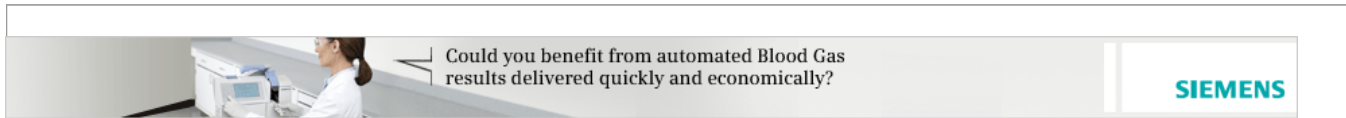


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## Special to MLO



### Diagnosis for digital pathology

By Ajit Singh, PhD, and Robert Monroe, MD, PhD

The pathology industry is undergoing dramatic changes as new technologies transition the field into the digital age with technology enabling pathologists not only to improve workflow but also to use these new analyses, algorithms, and abilities to collaborate globally. These new tools allow pathologists to offer patients more detailed diagnostic insights, which are critical when taking a personalized-medicine approach to treatment.

Pathologists depend on image quality to make an accurate diagnosis; the image is the single most important factor in an accurate, consistent diagnosis. Digitization of slides makes images available for pathologists' use in ways that are not possible with manual microscopy. These advances are particularly important as personalized medicine becomes a reality in areas (i.e., breast cancer) and as physicians look to pathologists for critical support.

Image analysis can more accurately and reproducibly quantify various features in different types of studies, including immunohistochemistry, immunofluorescence, and fluorescent *in situ* hybridization (FISH), which are being used by pathologists to arrive at a specific diagnosis and to guide clinicians in therapeutic decisions for a subset of their patients. Depending on study results, therapies are personalized for patients, for more precise, targeted treatment and disease-state monitoring.

Traditionally, community pathology practices are geographically fragmented and small. Systems must be designed with space restrictions in mind; a small footprint is critical. If a system relies on other components (e.g., power supplies, cooling systems, or computers), locate those components remotely and flexibly.

Imaging, computer, and storage technology have advanced to the point where digital pathology is available to every lab to support better decision making, workflow, and, ultimately, patient care. Web-based software applications designed to work with slide scanners enable pathologists, histo-technologists, lab administrators, and clinicians to improve the efficiency and quality of the various steps in the anatomical pathology workflow. Technologies now allow users to first scan glass slides and — with whole slide images in hand — to view, manage, manipulate, analyze, report, and collaborate within a digital environment.

Moving to a digital format has increased the need for pathologists to stay connected with their professional networks to keep up to date with the latest advances. Launched in March, PathXchange.org (PX), a not-for-profit professional networking portal for the global pathology community, brought pathology into the digital age with Web 2.0 features designed to promote exchange of pathology cases, ideas, knowledge, information, products, and services. Cases and information can originate from anywhere, from any platform, and can be shared with sub-groups of a user's choice.

The pathologist will play a critical role in testing for specific biomarkers to predict patient response to given therapeutic agents, as will the primary physician analyzing and processing the tissue. Digital pathology can provide these results. Within a few years, the number of specific biomarker assays is expected to expand rapidly as a result of the increased number of drugs being developed with companion diagnostics. Processing cases in a digital, mineable form is important so clinical decisions can be extracted and made available at the point of care, allowing physicians and caregivers to make the most appropriate decisions in personalizing medicine.

Herceptin highlights the crucial role digital pathology can play in selecting patients for a given therapy. Based on the pattern and quantity of the human epidermal growth factor receptor 2 (HER2/neu) protein in the membrane compartment of breast cancer cells as assessed by immunohistochemistry, patients are selected for treatment with the monoclonal antibody Herceptin or, in equivocal cases, for a second FISH-based assay that assesses amplification of the HER2/neu gene. Interpretation of both the immunohistochemistry and FISH tests relies on quantitative assessments facilitated by digital pathology and image analysis. Misinterpretation of results by under- or over-estimating HER2/neu signals can lead to suitable patients not being treated with a potentially life-saving therapy and unsuitable patients being treated with an unnecessary, high-cost drug with potentially devastating cardiac side effects.

Pathology has only started to make the leap toward adopting digital solutions in the past decade and faces challenges associated with this transformation. As an example, many consider digital pathology to be a "disruptive" technology that will have to displace existing systems. Pathology labs face internal competition from other departments for scarce capital resources. Systems are available, however, with low or no capital outlay that can often be approved at the departmental

level, saving resources for other uses within the lab or hospital.

When deciding to purchase a digital pathology solution, health systems need to consider how quickly and with what effort can a system be deployed. Thanks to advancements in technology, systems are now available that can be deployed rapidly — with little, if any, optimization — and are intuitive to operate with minimal training requirements. Although adoption is still in its adolescent stages, the move toward a digitized realm in pathology is already proving to be "the missing link" as physicians strive to make personalized medicine a practical, broadly based reality.

**Ajit Singh, PhD**, is the CEO, and **Robert Monroe, MD, PhD**, is the CMO of BioImagene, a digital pathology solutions company, based in Sunnyvale, CA. BioImagene products are FDA-cleared for specific clinical applications and are intended for research use for other applications. To learn more, visit [www.bioimagene.com](http://www.bioimagene.com).

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