Labs solve price, space squeeze to welcome TLA

Kevin B. O'Reilly

May 2015—After several years of watching their European counterparts have all the fun, a handful of American microbiology laboratories are going live with systems touted as providing total automation of diagnostic bacteriology. The systems automate how specimens are barcoded, plated, and inoculated, then move the plates on a track to an incubator, photograph them at a preset incubation time, discard or keep the plates as appropriate, and offer up the digital images for interpretation by medical technologists viewing them on computer screens.

Leaders at American microbiology labs making the move to total automation say it marks a profound transition that dramatically improves turnaround times but also can be wrenching, hindered by technical and management challenges that come with adopting state-of-the-art technology.

For other laboratories, the journey toward total automation is progressing more fitfully, and may begin with adoption of standalone automated specimen processors. Even as microbiology labs argue the case that automation can offer a return on investment for their institutions, they must first solve a more basic problem: how to make the new equipment fit into their workspaces and workflows.

Finding, or creating, adequate space in the microbiology lab to accommodate a total automation system is one of the perplexing elements of adopting an instrument such as the BD Kiestra TLA installed at NorthShore University HealthSystem in Evanston, Ill.

"I never thought microbiology could be this automated. It's amazing," says Irene K. Dusich, MT(ASCP)SM, microbiology manager at NorthShore University HealthSystem in Chicago's northern suburbs. "Our positive cultures are turned around much quicker because we're able to read them when they are ready to be read. We've got the images there at 12 hours and things that are floridly positive—you know it."

The four-hospital system's laboratory performs about 300,000 microbiology tests annually, and in July 2014 brought in BD's Kiestra TLA. After several months of setup, the system went live in December. Dusich tells CAP TODAY it's already making an impact.

"Before, people would come in and there would be the shelf in the incubator with all the urine cultures, and they would bring out all 300. Now, they are sitting in the incubator until it's time to actually read it. It's not sitting out in room temperature in the ambient air," she says.

“There’s a lot to be said for reading a plate when it’s ready to be read, rather than when it’s too early. In the proper atmosphere, colonies will be more robust, and you will be able to distinguish whether it is well isolated enough to do tests on,” Dusich adds. “The whole process is much improved, because of the Kiestra and because of MALDI.” NorthShore acquired the Bruker MALDI Biotyper in December 2013.

Data collection and analysis regarding the impact of the Kiestra TLA implementation on NorthShore’s turnaround times and patient care is still ongoing, Dusich says. Anecdotally, however, the outcomes are clear.

“We’re definitely getting positive results out much faster, maybe even a day faster,” she says. “Before, when sometimes things weren’t dropped off till midnight or 1 AM, we wouldn’t look at them today; we would look at them tomorrow. Now on Kiestra, if it’s set up at midnight last night, we’re looking at them at noon today. Because it’s taking the images at 12 hours, if the growth looks good enough, then we’re going ahead and doing the identification and the susceptibility testing today instead of tomorrow.”
The BD Kiestra TLA’s automated specimen processor, InoqulA, offers another big advantage by reducing the proportion of specimens that require subculturing. Because the machine performs the streaking the same each time—as customized by the laboratory—the human element of variation is lost, Dusich says.

“Some people are just good at [streaking], and some people are not,” she says. “What this has done for us, with its consistency and the way we get well-isolated colonies, is that we do very, very few subcultures anymore to gain a pure isolate to do identification or susceptibility testing.”

Poor streaking that necessitates subculturing means “more work and more media,” Dusich notes. “And it’s going to delay turnaround time and results. We have really seen a drastic decrease in the number of subcultures that we do.”

For Susan Kannady, BSMT(ASCP) SM, the promise of predictable streaking would be one of the big bonuses of bringing more automation into the microbiology and immunology laboratory she manages at Virginia Commonwealth University Health System.

“The greatest savings would be with the specimen processor,” Kannady says. “We’d have the instrument streaking all the plates and each plate would be uniform. It would be consistent, and you would get better isolation and you would improve workflow on the other end. Right now, you’ve got humans doing it on three different shifts. You have three different people, and not everybody streaks the same.”

Laboratory professionals report that the TLA systems available from BD, Copan Diagnostics, or BioMérieux cost $1.2 million or more depending on the number of incubators and workstations customers choose, as well as the capabilities of the conveyor system they opt for. Automated specimen processors, on the other hand, cost between $125,000 and $300,000 (Ledeboer NA, et al. J Clin Microbiol. 2014;52[9]:3140–3146).

That cost differential makes the hands-off specimen processor a more palatable first bite at the total automation apple, even for a high-volume lab like Kannady’s that performs 365,000 tests each year with the equivalent of 41 full-time staff.

“Total laboratory automation—we would love to have it,” she told the crowd at the American Society for Microbiology’s 2014 annual meeting during a presentation called “Squeezing Automation into the Laboratory.” TLA would help with a staffing shortage the laboratory has been struggling with and save a great deal of time for technologists who would no longer have to read negative cultures. But, she concluded, “We just don’t have the space.”

It is not just the cost of the equipment that makes moving to a TLA system such a pricey proposition. All the systems available require a major footprint and an open plan. A TLA system certainly changes the look and the layout of the laboratory. It’s goodbye to rows of workbenches and hello to a conveyor system straight out of a factory assembly line. And VCU’s microbiology laboratory has not been redesigned since the mid-1980s.

“We didn’t realize it,” Kannady said, “but just the cost for the architect ranged from $300,000 to $600,000, and that’s before you even begin renovating.”

For now, any renovation of Kannady’s laboratory is on hold pending a broader review of the entire pathology department’s workspaces.

“The question is whether to renovate where we’re standing or find somewhere else,” Kannady says. “In the meantime, we’re going to push to get the automated specimen inoculator part.” That would be either the BD Kiestra InoqulA or Copan’s Walk-Away Specimen Processor.

Despite the hurdles Kannady and her microbiology colleagues at VCU face in moving toward automation, they do have a head start on some others in one area that is essential to taking full advantage of automation. They have moved to a total liquid collection system.

“We’re ready as far as specimen collection goes,” Kannady says.

This is key because the TLA systems only work with liquid-based microbiology samples. This requires a different method of collecting throat, wound, stool, genital, and other samples using flocked swabs that release the entirety of the sample when it is mixed with reagents or placed in a buffer solution.

The switch to the flocked-swab method of specimen collection is one element that has delayed complete implementation of TLA in NorthShore’s microbiology laboratory. For now, they are using the BD Kiestra TLA for urine specimens only. They must verify the new swabs and train clinicians on how to use them properly.

NorthShore University HealthSystem pathology chair Karen Kaul, MD, PhD, and others championed the investment in total laboratory automation. NorthShore expects to achieve its ROI principally through a reduction in FTE staff.

“We have four hospitals with various nursing units. This is a huge outreach effort,” Dusich says. She expects NorthShore will be working with all liquid-based samples by the end of 2015, “hopefully by fall.”

Finding the space to accommodate the BD Kiestra TLA at NorthShore was a hurdle to overcome, but use of modular workbenches has helped greatly, Dusich says. She recalls a period during the transition when her office

was outside the microbiology laboratory. Dusich counted 200 steps from her office to the laboratory each time she needed to visit during her workday.

There have been other complications in the move to automation, Dusich says. Some members of the staff did not take well to the change, for example.

“Sometimes it’s hard for people, for microbiologists who have worked on the bench for 30-plus years, to do something like this,” she says. “That would be another [challenge] is getting acceptance. I had someone retire in December and she just said, ‘This isn’t microbiology.’ She didn’t want to do it.”

In addition to the people problems came IT issues. After going live with the system in December 2014, there were days when the TLA would lose the connection to servers that it needed to operate.

“We’d be down for hours,” Dusich says. “There were times we were down the entire pm shift.” Eventually, the issue was resolved. Setting up the interface to the Soft Computer laboratory information system also posed problems.

“Thank goodness we have such a great LIS person here working very hard with us to get us interfaced as we are right now, and to help us troubleshoot these problems. It really is a group effort, and BD has put their full support behind us in making this a successful implementation,” she says.

To start, the biggest hiccup came from the InoqulA specimen processor. With plates that had higher sugar content, MacConkey plates in particular, the lids would get stuck.

“We had a lot of plate crashes and smashes until some genius at BD figured this out,” Dusich says. “It was terrible. This machine would be beeping all the time. You’d try to run a rack of 10 and you might end up in trouble with eight out of 10 because of the MacConkey plates, and we wasted a lot of media and time.”

BD installed plate clamps to fix the problem in early 2015, “and everything’s been going much better.” Such problems are to be expected, Dusich says. As one of the first microbiology labs to adopt TLA in the U.S., “we’re basically kind of guinea pigs.”

“Although things haven’t been perfect, I’m very happy with the way things are progressing. I like the system. I think it’s going to do everything they promised it’s going to do,” she says.

One promise yet to be realized is a return on investment, which NorthShore expects to achieve within three years principally through a reduction in FTE staff. The lab has cut several full-time positions through attrition, but hasn’t yet seen a big drop in overall worked hours because it is using part-time and resource staff to help fill in until the TLA implementation is complete.

The support of pathology chair Karen L. Kaul, MD, PhD, and others was critical to gaining approval for the BD Kiestra TLA purchase, Dusich says.

“It was a collaborative effort of the chairman and the finance people going to upper administration and saying, ‘This is going to put NorthShore on the map,’” she adds. As for the return on investment, “we’ve had some bumps in the road and we’re getting past it. We will get there; it will just take a bit more time.”

At Dynacare Laboratories, which is a joint venture of Milwaukee’s Froedtert Hospital and Laboratory Corp. of America, approval for the purchase of Copan’s TLA, the WASP-Lab, “was a bit of a challenge,” says clinical microbiology and molecular diagnostics medical director Nathan A. Ledeboer, PhD, D(ABMM). Dr. Ledeboer’s lab performs about 1 million tests a year, and has about 60 FTE staff.

“We went through a number of revisions with our board, with them wanting us to pare it down to show exactly how we were going to justify it,” Dr. Ledeboer says. “We came in at ROI of about two years.”

That will be achieved in large part through retasking staff to molecular diagnostics and transitioning positions to off shifts, which have happened already, and research agreements.

Dynacare adopted the Copan specimen processor in 2012, so Dr. Ledeboer and his colleagues were asking for less money to round out their TLA system. Also, they opted for a less expensive version of the WASPLab by giving up some of the future instrument capacity, says Dr. Ledeboer, an associate professor of pathology at the Medical College of Wisconsin.

From left: Irene Dusich and microbiology laboratory staffers Emmylou Dela Cruz, Becky Lindgren, Steve Diederich, Ivy Villa, and April Victor formed the key user group that helped NorthShore University HealthSystem go live with the BD Kiestra TLA system late last year.

“The length of the track that you want will affect your cost. In our case, we chose a hub-type model where the instrument will read all the plates and kick the plates out into silos based on what the tech needs to do with it,” he says. “The alternative choice is to have plates delivered via track to the bench and that adds a significant level of costs.”

The extra automation afforded by conveying the plates directly to the technologists’ workstation also makes reconfiguring the laboratory in the future more of a headache, Dr. Ledeboer says.

“Our track brings the plate to the hub, and techs pick it up there.”

Dynacare went live with its TLA system in November 2014 and, like NorthShore, is handling only urine specimens because of the work needed to switch to liquid-based collection for other specimen types using Copan’s ESwab.

“We wanted to do fairly extensive verifications when we switch to the ESwab. And when we make the transition, I don’t want to have to ask our clinicians to deal with one more swab type. So the challenge we’ve faced is verifying all our molecular assays so they could accept ESwab as well. That’s been an extensive process we’ve had to go through. We’re going to continue phasing it in for the next year or so. In large part, right now we are continuing with our ESwab verifications. It’s been the part that slowed us down the most.”

But the biggest challenge in the TLA adoption, Dr. Ledeboer says, has been the interface to the LIS, Cerner Millennium.

“Cerner was a great partner, as was Copan in the process,” he says. “But it’s such a dramatic change, and since we were among the first, that complicated the challenge a little bit.”

Dr. Ledeboer, at this article’s deadline, planned to present preliminary research on Dynacare’s experience with TLA

at the ASM meeting in New Orleans, May 30–June 2. This research has involved comparing performance of manual reads with performance using the WASPLab-generated digital images.

“We found that our techs were overcalling prospective enterococci when, in fact, the organisms were coag-negative staph,” Dr. Ledeboer says. “These colonies may look slightly different on a screen versus a manual plate.” Also, there were four cultures called as contaminated on manual read but when viewed digitally showed a significant number of pathogens, and procedures would require further workup.

Dynacare has seen a 14- to 18-hour cut in time to final results on its urine cultures. While the automation itself was necessary to achieve that sort of improvement in turnaround time, Dr. Ledeboer cautions that it was not sufficient.

“One of the key components to all of this is changing the workflow in your laboratory. The boxes are good, but if you look at the studies out of Europe they basically show that the boxes by themselves don’t have a significant impact on your workflow, turnaround time, or efficiency,” he says. “This is about changing the way your lab does its work, changing the times when you read your plates combined with the boxes, that ultimately leads to benefits in turnaround time and making your laboratory more efficient.”

Dynacare’s microbiologists, for example, were reading plates 20 hours a day before implementing WASPLab. Today, thanks to the system and attendant workflow changes, they are reading plates 24 hours a day.

The changes, he says, have been “all encompassing.”

“We started looking at it from the time the specimen hit the lab,” he says. “We looked at where our benches would be, their proximity to the incubators where techs picked the plates up. We looked at how do we staff our lab and when do we want people to come in.”

“The automation system has allowed us, basically, to more efficiently staff our laboratory,” he says.
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