Volume, value, technology steering 2017 instrument buys

Anne Paxton

July 2017—For at least some laboratories, economic conditions and capital flows are calling for a cautious approach to purchasing new laboratory instruments. As one analyst of the clinical laboratory services industry was heard to say recently: “Because of tight capital, nobody is buying anything unless it breaks.” But laboratory executives and medical directors at some of the nation’s largest health systems in the Northeast, West, and Midwest take a different view. Outlining their systems’ plans to broaden test menus with new instruments, embrace more automation, and delve into data analytics over the next several months, these executives reveal some of the dilemmas and tradeoffs that are arising along the way.

The common theme is deciding what kinds of instrument acquisitions are the best response to growth. At Sutter Shared Laboratory, which provides reference testing for Sutter Health in the Northern California and San Francisco Bay area, a growth rate of 10 percent each year has resulted from the increasing number of physicians—now more than 5,000—who belong to the system’s five foundations. The core lab is considered a mid-level esoteric reference lab, says Jennifer Schiffgens, MBA, MT(ASCP), vice president of operations, who advises on purchasing for laboratories for the whole system. “We still perform chemistry and hematology for our foundations, but our focus is the esoteric testing.”

Schiffgens was brought in two years ago from her former job as regional director of Sutter’s West Bay laboratories to grow the core laboratory. Expanding the core lab’s test menu with new technologies has been her recent focus, with the system budgeting $1.5 million for such purchases this year.

“For example, we just brought in Euroimmun to do automated ANA testing. We perform all the QuantiFeron testing for tuberculosis here, and we’ve expanded our menu to perform both basic vitamin D and specialty vitamin D. We’re bringing in the Binding Site Optilite for light chains testing. We’re in the process of negotiating for capillary electrophoresis from Sebia to replace our electrophoresis system, and we’re bringing in a Tecan Diagnostics aliquoter.”

Meanwhile, as testing becomes more moderately complex or easier, or for things where a more rapid turnaround time is needed, some of the core lab’s molecular testing—for influenza, *C. difficile*, and rapid ID for blood cultures—is being shifted back to the hospital labs. For those tests, “we need faster turnaround time, and the technology has developed to the point where they’re easily done in a hospital setting.”

The lab’s core team, of which Schiffgens is the past chair, has already set the core instrument lines for all of Sutter’s affiliates and the core laboratory. Among those lines are the Siemens platforms for chemistry for the past 10 years, including Vistas, Centaurs, and Immulites; Sysmex for hematology; and Stago instruments for coagulation. “What we’re doing now is looking at rightsizing our hospital labs and core lab to assess if there’s an opportunity to reduce costs through consolidation.”

Schiffgens expects the core lab testing, running now at about 4 million per year, to jump to 6 million by the end of 2018. “We will be buying some instruments. In fact, we’ve now reached a point where the volume in the core lab will support a new automated line from Siemens called Aptio, now that we are doing more basic chemistry, and we can put the Centaurs and the Immulites on that line.”

The core laboratory does not yet have automation in hematology, but is looking at upgrading to the Sysmex XN-9000 system, which will include three XNs plus the SP-10 slidemaker/stainer module. “We have the capital dollars for that, and it’s part of our project. We’ll go live with it in 2018,” Schiffgens says.

The testing niche that is a “pain point” at Sutter is sepsis, she says. “Sepsis is a huge issue. Trying to figure out quickly what may be going on with the patient if sepsis is suspected, to get an answer on what kind of organism the patient may have in order to tailor the treatments more quickly—that’s the holy grail right now.” To address sepsis, the laboratory is considering BioFire, Luminex Nanosphere, and MALDI-TOF solutions. “We have the MALDI and Nanosphere at the core lab and I’m looking at T2 Biosystems. They’re not FDA-approved for everything we need, but if they get that approval, we will take a serious look.”

In June, Sutter already went live with a new 8,000-square-foot microbiology lab and installed Copan WASPLab. “We do a huge amount of micro testing, almost 600,000 specimen accessions a year,” she says, “so the WASP was actually a quick decision. There are not enough microbiologists out there to do the work; it would take 12 more FTEs to do it manually. So the payoff of the WASPLab was a slam dunk.”

“We were actually given the capital pretty quickly to go ahead and implement it because we’re bringing in volume across the entire system for microbiology.”

Schiffgens

She points to the consolidation of microbiology across the system as the factor making the volume growth possible. “We’re hopeful that we’ll have full consolidation by the end of 2019,” Schiffgens says. In the process, the affiliates’ instruments may get transferred to the core lab. “If it’s newer, we’ll take it. If it’s at the end of its life, we won’t replace it.”
The laboratory does not do capital leases of instruments, but does instrument placements instead. “We negotiate rates that sometimes allow us to get the instrumentation without utilizing capital,” Schiffgens explains. For example, “We’ve purchased the Sysmex Clinitek AUWi urinalysis instruments, the Euroimmun, the Optilites, and the Tecan. We’ll be doing instrument placements for the Sebia and the front-end automation.”

She is also turning her attention to IT. “We are outgrowing our middleware system, so we’re looking at vendors to see what solutions are out there.” The middleware is exclusive to the central lab; Sutter’s affiliates use Sunquest rather than middleware. “But for the central lab, there’s a need for instrument management and result management that is different than at the affiliates.”

Data analytics have helped her lab determine test utilization and see where changes are called for, whether due to overuse or underuse. “Myoglobin, for example, is one that is overutilized.” Thyroid testing is another area where the lab is recommending ordering a basic TSH first, then deciding whether to reflex to the rest of the panel.

Taking data analytics to the hospital administration to affect purchasing of laboratory instruments is not feasible yet, Schiffgens says. “That’s one of the things we’re working on. We’re talking with HC1, as well as Quest, which has a new product for the tests you refer to them to assist with utilization. So we’re in discussions with various vendors on how we can get that data. We know there’s a true need.”

Rapid molecular diagnostics are the hottest topic in instrument acquisitions these days, says John Waugh, vice president of Henry Ford Health System Pathology and Laboratory Medicine in Detroit. “Microbiology has been so manual for so many years, and rapid diagnosis and targeted treatment are extremely important for us. A lot of my colleagues would say the same.” Next in importance, he says, are next-generation sequencing and other molecular diagnostics.

Waugh

Henry Ford decided to make an investment in rapid flu testing after the FDA reclassified as CLIA waived some rapid flu antigen tests that promised improved sensitivity and specificity in their testing methods. Because the flu season has ended, “we probably won’t pick up the flu testing instruments until we reach the fall,” he says. “But we’ve made investments in other rapid diagnostics as well: respiratory virus panel, enteric pathogen detection, and just moving some of our viral culture studies over to more robust molecular diagnostic techniques for earlier detection and more rapid intervention.”

The number of offerings in this space is impressive, Waugh says. Mostly mid-tier or second-tier manufacturers predominate, although Roche, Becton Dickinson, and Hologic (Gen-Probe) are still big players. “But some of the smaller second-tier companies are getting gobbled up by the bigs,” he points out, citing Cepheid, bought by Danaher; BioFire, bought by BioMérieux; and IQuum (now Liat), bought by Roche for its rapid flu testing by PCR. Mergers and acquisitions like these give good products a better chance of navigating through FDA approvals more rapidly because they have the larger companies as sponsors, he believes.

Antibiotic resistance markers are developing and Henry Ford is paying close attention because of antibiotic stewardship. “GenMark has some good products in that area that we’re looking at closely. And the [Luminex] Verigene BC-GP/GN assays are also competitive.”

Sample prep systems have also been on Henry Ford’s instrument shopping list. “We’ve acquired systems to prep samples for sequencing analysis [Eppendorf epMotion], and we’re also doing single point mutations or small panels where we are using systems from Qiagen and GenMark, in addition to NGS with Illumina.”

Growth has been somewhat lackluster at Henry Ford, Waugh says, but he doesn’t regard that as a bad sign. “We have about a two percent uptick in volume this year, largely coming from our lab outreach. We’re actually trying to trim utilization in certain areas and shift from volume to value, and that can have a downside in the near term.” He expects the growing emphasis on performance analytics to pay off.

“We have a lot of different supplier streams: inpatients, outpatients, outreach, research, the ‘home health’ patients,” he notes. “Some samples arrive instrument-ready, they’re labeled, and they can go right into the instrument or automation system. Others require significantly greater handling at the front end to create orders and labels, and to prepare samples before testing.”

Because of the variability in workstreams, he says, “We look analytically at where the volume is coming from. What time of day is it coming? Are there defects associated with samples? How is our turnaround time with different customer groups? And how does staffing match up to volume?” Using performance analytics will help the system align the scarcity of its workforce with the volume by time of day, day of week, and different customer groups, and understand what is affecting on-time courier arrivals and departures.

The point is to get beyond the analytics available in the laboratory information system alone, Waugh says, noting that Visiun is one of the standalone players in this area that Henry Ford has worked with successfully for some time. He considers Henry Ford to be “kind of on the frontier” of what is referred to as “Laboratory 2.0”—analyzing everything from ordering to billing to explore what is driving value for the entire health care system. (See “Laboratory 2.0: changing the conversation,” CAP TODAY, July 2016.) Those analytics could reveal opportunities to reduce ED or ICU length of stay, get patients on or off medications more quickly, or leverage rapid diagnostic tools.

Also part of Henry Ford’s game plan is the general category of “instrument refresh.”

“These instruments operate 24/7. If you ran a photocopier 24/7, at the end of five years it would be like a 12-year-old copier. The reality is some instruments do fatigue, and you have to be proactive about replacements so you don’t have service in there every day of the week.” Over the past 18 months, a lot of basic core lab or rapid-response instrumentation at Henry Ford has been replaced with this in mind.

The whole slide digital imaging market has new entrants, and Philips’ IntelliSite Pathology Solution has now been cleared by the FDA for primary diagnosis. Waugh thinks purchasing might be premature. “The systems are just not at that level of capability and affordability to image 100 percent of your work. They are pricey, they require special capabilities in their networks to be able to send large files, and there are limitations on storage capacity, network bandwidth, and the system’s ability to digitize a high volume of slides. So this is still a pretty young field, and what we see are people taking a kind of shallow dip to get introduced. But committing to digital imaging of an entire workload is pretty rare.”

Henry Ford has had no trouble committing to massive automation. In late 2016, HFHS announced it had an agreement with Beckman Coulter to fully automate the Henry Ford Hospital laboratory and modernize equipment at 12 other locations. “We installed the most complex laboratory automation system in the Americas,” Waugh says. “It is an open system from Beckman Coulter involving instruments from Beckman Coulter, Siemens, and Stago.” To provide perspective, he describes the system as “eight feet longer than the Statue of Liberty from the base of the statue to the top of the torch.”

The logistics of instrument installations have to be factored in. “Some of our capital resources get put into making physical changes in our lab,” he says, “whether it’s site preparation and placement of new instrumentation, site prep for lab automation that might go in, or upgrades to relocate and reshape the labs to optimize the efficiency of workflow. Some of our money just springloads into those kinds of things.” Despite the automation system’s size, the lab’s footprint has remained the same.

Henry Ford has acquired three of Illumina’s next-generation sequencers “because we’ve had success with them and standardized with them,” Waugh says. “The surgeons and oncologists in our organization expect us to have very rapid turnaround time for 16 tumor boards each week, and a lot of the samples obtained from biopsies by fine needle aspiration are smaller samples. Being able to use NGS on those can yield important information on targeted therapy.”

In planning for 2017 instrument purchases, the core laboratory at Geisinger Health System, Danville, Pa., had a luxury that many labs don’t: a practically brand-new building with twice the testing space it had two years ago. Geisinger, an eight-hospital system, moved the core lab into a 140,000-square-foot-space in Danville in early 2015, and the space opened up new opportunities, says Myra Wilkerson, MD, chair of the Division of Laboratory Medicine.

“We took advantage of being able to put in much more sophisticated automation, and with our Roche 8100 automation line, we have hooked up all our chemistry, immunoassay, coagulation, and hematology to automation.”

She is particularly pleased with the specimen storage piece of the automation line. “We used to spend 1.5 FTEs time every day doing nothing but retrieving specimens out of refrigerated storage. All of that is automated now.”

This year, Dr. Wilkerson says, the laboratory is working on expanding its liquid chromatography mass spectrometry capabilities in toxicology testing, looking at bringing in some endocrine specialized testing, and planning to automate its microbiology testing.

For now, the laboratory is using its BD Kiestra system only to automate up-front plating. Many of the other automation systems the lab is interested in are in development and have not yet been released. Her team has automated the inoculation of the urine specimens, and they’re planning to begin inoculating other specimen types. “I’m assuming installation will have to be staged somewhat,” Dr. Wilkerson says. “First we’ll be getting the core specimens as far as plating, then automating between the automatic plater and incubator, and eventually we’ll be figuring out how to get the specimens to the MALDI-TOF.” Geisinger hopes to have its microbiology automation

complete by the end of 2018.

Improving data analytics has been another of the laboratory's goals. "Roche had a rather basic analytics package that came with its automation line. We've been working with them and Data Innovations to enhance that package to offer both clinical decision-making and the business analytic side."

"We're starting with some basic things like how to do quality control across our entire system to have a real-time peer comparison," Dr. Wilkerson says. "This way, you can do analytics in real-time on a daily basis, which allows us to pick up potential issues earlier."

As Allina Health has expanded to include 12 hospitals covering a large portion of Minnesota, the Allina Health Laboratory is now performing 8.5 million tests a year. A few years ago, the core laboratory was inconveniently split out and squeezed into different corners within Abbott Northwestern Hospital in Minneapolis, says laboratory medical director Lauren Anthony, MD. But in 2012, everything was consolidated into a new facility, converted from a warehouse, where the core lab has a footprint of 86,000 square feet.

The laboratory has made several recent acquisitions including a BD Kiestra automation system and an Inova Quanta-Lyser to do ANAs and automated EIAs. But the transition to automation is not proceeding without bumps, says Brenda Katz, MD, a clinical pathologist and medical director of the Allina Health core lab.

"We have talked to a couple of different companies, including Bio-Rad and DiaSorin, about being able to put their instrumentation on a line and they gave us options. Our line as it stands now is not sophisticated enough; we would have to do a whole new build-out to plan for that. But these are changeovers that we're starting to see."

Throughout Allina Health's system, the core laboratory and the smaller labs are integrated and use instruments from the same manufacturers: Abbott Architect, Sysmex, and Stago. But whether to consolidate an automation system with one company or to go with more specialty companies is a decision the laboratory is weighing.

Breaking down department silos within the laboratory is one of the managers' aspirations. Traditionally, Dr. Katz says, "we look at a chemistry RFP, a hematology RFP, and so on. We're trying to look at the whole lab, to issue a 'laboratory RFP' rather than purchase by department."

In that vein, Allina Health has a long history of integrating laboratory services. "Our pathology group joined together around 1995," Dr. Katz says, "and since that time they had argued for a core lab. It basically took about 20 years, but the labs became the first integrated service in the system."

Dr. Katz

"The labs immediately recognized that consolidating and streamlining testing into a central facility could save the system millions and millions of dollars." The construction of the new core laboratory, which cost $30 million for the building and instrumentation, was a milestone of the integration process.

That the instruments were all replaced at once five years ago and are nearing the end of their normal life may seem to call for replacements on a large scale. But Dr. Katz doesn't go along with that notion. She and other clinical chemists in the region believe "you have to have a good plan for when they break, but there is no requirement to change instruments if they are working." At this point, she says, "we may want to stretch things out so we could potentially get to a line that has chemistry, immunology, coagulation, and hematology on it."

The proposed line would be similar to the automation system operated by PCL Alverno in Hammond, Ind., she says, which allows multiple different instruments. The line Allina Health has now, an automation solution by Impeco, needs updating. “We don’t have that many lanes, different size test tubes are a huge problem, and how the lanes work in terms of computer programming is just old technology, not as sophisticated as the new versions are.”

Over the next six months, Dr. Katz says, the laboratory is bringing each of the major companies in to give a vision of where they think automation will be. “We don’t just want to see what their lines can do for us right now. We also want to see what they’re having in 2020 or 2022. We’re asking them to give us a visionary statement.”

She hopes Allina Health can follow the Alverno model and integrate its testing. “But that would mean we’d be tearing down a fairly large portion of the lab and replacing the line we have. In terms of the health system’s point of view, they just gave us $30 million, and I don’t know if that would be able to happen again in 2020. So we may be forced to do something in the interim”—at least to get a better-functioning line.

The laboratory will certainly need to change out its chemistry and immunology, Dr. Katz says. “That would come with any new instrumentation we bought, no matter what company we had. And we’d be able to get some other more specialty immunology testing instrumentation that would be compatible with an updated automation line, maybe with hematology too.” But it’s possible that the next remaking of the lab may have to be staged out over five years or possibly 10.

Dr. Anthony

This year Allina Health is implementing a whole platform shift on blood gas analyzers by purchasing 23 Gem Premier instruments made by Instrumentation Laboratory. “We don’t have them yet and we’re trying to figure out how they will work with our LIS, but it’s happening.”

The most time-consuming “pain point” is specimen processing, and that opens up multiple issues when considering an automated line. “The personnel are not MLTs, so their sophistication in terms of weeding stuff out and making decisions is not the same. We haven’t been good in how we centrifuge to get specimens online. Throughout the core lab, there was this idea that everything would be automated and super fast, but we gradually figured out that with things like vitamin B12, which was a high-volume test but the reagent itself is fussy, the techs were spending hours and hours doing lot changes.” Then the troponin turnaround time suffered, Dr. Katz says, because the vitamin B12 was blocking up the Architect immunology instrumentation. She sees fixing the specimen processing problem as a work in progress, largely guided by technologist observations of workflow.

Trying to push the technology a little further is Allina Health’s challenge. “We’re okay now. The scary thing is, how do we get from this stage of segmented departments to the next stage? How do we negotiate that transition without having a major shutdown that would affect our ability to test?”

To dodge that risk, she says, it’s understandable that some labs want to take everything, even instruments that are working, and change them every five years. “The question is, can we negotiate our way through a longer period of time, not be as wasteful, and also get to another further technological leap?” For Dr. Katz, that’s the balancing act that laboratories must continue to perform as they make tricky decisions about new instrumentation.n
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