. “But digital pathology now allows pathologists to be in a different location from the physical specimens. This increases the flexibility and productivity of pathologists.

“Digitized images also make it easier to have subspecialist pathologists review specimens,” he noted. “At the same time, use of digitized pathology images and systems allow pathologists to serve a wider community of hospitals and specialists while cutting down on travel and reducing the cost of shipping glass slides.

“Digitized pathology technology has important implications for a pathology profession struggling with a workforce shortage,” observed Eichhorn. “Pathologists face increased pressure for a number of reasons. First, the absolute number of cases are increasing. Second, new diagnostic tests are introduced every week and pathologists must become proficient in using these new assays. Third, the number of pathologists is not increasing in proportion to increases in specimen volume. Thus, any technology that helps a pathologist become more productive is important.

“Digitized pathology technology has important implications for a pathology profession struggling with a workforce shortage,” observed Eichhorn.

“Currently, there are few examples where a pathologist handles nothing but digital images throughout the day,” said Eichhorn. “Rather, digital pathology applications are finding greater use in specific clinical activities, such as preparing for tumor boards, doing secondary consults, IHC quantification, use in medical education, or building up reference libraries. Like other areas of informatics and computers, as pathologists gain more personal experience with digital technology, they will be more comfortable in expanding its use in other areas of anatomic pathology and laboratory medicine.”

Digital pathology systems are moving through the regulatory approval process. For example, in January, Aperio received clearance from the Food and Drug Administration (FDA) to market the manual read of digital HER2 slides from a computer monitor using its ScanScope digital slide scanning system. The FDA-cleared system is intended for use as an accessory to **Dako’s** HercepTest to aid pathologists in the detection and meas-

urement of HER2 protein expression to assess breast cancer patients.

“This FDA clearance was an important milestone in pathology digitization,” stated Eichhorn. “It is the first time the FDA has cleared any technology that demonstrates that what a pathologist views on a computer monitor is the same—for diagnostic purposes—as what the pathologists would view through a microscope.

“Previously, Aperio received clearance for an image analysis algorithm that quantifies HER2 by actually measuring the membrane staining of cells to show whether the protein is present,” explained Eichhorn. “The software analyzes an image and produces a quantified result.

“Now that the FDA has cleared this technology for the manual read of a digital pathology image from a monitor,” he added, “it means we can market the technology to the pathology community. It will permit pathologists to view the specimen image on a monitor in the same fashion as they would view a glass slide through a microscope.”

Eichhorn thinks that the digital pathology technology will advance the quality and accuracy of diagnosis. “We believe this technology has the potential to reduce false negatives and false positives, but, we will be cautious about such claims and wait for the results of further clinical studies. Anecdotally, pathologists who have been early users of this system tell us they often find things in the digital pathology image that they might not have found otherwise.”

► Exclusive Worldwide License

Last fall, Aperio secured an exclusive worldwide license from **Los Alamos National Laboratory** (LANL) to LANL’s Genetic Imagery Exploration (Genie Pro) image pattern recognition technology for digital pathology applications.

“This development is also significant,” Eichhorn said. “The Genie Pro technology was developed for the military to identify rare events from satellite imagery. We have licensed it exclusively for pathology because

it is very useful for looking for rare events in digital images. Pathologists spend a lot of time looking painstakingly through large samples to find something that’s hard to find, such as metastasizing cancer cells in a lymph node, or bacilli in a lung sample infected with tuberculosis. This work is critical because if the pathologist misses something, you’ll have a false negative, which affects patient treatment. So, in this way, the technology allows us to create products that will help pathologists do their jobs more efficiently and more effectively.

► Four Elements In The System

“In our systems, there are four pieces,” he explained. “First, there’s the hardware to scan the slides and create digital images from the slides. Second, the technology allows the slides to be viewed. We give pathologists a viewing experience that allows them to zoom in and out and pan through large images. Third, there’s image management, which includes workflow, access, security considerations, archiving, and other similar activities. Fourth, we have analysis tools that let pathologists measure things and find things in images.

“The software presents the 20 (or whatever number you choose) most likely instances of whatever you’re seeking,” Eichhorn added. “It saves the pathologist from having to pick through the entire haystack to find a needle. The software will do the work for them by identifying the 20 things that look most like a needle. And then the pathologist can decide whether each instance is a needle or not.

“We believe this technology has a lot of potential, but pathology is a conservative field,” he said. “Although pathologists are not early adopters in general, they are starting to use this technology. As they do, others are becoming aware of it and we’re starting to get a critical mass now—whereas a few years ago not many pathologists were aware of this technology.” **TDJR**
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