

AP tracking: an eagle eye on blocks and slides

Anne Paxton

February 2014—A high-tech blend of hall monitor, bloodhound, and lost and found, tracking systems to manage tissue specimens, blocks, and slides have gradually been taking root as part of an automated workflow in some anatomic pathology laboratories. As manual labeling, logging, and data capture give way to bar coding and even radio frequency identification, it's a revolution of sorts, but a quiet one.

"Tracking systems have been in the clinical laboratory for at least a decade and AP has been really slow to catch up, largely because the volume was never quite there and AP is very much a manual process," says John H. Sinard, MD, PhD, professor of pathology and director of pathology informatics at Yale University School of Medicine. "There's still an art to getting a good histologic section. It's something that requires skill and training." Now, however, the volume has increased along with the need for efficiency and patient safety, and tracking technology has matured.

Unlike robotics in the clinical laboratory, the modest automated processes available in the AP lab may not seem like game changers. Moreover, tracking systems aren't cheap. The software alone for a tracking module from a laboratory information system vendor or a middleware solution from a third-party vendor can run from \$50,000 to \$100,000 or more. And even labs with the in-house informatics expertise to design and install their own tracking systems attest that the outlays are likely to be substantial.

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The systems profiled in this annual product guide are commercially available in the United States. In this year's lineup for the first time is information pertaining to whether vendors provide a list of client sites to potential customers on request.

The data presented for each product are based on vendors' responses to a questionnaire. We encourage anyone interested in purchasing an anatomic pathology system to verify the validity of the information provided, particularly a company's claims of having innovative product functionality installed in all of its client sites.

We also encourage readers to ask vendors whether they charge for the software modifications necessary to render their AP systems compliant with current and future government regulations, such as meaningful use requirements.

New to the anatomic pathology systems product guide is AIM Clinical Software Systems, which markets the AIMPath anatomic pathology system. Please note that McKesson is listed in the guide as a marketer of NovoPath's AP system, also called NovoPath.

However, Dr. Sinard says, there are good reasons to implement tracking and to view it as an essential element of quality assurance. The surgical pathology laboratory at Yale saw the need for better workflow efficiency, improved integration with the LIS, and minimization of errors some years ago. "The traditional way of handling assets in anatomic pathology involved a lot of hand-labeling or stamping, logging, consulting of lists, manual reconciliation of lists and blocks, and trying to figure out what to do," says Dr. Sinard. "It was just a very inefficient process."

Just one example: "If you had eight people cutting in parallel, they would each mark off the work they did on their copies of the work log, but then they'd spend a lot of time looking for the master log to transfer their notes. And with so many assets floating around, and that many cross-checks and compilations of lists, if something got missed it wasn't noticed until a day or two later."

Add to that the concern about slides getting mixed up because they were improperly labeled. Studies show that a mislabeling or mismatch error rate of 0.1 percent to three percent can result from manually labeling items, he says. "Typically, in a lab like ours, you would catch a mislabeling pretty quickly. I'd expect to be looking at a uterus and instead I have a colon polyp. But occasionally one prostate biopsy gets labeled with the number of another prostate biopsy, and you may never notice that. Those are potential concerns."

The laboratory did some tracking and found minor errors that were caught at various points in the system. "But it did make you wonder if there were things going through that weren't caught. So both for purposes of patient safety and for improving and speeding up the overall workflow, we decided to go with a tracking system."

In 2009, Dr. Sinard and his in-house team of developers built their tracking system internally, helped by the fact that their LIS vendor allows them to customize their system at the code level. "There was nothing commercially available that we thought would serve our purposes at the time," Dr. Sinard says. "There was one available for our LIS, but at that point it was in the rudimentary stages and didn't have some of the patient safety features and workflow enhancing capability that I wanted to yield from the project."

"Since then, the laboratory has continued to enhance and develop the system with different modules. We're integrating it into our automated stainers and we're creating a specialized workflow to handle molecular diagnostic testing, so it's been constantly evolving. We're still pushing the envelope of trying to tailor our solution to give us the maximum yield and workflow efficiency."

But Dr. Sinard can point to a marked reduction in block and slide tracking errors. After the tracking system was implemented in 2009, the number of missing and mislabeled cassettes and slides and wrong stains dropped steeply. That includes errors that aren't patient safety errors, but are significant nonetheless.

"For example, if a block showed up in histology but somebody forgot to enter it in the computer system, that's technically an error related to labeling, and it meant somebody had to track down the resident, verify that the tissue did come from that case, get it entered into the computer system, and basically say, please don't do that again. So there's a huge time saving from the tracking system not having to manually follow up on all of these workflow mishaps."

Tracking has made a big difference in quality assurance. "You could take the standard QA approach of once a month posting how many errors each person made, and hope to shame them a little into trying not to make so many errors. But it's not necessarily a fair thing to do, because a resident on a busy service who might be responsible for 300 blocks a day is more likely to make more errors than those doing only 30 blocks a day."

One-piece workflow, he says, is a key means of keeping errors down. "With batching you typically have to finish everything in the batch before you can move on to the next step in the process, while with a one-piece workflow, as soon as you're done cutting a block, those slides move on. But the main advantage is patient safety because with batching there is a risk of mixing things up. We used to print out reams of labels, and slides would be manually labeled. Now, the way the workflow works, you sit down at the microtome station, they scan the block, the computer tells them to cut three slides, three labels come out of the printer right there, and those three go onto the three slides they've cut."

To operate this way required the workstations to be reconfigured. "We had to have a computer at each workstation and we added six or seven printers, one for each microtome station. So it's important for people thinking about buying a tracking system and getting a quote of \$50,000, remember, don't assume that's the cost of the project; it might only be a third of the cost. There are the printers to buy and workstations to upgrade, and then there is the cost of implementation."

What is the cost savings of a tracking system? "It's not an issue of using fewer reagents; it's the staff hours saved," he emphasizes. The direct cost savings comes from the reduction in overtime hours, plus fewer recuts or re-dos of lost slides. Indirect cost savings accrue from the reduced time spent looking for missing assets, managing paperwork, and repeated filing and pulling of the same blocks. An added benefit is that there are fewer interruptions of the histology workflow by attendings or residents checking on the status of slides, Dr. Sinard says.

One of the challenges was to build a tracking system that could deal with exceptions, and the result was a very complex system. "In the routine course of doing histology, probably 95 percent of blocks and slides take a standard pathway through the histology lab, but there's a small percentage that take the non-standard route. It might be a particular stain that needs to be cut thicker, a slide that needs to be treated differently, or a slide I dropped and need to replace."

"If the tracking system can't deal with the exceptions, then what happens is people need to do workarounds. And then it becomes part of their mindset that it's okay to work around the system, and that's a bad mindset to perpetuate. So we basically had to build in enough complexity to deal with exceptions, and that's partly why we're still developing the system and continually re-optimizing it for new exceptions and changes in workflow."

Sometimes, "hidden practices" can evolve and caution is required. "I don't mean people doing things covertly; I mean they're doing something the computer system or tracking system doesn't know about," Dr. Sinard says. Frozen section slides are one example. "Where standard H & E and stain slides are all ordered through the computer system, people don't order frozen section slides through the computer, so you have to think about how to track those." Another example would be "bonus sections," where a tissue block has only a small piece of tissue and only one section was ordered; if the histotechnologists get a few good sections, rather than throw the others away, they put them on a slide. "It's kind of a standard practice in the field, but not in a rigid workflow analysis."

So the system developers introduced a feature to track that exception. "We added a feature to the microtome module so that the histotech could order the additional section right there. Then the system informs the LIS and prints labels for slides." For laboratories considering a tracking system, he stresses the importance of doing a careful workflow analysis of the lab and identifying hidden practices like these before going to a tracking system, and then being sure the laboratory's needs will be met with the solution chosen, whether it is a vendor solution or a system developed in-house. "Implementation," he says, "is not as simple as paying money and installing a system."

Laboratories would be well advised to measure their "before" error rates, Dr. Sinard says. "In general, if you're going to rely on funding from your institution to purchase and install this tracking solution under the idea that it will improve patient safety or efficiency, then it would be valuable to collect data on those key metrics to have something to compare to afterward." In many cases, Dr. Sinard notes, people have instituted an improvement like tracking, then realized they don't have any way to show how much better they got.

The University of Pittsburgh Medical Center began rolling out bar coding for its AP laboratory specimens in 2009, says Liron Pantanowitz, MD, associate professor of pathology and biomedical informatics. "We started at one hospital, then a second, and we're now at a third hospital. It was a joint venture with the LIS vendor, our institution, and the companies that provided some of the hardware that was necessary—the printers and labelers."

The surgical pathology laboratory processes about a million slides a year. "So we're doing a high volume. However, the principles and the cost-benefit analysis for a tracking system would be the same regardless of your size, in my opinion. One mistake, one harmed patient, and one lawsuit can cost millions of dollars."

The pathology community is very aware of the possibility of misidentification errors, he says. "And people are looking at new ways to avoid them whether they occur at the bedside, somewhere in the laboratory process, or in getting to pathology."

His laboratory looked at the number of mislabeled slides six months before starting bar coding and six months

afterward, “and we went to zero.” It didn’t happen initially because there was a certain amount of adjustment. “Someone may manually enter a bar code or bypass it, or they may damage the paraffin block and you can’t read the bar code, and those things happened at our institution during the transition period.” Now, however, people are comfortable with the system and the bypasses have ended.

The histology laboratory is a harsh environment, Dr. Pantanowitz says. “Because of the chemical solutions, the equipment, the tissues, blood, and everything else, all of that has to be taken into consideration when you are trying to position new technology in this environment where space may be limited.”

But there are also smaller details that can bog down the process. “Although when you’re dealing with a tracking solution you’re looking at the big picture, the overall work process, culture of people, and work environment, unfortunately you also have to pay attention to the tiniest of details of this whole solution. Deciding where bar codes will go on the labels and how big they should be, for example, can take a lot of time.”

His laboratory decided to make the bar code small enough so there would be no scanning problems but with enough space to include accession details such as the patient name. At the same time, he emphasizes, it’s important to ensure that the tracking solution you choose does not lock you in. “You need to be sure your bar codes will work with future instruments, digital imaging devices, molecular testing, and so on.”

Dr. Pantanowitz has evaluated wireless technology for tracking systems because some other labs are using it. “It’s great if your institution can support it. The good thing about it is you eliminate a lot of cables, and when scaling or customizing, wireless is much better from the point of view that it’s much more flexible. However, some labs have problems because they may not be able to provide strong connectivity, there have been a few problems or reservations about security issues, and not all vendors will provide you with devices that work with wireless.”

The extra hardware is a factor that AP labs need to take into account when considering whether to implement specimen tracking, Dr. Pantanowitz says. “But the No. 2 issue that is often not considered is people resources. You need a lot of IT personnel involved from your lab or institution and they need to have time to devote to the project. Individual jobs for folks in the lab may change. Even though bar coding may make the whole process more efficient, the individual person at the microtomy station will now have to scan everything one by one, where before they might have batched a bunch of things to save time.” But the advantages of having a tracking system will make these problems seem small, in his view. “It’s definitely worth doing.”

Like most AP laboratories, Dahl-Chase Diagnostic Services, a private independent lab in Bangor, Me., was hand-labeling its slides before it decided to adopt a tracking system, says Clare Thornton, HTL(ASCP), assistant histology supervisor. At one point in August 2010, the laboratory was counting 1.4 slide labeling defects per 1,000 slides. “When you do 180,000 slides a year—50,000 surgical cases—that’s actually quite a few. But after we implemented and brought up our tracking system two years ago, our slide labeling defects essentially went to zero.”

The system’s benefits go well beyond defect-free labeling, Thornton says—starting with accessioning. “There’s an exact date and time stamp for everybody who touched the specimen, so you can follow a specimen entirely through the lab and know where it is at any point in time, right up to the dictation file, and the system has an archival function, although we haven’t used it yet. You can also do things such as pinpoint where tissue contamination might have taken place.”

Ergonomics is another. “If you’re hand-writing a slide and you’ve got a microtome in front of you and a waterbath on the side, you have to twist a little to write on the slide,” Thornton says. “Being able to wave the slide under a scanner and print out a label sidesteps that problem.”

To set up the tracking system, Dahl-Chase needed to upgrade its LIS. “That takes a bit of time, and then we slowly launched each portion of the tracking, so we’d get histology set up, then grossing, then pathology. The whole process, start to finish, probably pushed about six months before everything was running as it should be.” The cost

was in the \$80,000 to \$100,000 range, she says, but a laboratory considering a tracking system needs to realize that price is just for the software.

"You have to keep in mind that with a lot of tracking systems you'll need to purchase the hardware—for example, the scanners, the laser printers, or the slide etchers, since some people prefer to etch information on the slide as opposed to labels. There are options and ways to keep costs down, but it can get expensive too." At Dahl-Chase, "we have nine microtomes set up, each with its own printer and scanner, we have two embedding stations with their own scanner, and four grossing scanners."

The two-dimensional bar code, which stores information vertically as well as horizontally, is generated at accessioning; then the specimen label, the requisition, and the cassettes are all bar-coded. "Each bar code gets checked along the way by a scan of the requisition and specimen file. And if they don't match, they'll get a big alarm." After going through grossing and processing, histology embedding, and sectioning at the microtome, the slide is scanned at slide distribution. Then the pathologist scans the slide at his or her microscope.

Locating misplaced slides has proved to be a useful function of tracking. "That was a definite added bonus," she says. Also, tracking does give the laboratory the ability to monitor staff productivity. "It's a little controversial and not something we do on a regular basis, but if there are major gaps in scans when somebody is supposed to be embedding and cutting most of their shift, that's a red flag that something else is going on, and people are aware that there's a little bit of a monitoring element," Thornton says.

There can be snags in any system, and human factors have caused a few problems in Thornton's laboratory. "You can have a tracking system in place, but if people don't follow your policies and procedures for using the system, it can basically become obsolete." This can happen, for example, if somebody decides to scan 20 blocks from different cases one after another and batch-print the labels. "In that case you can easily pick and apply the wrong label. So we always use a one block, one slide method."

Another frustration has been due to an integration issue. "Our immunohistochemistry equipment is fully automated, and we do a lot of IHC and special stains, printing our own labels with our own bar codes. But we haven't been able to get our IHC slides married into the tracking system, and that is because of the particular equipment we use to run our IHC slides. The tracking system won't allow us to duplicate the bar code for use on the IHC slides, and we're not willing to pay for an expensive interface when we know the problem can literally be fixed with a mouse click," Thornton says.

"So as of right now, all of our surgical staining is on tracking but our IHC slides and special stains slides are not being tracked." Unfortunately, she has found that this problem is fairly common in AP laboratories with tracking systems. "If it's really important that you track your IHC slides, that's something you need to check on beforehand when you're looking for a tracking system."

Tracking systems are designed to handle specimens once they arrive at the AP laboratory, but there's a big point of vulnerability before that: before accessioning, between the originating site and the laboratory, says Walter H. Henricks, MD, medical director of the Center for Pathology Informatics at the Cleveland Clinic. According to a 2009 CAP Q-Probes study, 20.9 percent of mislabeling errors occur pre-accessioning. "I think this is a gap that's often not addressed because it's not easy to address. And because pathologists often get specimens from disparate sources—hospitals, offices in the community, suburban clinics with couriers, and so on," Dr. Henricks says.

For the last couple of years, his laboratory has used a module from its LIS vendor to keep tabs on specimens in the pre-accessioning phase. Significantly, this does not include the operating room which is right down the hall from the pathology suite because, he says, it was harder to get buy-in for that. "The OR also really wasn't identified as a problem area as much as getting these specimens from more distant places. But we're a very high-volume lab, and we receive specimens from a variety of different areas. So we identified pre-accessioning tracking as a priority."

A key component to launching a tracking system is deciding on definitions and configurations up front, Dr. Henricks says. That includes what locations are going to be called, what are the specific specimen types, how will you define couriers, and most important, what you're going to use for a tracking ID, which is what uniquely identifies a specimen. The best tracking IDs are those that are somehow linked to other information about the patient or specimen, he notes. "As with any information system in the lab, the lab has choices, and you have to set up the data elements in ways that make sense. That's the linchpin of all this."

"Because we receive electronic orders for anatomic pathology from the electronic medical record, we can use it in conjunction with our LIS to track down specimens that we expected to receive but didn't. For example, when we have an order in our LIS but we never accessioned the specimen, from the tracking system we might find it was never marked as dropped off, so we'd better find that courier, or if it was never picked up, we'd better call the nurse or check in the procedure room."

Ultimately, the goal is to reduce lost specimens, he notes, and tracking also helps locate things and uncover problems in the workflow that need to be improved. "It's not perfect, but it certainly fills a gap and we continue to find other uses for it. It can help us identify bottlenecks by seeing what locations specimens are tracked to, or identify whether we should have more frequent pickups. And it increases the overall confidence level of the lab staff that there is a really solid system in place." After the system was implemented, the number of unreceived specimens from the AP LIS "pending log" that were subsequently and promptly located with help from the tracking system has ranged as high as 70 in a single month, and averages about four surgical pathology specimens a month and 33 cytopathology specimens.

There's a learning curve for people with a surface understanding of tracking as they adjust to using the technology, Dr. Henricks says. "I used to get annoyed when people would say 'FedEx tracks packages all over the world, so we should be able to do that with our specimens. How hard can it be?' Tracking does insert new, incremental steps into the process of moving specimens. So we got some complaints when we first implemented tracking that this is additional work to be done, an extra step, it takes too long, it slows the couriers down, and so on. But I would tell people, if you want to track specimens, you have to track the specimens. It's not magic; it doesn't happen by itself."

So it's not a question of whether pre-accessioning tracking is valuable; the Cleveland Clinic has found it prevents specimen loss and reduces investigation time. "But it's a real investment to implement one of these systems, and we learned a lot of lessons the hard way about really looking at what the implications for people's functions will be."

There's little doubt that radio frequency identification (RFID), which uses tags attached to objects to wirelessly transmit data via electromagnetic fields, could be a more efficient way to track specimens than bar coding. "You don't need line of sight to detect them," Dr. Sinard says. "If you had a box that was filled with, say, 30 blocks, you could stick the box next to the scanner and it would automatically log all 30 blocks without your having to scan them. You wouldn't even have to open the box. So that's an incredible power beyond the line of sight requirement of a bar-code reader."

Also unlike bar codes, which can hold limited data, RFID tags can carry almost unlimited data, the data are scalable, and it can be updated. So tags have a lot of promise as a tracking technology, Dr. Pantanowitz believes. "Some laboratories have been testing them in clinical pathology and transfusion medicine, and RFID has been working very well to track forensic evidence pieces," he says.

Odin Technologies offers a commercial RFID solution for AP labs called EasySpecimen, which was implemented at Mayo Laboratories starting in 2007 across Mayo's 42 GI/colorectal endoscopy suites and its anatomic pathology laboratory. According to Odin, in a lab that tests about 100,000 specimens per year, the RFID technology has realized cost savings of \$1 million annually from reducing paperwork, and more than \$1 million annually from reducing the number of mislabeled specimens. The company believes that the investment in RFID can be earned

back by such savings in less than 12 months in a typical lab.

However, RFID tags are costly and the technology still has limited application. “It doesn’t work throughout the entire AP lab. It’s pretty much just the preanalytical phase. Once you get into the laboratory there aren’t any RFID solutions,” Dr. Pantanowitz says. In addition, since AP laboratories are already about a decade behind clinical pathology labs in implementing bar coding, “I think we have a ways to go before RFID is commonplace.”

Dr. Henricks believes there may be a shorter time frame before RFID takes hold, although he says it will still be at least a few years. The problem now is the high cost, usually a dollar or more per tag, compared with the cost of bar coding, a fraction of a cent apiece. “The last time I looked,” he says, “the price of RFID was a non-starter. You can ask, how could you put a price on patient identification? But the fact is we all have limited resources, and you have to prioritize. So first and foremost, the price has to fall. And second, the software that supports RFID has to be integrated into our systems somehow. The software that recognizes RFID is generally a little more complicated than bar-code software.”

But whether or not RFID pushes bar coding aside, AP laboratories that have implemented tracking systems maintain that tracking is a technology whose time has definitely arrived. At a recent presentation before histology lab personnel, Thornton asked the audience how many are using tracking. “And there was really just a handful—three or four. Right now, it’s new, up-and-coming technology. But I think it’s something that maybe 10 years from now will be fairly standard in most AP labs, especially as people are pushing to standardize how things are done in pathology, and for safety reasons.”

For her lab, a tracking system has been the right choice. “I would say our experience has been nothing but positive. On the very rare occasion that it might go down, we’re all kind of at a loss. So it has become pretty much invaluable to us.”

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Anne Paxton is a writer in Seattle.