

Menu, security, consistency: vendors point to priorities

July 2018—*Chemistry and immunoassay analyzers combined—that's what is new about the product guide. In years past, the chemistry and immunoassay analyzer product guides were published separately. This year we integrated them and are publishing them in two issues: last month for the low-volume and point-of-care markets and this month for the mid- to high-volume laboratory market. Each company decided on its own in which issue to list its analyzer(s) and used our revised questionnaire to provide us with the detail you will find in our [interactive product guide](#).*

CAP TODAY spoke with five of the companies that have analyzers for the mid- to high-volume market. We asked them what we asked a different set of companies in the June issue—about instrument acquisition trends, the concerns they're hearing from customers, and more. Here is what they told CAP TODAY senior editor Amy Carpenter Aquino. (Abbott Diagnostics' analyzer is not listed in the product guide because Abbott was in the process of launching a new product line in the U.S. and could not provide details about its analyzer [http://bit.ly/Abbott_Alinity] until it was officially announced, which was after CAP TODAY's deadline.)

What are two key trends in instrument acquisition?

Joe Amodeo, marketing manager, Atellica Solutions, Siemens Healthineers: We are seeing a longer life cycle for analyzers. Customers used to think about replacing equipment on a consistent five-year basis. That is lengthening to an average life cycle of seven years for a given analyzer, though it remains customer and instrument specific. The reliability of analyzers on the market today is always improving. As long as customers have that reliability and they're meeting the metrics they've assigned themselves, they'd rather reserve those dollars.

Changes to lease classification rules issued by the Financial Accounting Standards Board in 2013 forced labs to account for instrumentation on the balance sheet. That has created an environment in which customers are required to understand any financial implications of acquiring capital if funds are not readily available. That might mean finding new and creative ways to bridge different budget cycles if their specific project isn't funded in the preferred replacement time period.

Nadav Kaufman, senior director, product management, clinical lab menu, Ortho Clinical Diagnostics: Customers are looking for instruments that truly integrate chemistry and immunoassay diagnostic testing, with or without a track. They're seeking instruments that allow them to grow in menu and throughput as their laboratory's needs evolve, without requiring major capital investments like increased footprint or plumbing systems.

We're also seeing customers enter into longer-term partnerships with vendors based on alignment with that selected vendor's vision for the future and their capacity for continuous improvement in areas that deliver greater medical value.

Chris Cook, PharmD, senior director, antimicrobial stewardship, BioMérieux: One trend is consolidation of laboratory instruments, which means having a broader menu on the same instrument. Connectivity and analytical solutions tied to the instrument also are becoming more important.

Tamara McCarthy, senior product manager, systems, Binding Site: Approvals take longer and involve more stakeholders, which may be due to hospitals consolidating or becoming part of a larger network. Decisions made at a local level previously may now need to wait for approval from larger organizations.

Information technology departments are more involved now in the labs and health care systems. This is to ensure the safety of protected health information and compliance with HIPAA.

Vahe Ayyazian, U.S. marketing director, Abbott Diagnostics: Labs are looking beyond the instrument and assays at a total solution and how it can optimize their performance as well as add value to the entire health care organization.

We also see a concerted effort to purchase harmonized systems that are highly reliable and easy to use and address fundamental operational needs: broad menus for testing consolidation, scalability for future growth and operational capacity management, efficient footprint for return on investment, error reduction, commonality across system disciplines for ease of use, operational training, and staff optimization.

Which do you see most notably: a desire for one platform family to serve all sites, firm long-term pricing, compatibility with electronic medical record system, adaptability through middleware, ease of ordinary reporting, or menu expansion and development?

Kaufman (Ortho): Having one platform is critical to our customers as health systems become better organized. They're looking for a one-platform family and consistency across the reagents, values, training, service, and supplies.

We consistently hear that customers are interested in more novel medical content and expanding menus. They are particularly interested in tests that can help the lab play a bigger role in driving a change in how diseases are managed. For example, the NephroCheck test for risk of acute kidney injury allows laboratories to be involved in helping physicians get in front of a complication they were previously unable to predict and manage.

Dr. Cook (BioMérieux): Our customers are most interested in menu expansion and development. We aim to expand our offering through unique, high-value medical solutions like the Vidas procalcitonin, NephroCheck, and Banyan mTBI biomarker tests.

Amodeo (Siemens Healthineers): Labs are increasingly transitioning from buying individual analyzers to purchasing total solutions from a single partner to meet their equipment needs. Total solutions encompass a variety of offerings, including equipment for sample management, a broad menu of assays, IVD analyzers, automation systems, and informatics. Taken together, such total solutions are designed to anticipate and address the existing and emerging needs of laboratories—for example, the staffing crisis and needing to generate greater throughputs at lower total cost of ownership. Laboratory and medical directors also are seeking out “end-to-end” solutions that correlate results across the lab and at the point of care for trustworthy results no matter where the testing is done. This is increasingly important as health systems continue to consolidate.

In the past 12 months, what new concerns are customers and potential customers raising?

McCarthy (Binding Site): There have been a few questions about PAMA and reimbursement. Customers are seeking more efficient testing and analyzers that can drive down costs. IT security questionnaires are becoming more prevalent. Organizations are consolidating, growing, and creating different levels of IT security. We're seeing all of that go hand in hand.

Amodeo (Siemens Healthineers): IT security concerns and complexities are fairly new. The lab and the vendor have to support data security, risk assessment, and the ability to mitigate cybersecurity attacks. The problem is the average lab employee and vendor representative don't have the specialized skill set to answer these questions. Trying to align laboratory, IT, and vendor resources can slow down the sales and installation processes. Everyone can do a better job of aligning to determine what security is essential so that hospitals feel comfortable giving access to vendors and connecting instruments to their network. Key stakeholders should continue to create a more robust conversation about cybersecurity.

Ayvazian (Abbott Diagnostics): Health care systems are consolidating, budgets are under more pressure than ever, and new payer models are beginning to surface. Patient volumes are higher and the demand for analytics and information from the lab is greater, and customers are turning to their diagnostic partners to help them navigate these new waters. Instead of looking simply at throughput or the variable cost per test, they now want to take a more holistic view of the total value a system brings to them and how they can add more value throughout the care process. We are partnering with labs to help them understand the total value of their system's policies and procedures, to help them better achieve operational efficiency and clinical care excellence.

Kaufman (Ortho): One of the big areas is to identify ways to better manage diseases and get patients treated faster and more efficiently and with fewer complications. It's about enabling the shift from treatment to prevention, and it's becoming easier to quantify the medical and economic value of that shift. We're also finding that customers increasingly value service and support, including predictive analytics and e-Connectivity, which are differentiators for Ortho.

Dr. Cook (BioMérieux): PAMA and its impact on outpatient testing is a concern. Antimicrobial stewardship is becoming a more prominent topic, especially the role of the lab as the primary objective data source—for example, testing for procalcitonin, AST, and *Clostridium difficile*.

Can the industry's success with automation and ease of use successfully match the worrying decline in skilled labor availability, or does there become a point at which this problem must be addressed by others (in the systems, schools, societies)?

Kaufman (Ortho): It has to be a balance. The role of the clinical laboratory scientist is becoming more important. We will need to continue growing the field of the clinical lab scientist to make up for all the retirements, but the ones who stay will continue to deliver greater value. Automation may automate many of the manual tasks they had to undertake previously, but that means the tasks we rely on the clinical lab scientist to perform are more critical and complex.

Amodeo (Siemens Healthineers): Skilled labor is indispensable, but in many situations vendor-supplied automation will be able to offset the decline for the short term. A shortage of skilled laboratory workers has been decades in the making—the result of a retiring workforce and a shrinking number of accredited training programs. Vendors have been designing products with this issue centrally in mind. When we developed the Atellica Solution, for example, we knew more customers needed analyzers with automation-level capabilities. The Atellica Solution saves time with sample loading, sorting, and routing to multiple analyzers. These types of product innovations make automation more accessible. A lab that outfits itself with the right complement of products can remain viable for five to 10 years even while sustaining some staff losses to retirement.

Ayvazian (Abbott Diagnostics): We are designing our innovative systems with automation that provides the flexibility and efficiency to meet changing demands with confidence. This includes using labor efficiently but also improving turnaround times, reducing human error, and adding the capability to manage increased volumes.

McCarthy (Binding Site): There will always be a need for skilled labor. In a few years we will have to reassess if the decline in skilled labor should be addressed and determine if additional action by schools or societies is needed. Labs are working well with the instruments offered today, and the ease of use of the instrument, such as our Optilite instrument, is helping in that situation.

Dr. Cook (BioMérieux): Increased automation allows laboratory managers to release trained staff from repetitive tasks. Simpler systems, such as the Vidas system, also offer the benefit of increased reliability, which is critical for high-value medical stat testing.

Cost concerns are always with us. What new approaches to cost and value do you see from customers and wish to pursue as a corporate matter?

Ayvazian (Abbott Diagnostics): We see forward-looking customers taking the approach of total value of ownership. Rather than looking simply at a technical specification and the cost of an instrument or assay in isolation, total value ownership looks at the entire value equation. Things like access to real-time data, long-term sustainability, waste and environmental impact, site impact, exception management, inventory management capabilities, multisite management capabilities, and more need to be considered. Approaching it from this perspective provides the tools and insights not only to better manage the lab but also to enable the lab to provide more value to its stakeholders to help achieve measurably better health care performance.

Amodeo (Siemens Healthineers): Doing more of the same is not necessarily an option for laboratories. They're

thinking about outsourcing some of their business or figuring out how to become more efficient. We want to arm them with IT and workflow transparency. When we put an inventory management or reagent efficiency tool in place, they can see more clearly from their own data whether it makes sense to run a test at a certain price. Maybe that's an opportunity for cost improvement from an inventory management perspective. Some laboratories don't know what they don't know. We've seen these tools lead customers to optimize their ordering habits.

From a workflow perspective, we offer consultative observations and engagements for customers. Once labs realize how many minutes per day or year are being spent on repetitive activities, they can consider whether automation can handle their workload into the future, even after expected attrition of staff. Many times it can, and that can significantly lower operational costs.

Kaufman (Ortho): It's about looking for tests that deliver greater medical value. If you can directly tie the use of a test and an application within a treatment protocol to reducing length of stay or having a lower level of complications from cardiac surgery, that becomes very impactful. As a vendor, we have a responsibility to help customers identify and promote those opportunities within their medical system, so that the medical system can decide if it wants to engage in adopting those new tests to get the associated improvements in patient care and savings. We may help them by providing tools to calculate the potential impact of new tests, using inputs that the laboratory or hospital would provide, and they in turn use those to help justify novel testing that goes beyond what their lab budgets would historically support, because the value they deliver to the hospital is many times greater than the incremental costs.

Dr. Cook (BioMérieux): The BioMérieux approach is to provide high-value medical tests that require rapid turnaround: procalcitonin for sepsis and antibiotic stewardship, NephroCheck for kidney injury through our recent acquisition of Astute Medical, and concussion-related biomarkers through our partnership with Banyan Biomarkers. The human suffering and dollar costs of antibiotic resistance, acute kidney injury, and traumatic brain injury are enormous. High-value medical immunoassays provide complete and accurate information to help clinicians make faster decisions in diagnosing and treating these conditions.

Our customers play an increasingly important role in antibiotic stewardship teams that are now mandated for every hospital in the U.S. The lab's information sets in place the trajectory of patient care for every patient with a suspected infection. Incorrect or excessive therapies can be avoided.

Another cost-saving measure is longer-term agreements. Customers want a partnership that offers savings and added value in the form of enhanced education or support. Our education support and service response times are excellent. We help labs articulate their value to their institution in the form of stewardship, data integrity, and more, instead of being seen as a cost center.

McCarthy (Binding Site): We are working with customers to understand how to mitigate reduced reimbursement due to PAMA. We also look at the big picture with HEOR (health economics and outcomes research). This new approach is meant to help customers weigh the costs of diagnostic tests with the effectiveness of earlier diagnosis and treatment. Labs affect patient care by helping to provide an accurate diagnosis earlier, which enables treatment to be started sooner and reduces overall health care expense. □

If you have thoughts about the following product guide—where it works well, where it doesn't—we'd like to hear from you. Send comments to Kristen Eberhard at keberha@cap.org.