The inside track in AP automation: new product guide

Access interactive product guide

February 2015—*Tissue processors, tissue embedders, microtomes, slide stainers—we tackled them all in our first-ever product guide to anatomic pathology automation. (Yes, we realize most tissue embedders are largely manual but included them because they are vital to the automated process.) Zeroing in on what questions to ask the vendors—that is, knowing what you, the readers, need to know—was no simple task. And we couldn't have done it without tapping into the expertise of William DeSalvo, BS, HTL(ASCP), AP manager at Sonora Quest Laboratory; CAP TODAY's informatics experts, Raymond Aller, MD, and Hal Weiner; and product specialists at Leica and Roche. The companies that market the instruments profiled in the following product guide, which begins on page 19, supplied the information about their products in response to our questionnaires. We asked each vendor to list their one or two premier products but allowed up to four entries per company for stainers to accommodate the various types. We would appreciate feedback and suggestions on how to improve future editions of the guide. But first, CAP TODAY writer Anne Ford asked the companies that supply AP automation instruments how they help laboratories understand the clinical and financial benefits of adopting such automation. Here's what some of them told us.*

—Kimberly Carey, managing editor, kcarey@cap.org

Robert Jacox, manager of global tactical marketing for anatomic pathology, Thermo Fisher Scientific: If I really think about it and take a look at where our customers are spending their dollars, the largest area of laboratory automation right now is specimen identification. From a market standpoint, that's where most of the larger accounts and even midsize hospitals are placing a lot of their growth dollars. So what we have done is made sure that, since customers are speaking with their dollars, we are launching new products that make it easier to automate patient identification.

Many people understand where they want to go, but they haven't contacted their LIS vendor to figure out how to create a total solution. So we've done work with each LIS to figure out how our system will integrate with it so that what we're designing fits easily and seamlessly into the LIS.

There are also, I think, many new laboratory consultants coming into this market space to help people make that transition. We have forged a relationship with several of them in case a customer needs people who can walk them through implementation—not just with labeling and tracking but also with tissue processing and other workflow improvements.

Dave Sanford, general manager, Milestone Medical: Milestone focuses on what we feel can aid lab functionality. One is standardization and documentation, two is ease of use, and a third is to provide systems that fit into a lab setting and can be flexible enough to meet the laboratory's workflow needs.

We also focus on management of specimens when they enter the lab. To a high degree this is still manual. There's limited automation or documentation from grossing through preprocessing fixation to processing. We identify those manual, non-documented steps of specimen handling and work to standardize a process for each of those steps along the way.

Rhonda Henshall-Powell, PhD, director of marketing and education, Biocare Medical: At Biocare, we're conscious of the cost per slide to users and work closely with the lab's financial team to demonstrate the cost benefits of adopting AP automation. When Biocare's IntelliPath is used along with IntelliPath reagents, we can minimize cost per slide and provide consistent staining. The IntelliPath also allows you to perform multiplex IHC, staining a tissue section with multiple antibodies on a single slide. Compared with single stains, multiplex IHC can be clinically and ethically better for patient care in certain disease states because it conserves patient tissue while

reducing reagent and labor costs.

Automating IHC is beneficial to providing routine, consistent results, but that can come at the expense of flexibility. Our IntelliPath is well established as being one of the most flexible stainers; its semi-automated nature allows for maximum protocol manipulation. It is also accessible as a completely open system, allowing antibodies and reagents from any source to be used.

For labs that prefer full automation, we launched our Oncore slide staining system in 2014.

Kevin Kraus, vice president of marketing, Roche Tissue Diagnostics: We partner with our customers to offer the total solutions they need. When we started out, we just automated immunohistochemistry and special stains, and that's what we were well known for. But over the past 10 years we've introduced further automation, and we've been focused on H&E testing, digital pathology, workflow, and positive patient identification through our tracking solution.

On the clinical side, we focus on understanding the menu of tests the customer is going to run, and we break down those tests into routine testing and high medical value assays. Many customers have chosen us for their breast cancer testing, as we were one of the first to have a fully automated and validated breast panel for IHC. We also have a broad menu of 510(k)-cleared breast panel algorithms for breast markers with our digital pathology solution, iScan Coreo. Customers are able to use the algorithms as another quality control mechanism and capture information on their IHC slides and share that information remotely.

The financial piece really comes down to testing efficiency. Turnaround time is important, but we also look at how the systems work together. When we implement, for example, our Vantage workflow solution, we have the ability to track the sample from the time it arrives in the laboratory through staining, scanning, and case signout. That also enhances patient safety.

Pawan Singh, director of workflow solutions for pathology imaging, Leica Biosystems: A common theme is that laboratories are trying to do more with less, and they're trying to make their workflow process be more of a science instead of an art. We have the tools to help with this.

Let me talk about the diagnostic step, which is ultimately what the entire value stream is driving toward. One of the benefits of imaging is that it enables wider access to experts. So now there doesn't have to be this scenario of pathologists having to have physical glass slides shipped to them. Using images versus glass slides is not only 94 percent faster than traditional methods, it also opens the door for a number of possibilities, like better collaboration between pathologists as well as image analysis. All of that leads to faster and better diagnosis. That's an example of where we're trying to drive value through automation and adoption of whole-slide imaging.

One of the areas that continues to be a big opportunity with pathology laboratories is elimination of manual steps in sample identification. The benefit there is obvious in terms of safety. It also improves efficiency and traceability throughout the entire workflow. We expect to see up to an 80 percent reduction in internal errors, and for a relatively small laboratory, up to a 35 FTE hours per week savings from the elimination of manual staining, manual inspection, and review of slides and identification.

Dustin Campbell, manager of health care instrumentation, General Data: This is a recurring question within the industry. Given recent changes in health care policy, we believe a leap forward in laboratory automation can, with time, introduce growth back into the market. To answer the question, we take the personal approach by understanding our customer's individual workflow and analyzing their needs and, more important, their growth opportunities and expectations. By understanding their laboratory environment, we are able to identify the benefits of automation and focus on what makes sense to the customer.

Anthony Tong, PhD, senior marketing manager, BioGenex: Xmatrx Elite, one of our "eFISHiency" platforms, is a high-throughput, fully automated system for IHC, FISH, microRNA ISH, in situ PCR, and more. It can automate

from tissue pretreatment to final coverslip on glass slides as well as pipette as little as 10 µL of reagents. Some of the assays, like FISH, are still performed manually and use expensive probes. That is how the Elite system brings clinical and financial benefits to cytogenetics labs: We help those customers standardize their assay protocols and use a very small amount of expensive reagent.

Our Xmatrx Nano is primarily designed to run FISH, but it can also run ISH as well as in situ PCR assays. With the Nano, the lab technicians have to manually pipette the FISH probe to the slide and decide how much probe they want to apply. They can apply only a few microliters of probes, let's say 3 µL, to save cost because even 5 µL or 10 µL of probe can be too expensive for the lab.

Another way we minimized costs was by reducing manual steps from 33 to six due to automation. Steps like dewaxing, oil sealing, and final coverslip are done onboard. With this reduction, the hands-on time for the technician is cut from 7.5 hours to just one hour.

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