Look, wait, buy: labs share instrument plans

Anne Paxton

July 2018—"Robbie," the autonomous service robot that transfers specimens for Florida Hospital's central laboratory, may not quite be ready for his gold watch. But after five years of faithful service delivering samples between the different esoteric testing units, he's nearing the end of his natural lifespan with signs of wear. "He hits the walls every once in a while," says Julie Hess, executive director of Florida Hospital's Central Florida Division of Laboratory Services, Orlando. The lab's use of robots like Robbie may double soon; two robots are on the laboratory's draft new equipment plan.

That's just one example of how Florida Hospital's laboratory, which already performs more than 10 million billable tests per year for its 10 laboratory locations in central Florida, is planning to accommodate its steady increase in test volume, about three to five percent year over year, with newer models of equipment and instrumentation. Central Florida is experiencing a population boom, Hess notes. The laboratory managers at Florida Hospital report that both growth and technological advances are driving the kinds of instrument purchases they are contemplating and the timeline for those purchases.

That trend is not universal, however. At Minnesota-based Allina Health Laboratory, interviewed by CAP TODAY a year ago about its instrument purchasing plans, some add-ons and instrument refreshes are planned. But other acquisitions are on hold as the laboratory analyzes how vendor offerings fit with Allina Health System's changing needs.

Florida Hospital's major acquisitions this year include replacing all of the system's aging chemistry equipment with newer models from the same vendor (Roche)—that instrument update is halfway completed—and the laboratory expects to do the same with hematology systems from Sysmex. Florida Hospital is unusual in that its centralized laboratory supporting outpatient testing is within the hospital. "We want to capitalize on test utilization," Hess says, "making sure we're not doing unnecessary testing, especially for our inpatient population. But we also continue to grow well in our outreach area. That pattern ensures a viable balance of tests through utilization and continued outreach growth."

In the future, Hess sees instrument purchases as having to also adapt to Florida Hospital's pattern of building micro-hospitals or freestanding emergency departments, which currently total two. "We've had to purchase new equipment to outfit those laboratories. There's been an interesting change in the hospital model—what I like to think of as a 'tiny-house' movement of hospitals. They want a full-service laboratory in a very small space. It's been challenging to make sure we can have a full breadth of test menu for an ER setting that may potentially have overnight patients. In addition, we would like those instruments to be consistent with what we already have in our larger lab facilities."

Molecular diagnostics has been on the increase, particularly in oncology and infectious disease testing, and Hess expects continued expansion. The laboratory has Verigene (Luminex) analyzers that perform blood culture bacterial identification by molecular testing, and recently added the Enteric Pathogens panel. A respiratory panel is performed on the BioFire FilmArray. "The technology and test panels supporting oncology are changing rapidly, so requests will be made to upgrade existing equipment," Hess says. Looking ahead, the laboratory is considering new sequencing platforms for its HLA typing, instruments to support pharmacogenetics, and, probably a few years down the road, instruments to sequence organisms for microbiology.

The budget for new instruments is adequate in some ways, inadequate in others, Hess finds. "As new locations are being built, we are given a capital budget to buy the equipment, so with hospital expansion we can get laboratory equipment. It's in our established hospitals, when we need to update and refresh both the equipment and the facility, that it's been a challenge to get capital dollars approved. We have to focus our capital requests on improved patient outcomes. As long as we can connect a request to improving the length of stay or driving overall cost of care or more excellent patient care, possibly through increased sensitivity with new test methodology, that

helps move those purchases forward."

Hess cites one molecular microbiology test that was brought in-house, allowing the laboratory to provide antibiotic resistance or susceptibility results within an hour. "We calculated about $350,000 in savings per year for the pharmacy by our spending about $40,000 in lab to add CRE testing on the Cepheid Infinity." And that impressive return on investment convinced hospital administrators to sign on to the purchase.

Sepsis continues to be a "pain point" for her laboratory. "We are looking closely at how we're managing infectious disease and considering automating microbiology with the BD Kiestra. The potential to reduce the turnaround time of cultures could translate into a different model of care for our patients and our management of antibiotic usage. But that would be a multimillion dollar spend for us."

The overarching issue for the laboratory is a shortage of space. "Every change we need to make, we continue to have to consider our space constraints. Especially as we are in a legacy institution here. The walls around us really can hold us back." Just to be able to get the replacement chemistry and hematology instruments in, "we had to go through a major construction remodel. And not just at our main laboratory, but all of our satellite hospitals as well." In looking at microbiology automation, for example, "We've been working with architects to see how we can gut what we have and remodel it completely so that we can fit equipment in and improve the workflow. All of this is happening with limited or no interruption to lab services."

Hess is not worried about the impact of the reorganization of the diagnostics industry signaled by, for example, Danaher's acquisition of Cepheid.

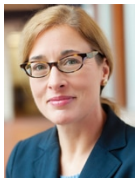
"Overall, I would say, regarding those mergers, we're looking at what the particular product offers us and our patients. If it meets our needs with one owner, then it would probably meet our needs with another owner, unless we hear rumors of their discontinuing an instrument line because it duplicates something they already offer." Florida Hospital has some of the Nanosphere platforms, so there were questions when Luminex acquired Nanosphere. "But we were reassured they weren't touching the platform we had or changing their timeline on development."

Improving data analytics, now performed on a homegrown system, is another priority for this year. "We are requesting capital for a lab analytics system that will overlay with our LIS." Hess doesn't expect a change in the Sunquest LIS anytime soon, "but getting access to our own data so we can tell a strong story of need or improvement may help us acquire needed equipment capital in the future."

Information technology is another pain point, Hess says. "Connecting lab and IT to get IT-related projects approved has been a significant challenge the last few years." The laboratory and IT must work together to ensure data security before moving forward with any acquisition. "We want to avoid data breaches and the risk of ransomware that could cripple normal operations. So now selecting the best equipment is only the first step, but ensuring data security may be one of the most important steps." In one case, equipment the hospital had acquired already could not be interfaced for more than a year because the vendor did not meet security standards.

Competition from the other large hospital system in her region does sometimes influence the hospital's business model. "They keep us sharp and on our toes," Hess says. But instrument acquisition is more likely to be affected by Adventist Health System, Florida Hospital's parent organization. "If there is significant buying leverage that we can utilize, then we want to go with something that's better for the overall organization."

After a year of evaluation, the Allina Health Laboratory has dialed back to more of an exploratory, wait-and-see mode. "I think we're still in the hunt," says Lauren Anthony, MD, system medical director of the laboratory.



Dr. Anthony

Allina has found it difficult to get a fix on what current automation capabilities there are, says Larry R. Rothstein, MT(ASCP), chemistry and immunology technical specialist. “We’re looking at whether you can actually put multiple vendors’ instruments on an automation line without competing with an instrument that is already operating.” And the laboratory has seen incompatibilities. “Everyone says they can put their instruments on a line, but we haven’t seen anything up and running yet. The vendors would rather talk about what is coming down the pike,” Rothstein says. So that purchase is on hold. “We’re still exploring where we’re going in the next couple of years.”

Microbiology is taking a similar approach. “We’re still examining opportunities for automation,” says Mary Colson-Burns, MLS(ASCP), Allina microbiology technical specialist. “There’s a desire to add to our lab because volume dictates we can handle it, but with all the expected capital constraints everyone is experiencing, we’re having difficulty getting it funded.”

Another obstacle is that return on investment is difficult to calculate, she adds, because of the focus on the lab side. “There are downstream impacts on the patient side, but some of them are exceedingly difficult to quantify. We certainly receive a lot of added benefits from a quality perspective, but the cost is pretty enormous. Financially committing to improved patient care impacts that somebody else is going to be responsible for measuring and reporting on is complicated.”

With other instrument lines in the laboratory, the choices are a little clearer. Dr. Anthony points to viscoelastic coagulation testing as an example: “There’s an ongoing need for fast intraoperative coagulation testing, and viscoelastic testing can be helpful.” The two key vendors are Haemonetics, which makes TEG, and Instrumentation Laboratory, which now owns ROTEM, the instrument her laboratory uses. “Viscoelastic testing uses whole blood and monitors clotting in real time, so it’s potentially the best method, and it’s advocated as a way to target transfusion therapy because it shows all the different aspects of clotting. And based on the parameters, it can guide you to transfuse certain products instead of others.”

Despite these benefits, she finds that viscoelastic testing is vastly underused by laboratories similar to Allina’s. “For example, if someone in the OR wants a fast partial thromboplastin time, that requires spinning the specimen, separating the plasma, then running the test. With viscoelastic testing, on the other hand, you put it right on the instrument and monitor the clot and get information.” The low utilization of viscoelastic testing, in her view, is due to the manufacturers’ choice to issue a graph tracing instead of the numerical parameters of the test results, which physicians prefer based on their experience interpreting prothrombin times and partial thromboplastin times. “We’d like the vendors to adjust their reporting to be more numerical than graphical. We’re looking to change platforms, if necessary, to get the results and reports that are going to be most useful to our physicians.”

One of the newest tests Allina has brought in is the Verigene Enteric Pathogens molecular panel, which has greatly boosted diagnostic capability. “The big change is not just turnaround time,” Dr. Anthony says, “but also the fact that the two most common things we’re finding with the panel are pathogens we didn’t have a useful test for in the past: rotavirus and norovirus. Before, those had to be diagnosed based on clinical symptoms and negative culture results. But now physicians are getting definitive diagnoses of viral gastroenteritis from the tests, and the implementation of the stool culture panel has had a seamless transition that everyone is happy with.”

The laboratory would like to see the same transition in a conversion to molecular streptococcus testing. “We use rapid strep testing and that has advantages for patients, especially children, that we don’t want to lose. We do backup culture for negative results, which detects additional cases of strep, and that’s important.” But since the laboratory now does 80,000 strep tests a year, “The molecular instrumentation is not yet at the scale we would

want to make a full conversion. The instruments currently available can't handle the volume we would need them to. So we're planning on converting as soon as possible," Dr. Anthony says.

More progress is being made on next-generation sequencing, which is currently send-out testing for Allina. "We've had an interest in NGS for many years," says John R. Mendiola, PhD, molecular diagnostics technical director with Allina. "But every time we've looked, we've decided that that particular platform was not right for our lab at the time, and in most cases was not even close. Right now, however, we're looking seriously, we've talked with vendors, and we have a business case we're presenting. And maybe now is the right time. The emerging clinical utility of many of these markers is becoming more obvious, and we like the automation that has come to the market in the last year or two." Reproducibility and hands-on time are less of a challenge than they were in previous iterations, he says. In addition, "The proliferation of genetic tests that we've been having to send out has driven us to think about more panels versus testing one gene at a time."

The cost of capital for instrumentation has come down, Dr. Mendiola notes. "It's still challenging, but less so. In the last few years, the manufacturers have made it much more reasonable to bring NGS in-house than previously. And some of the instruments are now more scaled to a medium-sized lab, so capital is not as difficult an obstacle to surmount. Since we're looking at about eight tests a week, we think the scalability of the new platforms makes it reasonable to think about bringing the tests in-house."

Dr. Mendiola

There has been a lot of excitement about using NGS for leukemias and solid tumors, he points out. "But to keep our heads from exploding with the complexity, we have focused our initial launch on lung and colon cancer," on the premise that the panel would be broad enough that the laboratory could quickly adapt the test to different clinical scenarios without having to revalidate. Validation, he notes, will be time-consuming and expensive and has been one of the big hurdles all along. Still, pending approval of the laboratory's business case and negotiations with vendors, he and others in the laboratory hope NGS might be brought in by the end of the year.

While most of the laboratory's molecular testing is set up with capital leases or reagent rentals, the NGS purchase will likely be a capital acquisition, though that arrangement hasn't been finalized. "We have also been talking to our hospital foundations about some philanthropic support," Dr. Mendiola notes. There is precedent for that, because about 12 years ago, a local cancer foundation paid half the cost of installing the capillary electrophoresis that the laboratory uses for sequencing. If philanthropic support is forthcoming for NGS, he adds, it can help ease the burden of showing a return on investment.

In contemplating Allina's next instrumentation in hematology, Diane Hutchinson, MLS(ASCP), says she is in an information-gathering stage, nowhere near ready for a request for proposals. The Sysmex system Allina uses today is a platform that comes in many different models, which can accommodate clinic and hospital needs, and new models have varying functionality. "To me, that's very appealing as I look at our sites and different patient populations and try to decide what is appropriate for their spaces."

Beckman Coulter is coming out with a new instrument menu of different-sized models that would also be able to be incorporated at various sites, and Hutchinson plans to look at Abbott's offerings as well. "There is always new technology that the vendors are trying to present to us. Some work and some don't. We just take what works the best for us." A single vendor makes more financial sense, Hutchinson believes. "But I'm never going to say we're not going to use more than one vendor because it's more work for me," she says. "We need to keep all options on the table."

One information technology feature that Hutchinson is seeking is digital solutions to hematology competency. “We have literally hundreds of hematology users, and personnel competency is a challenge that every system must face with each inspection that comes around.”

Hutchinson

Other new IT figures in Allina’s plans as well, as decision support and data analytics are becoming increasingly important in controlling test use, Dr. Anthony says. They are evaluating the CareSelect platform from National Decision Support Company, she says, which has partnered with Mayo Clinic to provide decision support for laboratory orders. “They can interface to our Epic system and provide a package of algorithms and decision support tools you can adapt to your ordering.” Data analytics firm Health Catalyst, in Salt Lake City, already has a charter partnership with Allina. “We have interactive dashboards to monitor and improve blood utilization, test utilization, and lab performance metrics.”

In the molecular arena, Allina has found Epic Beaker provides useful productivity tools, Dr. Mendiola says. “They’ve brought us real leverage and we’re trying to do the same thing with cytogenetics. We’ve had a homegrown workflow and reporting system for a number of years using FileMaker Pro, and we’re in the process of trying to get that into Beaker, but the workflows and reporting are complicated and it’s stretching the functionality of Beaker to get cytogenetics into that. We’ve been working with Epic on cytogenetics to help inform their future development to make it more compatible with those types of esoteric testing with complex workflows.”

If there is a pain point in chemistry from Rothstein’s standpoint, it would probably be ensuring reliability and how well the vendors are responding to the need for reliability. “There have been a lot of advances in automating chemistry instruments, but also a lot of advances in the instrumentation. The vendors are investing a lot in using camera technology to have more reliable sampling and results.” He likes to see advances that ensure reliability, not just produce faster results. “We’re not in the business of selling lab results. We’re in the business of providing that information to physicians, and we need to make sure we’re working well with physicians, rather than bringing in something just because it’s new.”

Other pain points involve other testing the laboratory does not currently provide, Dr. Anthony says. Due to the opioid epidemic, drug screening volume has more than doubled since 2015 with the development of new addiction medicine and pain centers to treat people. “That area of our organization is growing because we want to provide those services for patients. We don’t perform the definitive mass spectrometry drug screening here, but rather than build a new toxicology laboratory, we partnered with nearby Hennepin County Medical Center to perform our drug screens. This type of ‘make or buy’ decision has become crucial when we look at highly specialized testing.”

Developments like these, Dr. Anthony believes, will be important factors as the laboratory decides what equipment will best meet the diagnostic challenges ahead.

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