

Instrument acquisition, skilled labor on the table: Makers of chemistry, immunoassay analyzers answer our questions

June 2018—Broad menus, efficient workflows, single platforms, rural labs, cybersecurity, and economics are some of what one CEO and three marketing and product managers talked to CAP TODAY about when we spoke to four companies whose analyzers are profiled in the product guide. Details about their analyzers and those of eight other companies are provided in our first combined chemistry/immunoassay product guide, tailored in this issue to the low-volume and point-of-care markets. (See [“Simpler and condensed,”](#) for more on the revised product guide and what to expect next month.)

“The fun part of being a manufacturer,” says Nova Biomedical product manager Brad Bullen, “is trying to keep two and three steps ahead of clinical needs while providing quality diagnostic results that impact patient care now.” Here is more of what he and others shared with senior editor Amy Carpenter Aquino.

What are two key trends in instrument acquisition?

Wayne Brinster, CEO, MedTest Dx: Our customers are looking for flexibility, with the ability to run a broad menu of tests that allow them to create an efficient workflow. They want the instrument to change with the test mix they’re seeing, and they want the flexibility to respond to new tests and not have to do testing offline. They haven’t relinquished the requirement for the instrument to be efficient as far as the use of reagents, low maintenance, and a long time between failures. All of those things come into play to help the laboratorian increase the throughput of the highly automated core instruments.

Laboratories are getting drugs-of-abuse screening tests from the emergency department or saliva samples from their occupational health group. If these samples are just added into the normal throughput, they tend to slow down the larger, highly automated instruments. We’re seeing a desire to take different types of samples and tests while continuing to have a highly efficient core laboratory. They can put one of our instruments inside their core lab and dedicate it to offload these less efficient tests.

Brad Bullen, product manager, Nova Biomedical: The first trend is standardization of the hospital platform across the system. You’re able to train one set of employees to cover all hospitals. Trying to do more with less and having a single analyzer that meets the needs across the hospital system is ideal for purchasing agents as well as clinicians. If you’re changing from one analyzer to another, there can be subtle differences in the way results are produced and the timing of the results. Hospitals want a singular fix for their point-of-care diagnostic needs.

The second trend is cybersecurity. Somebody at a large university hospital in California said their laboratory receives about 3,000 external attempts to access their network daily. Hospital systems have had their patient health information accessed and held for ransom. Hospital systems and patients have to have confidence that the systems manufacturers provide are not going to be susceptible to malicious software. For a long time, diagnostic companies relied on the hospital’s firewall to protect patient data. Nowadays we can’t do that; we need to provide multiple tiers of defense.

Brittany Greiner, marketing manager, low-volume and specialty systems, Roche Diagnostics: We’re seeing increased interest in standardization and a growing need to have a large assay menu on an integrated platform. Specifically, when it comes to software interface and assays, it’s important to have the same menu, measuring ranges, and reagents for all the platforms.

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)?

Bullen (Nova): As the mean age of laboratorians is increasing every year, and with fewer enrollees getting into this career path, we're seeing staff having to do more with less. We are not necessarily looking at what's going to happen 12 months from now but in five years. Nova is developing analyzers that don't require as much hands-on time to provide quality results, with plug-and-play technology and no maintenance. Basically, take it out of the box, put it on the shelf, load it up with limited consumables, have a 15-minute training session, and you should be good to go. That's the approach we take when developing our analyzer platform.

Everyone is being asked to do more without an increase in staffing or reimbursement. Industry has to come to the table with an analyzer that provides outstanding quality results with limited or no hands-on time. Providing a flexible analyzer platform is a necessity because what might be perfect for one group or department may not meet the clinical demands of another.

Brinster (MedTest): The industry has made tremendous strides in ease of use. At the same time, there's this bifurcation of lab testing. You have some testing that's going toward the patient in the format of waived testing; conversely, there are other testing situations where a laboratory is needed, such as in the larger walk-in clinics. If the current trend in reduction of med techs continues, we will have a real shortage and it will become a problem. There is a need for organizations to continue to work with schools and government to try to promote getting more people into medical technology.

Greiner (Roche): Automation and true standardization—like a common user interface and measuring ranges—effectively support smart use of available staff, and this is critical in two key ways. Because of the decline in skilled labor, the instruments must become in a way “more skilled.” Lab optimization is an important piece of our R&D spend at Roche. But these “smarter” instruments and automation also allow highly trained, highly educated personnel to focus on their practice of laboratory medicine.

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?

Steve Ishii, MT(ASCP), senior marketing manager, strategic marketing global chemistry, Beckman Coulter: Regarding the desire for one platform family to serve all sites, integrated delivery networks are looking for scalable platforms that provide efficient solutions to meet the testing demands of different size laboratories in the health system. It is also important that the family of platforms provides standardization.

EMR compatibility, middleware adaptability, and ease of reporting are also important. Clinical information management tools provide centralized management of laboratory instrumentation and data workflows to deliver quality test results with shorter turnaround times; real-time operational analysis to support clinical and business decision-making; service-focused customized dashboards, real-time reporting, and automated notifications; and scalable infrastructure to minimize redundant capital investment and recurring costs.

For clinical chemistry, the discovery of new and novel assays is of paramount importance. Developing highly specialized assays will continue to be an important part of research and development.

Bullen (Nova): We are seeing the desire for one platform, compatibility with the EMRs, and adaptability through middleware. You can develop the best analyzer in the world but if it doesn't convey the data from the lab to the clinician, it's an expensive paperweight. It needs to be connected in a cost-effective way that minimizes hospital IT time and reduces a go-live time frame.

Nova has developed an open interface architecture where we can connect to and through anything. We proactively

approach middleware companies to ensure that our interface specifications and connectivity will be available at product launch. Nova's connectivity solution can act as middleware or go directly into the LIS or HIS, often minimizing cost. Our ability to offer flexible connectivity options affords customers the best option available.

Brinster (MedTest): Every day, in every conversation we have, economics comes up. Customers know they're providing great information for improved medical care, but at the same time they see the annual increases from suppliers, plus unknown costs for things they didn't anticipate, and see continued pressure on the reimbursement side, placing them on a path that is getting narrower and narrower.

In some instances customers want an agreement that's specific to them. The one-size-fits-all, large-blanket contracts lock them in and would not allow them to cover what they want to cover.

One of the ways we have responded to this is by offering contracts with 100 percent long-term pricing firmness. We refer to this as a cost-per-screen program. The lab tells us what tests they want to cover, and we provide all consumables, service, maintenance, and controls and calibrators at a single price. This makes it possible for the lab to offload some of the risk.

As we look at how many new tests are available and how much great information we have at our avail, it's a fantastic trend. We continue to feel the long-term result from the human genome project and the proteomics work that has been and continues to be done, and there's a consistent flow of excellent tests that are coming out. Many are protein-based tests that customers want to be able to put in and adapt, and it allows us to be truly important in all health management decisions, whether that is moving somebody to a different unit or determining treatment. I continue to feel that IVD testing is the best bargain in health care.

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

Greiner (Roche): A big one is continued access in low-volume, rural areas. Customers want to have the same menu as their midsize and large counterparts, such as the procalcitonin assay for sepsis management, as well the troponin Gen 5 assay. These assays have big impact in terms of cost, outcomes, and many other key metrics by which institutions large and small measure their successes. Small-volume rural labs want reassurance they're going to have the same menu as their counterparts at the core or reference lab. And in this era of integration and consolidation, it's smart to be scaled for change. Access ensures that game-changing tests aren't reserved for high-volume settings. Everyone deserves the best care possible.

Brinster (MedTest): The new trend is increased drugs-of-abuse testing. Many of our clients have an opioid task force, and some are also associated with a behavioral health center where they're looking at how to provide their community with the best and most efficient screening and confirmational testing. This has thrown a new set of requirements onto the laboratory, and they've been coming to us for help because it's an area of expertise for MedTest.

Ishii (Beckman Coulter): The modern laboratory is under increasing pressure to produce fast, accurate results while reducing costs. As a manufacturer we continue to seek solutions that will meet volume demands, produce precise results, and lower costs. Many of these solutions involve offering reliable systems characterized by scalable throughput, maximized uptime, and efficient reagent and energy use.

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?

Greiner (Roche): One is encouraging laboratory professionals to have long-term vision, to create and build that solution in the laboratory that's going to be sustainable for the future. The second is the laboratory management team being able to articulate to its leadership and stakeholders the value the lab provides far beyond its walls. For example, the lab plays a huge role in readmission rates, improving the standard of care, reducing costs, and

patient satisfaction.

It's also important for labs to take that long-term view so they are consolidation and integration ready. That's where that standardization piece becomes critical—you have to know, when you're bringing all of these different labs together in an integrated health network, that it's apples to apples.

Brinster (MedTest): As a relatively small company, we can be more flexible if an account needs us to write a deal that's a little different from what's normally offered. We make sure we're within regulations, but we work with the customer to make agreements as efficient and cost-effective as possible.

Bullen (Nova): From a buying perspective, we've seen hospitals in the past several years go from buying as a single institution to integrated hospital networks and/or group purchasing organizations. Nova goes through great effort to ensure that we're affording every hospital the best diagnostic results at a good price. This can be a big challenge.

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Tosoh asked that the listing for its AIA 360 immunoassay analyzer be removed from the following product guide because the company's regulatory review could not be completed by CAP TODAY's deadline.

Simpler and condensed

For the first time, CAP TODAY has combined its chemistry and immunoassay analyzer product guides rather than publish them separately. And we have done so in two easy-to-navigate listings: one for the low-volume and point-of-care markets (in this issue) and another for mid- to high-volume laboratories (to be published in the July issue). Each of the two listings profiles chemistry and immunoassay analyzers as well as analyzers that perform both functions.

"Users needed something simpler and condensed," says CAP TODAY publisher Bob McGonnagle. "The guides are a first step in seeing what is available. The commitment to a system is usually intended to serve the widest possible array of testing sites within a hospital system, with a uniformity of vendor, instrumentation, and method. It's in that spirit that we decided to revamp the chemistry and immunoassay product guides for 2018."

The revised product guides feature about the same number of companies as in the past but in fewer pages. "Since there are so many chemistry and immunoassay analyzers on the market, we asked companies to give us from each family of analyzers they market the one analyzer they would most like to highlight," says Kim Carey, CAP TODAY managing editor. In some instances, companies provided in their listings the names of other models in the same analyzer family.

Each company decided on its own whether to list its analyzers in the point-of-care/low-volume guide or in the mid- to high-volume guide. "They determined the best fit for their analyzer," Carey says.

CAP TODAY thanks the following experts for their guidance in the revision of the guides: David Alter, MD, DABCC, clinical/chemical pathologist, Spectrum Health Regional Laboratory, and clinical professor of pathology, Michigan State University College of Human Medicine; Frederick L. Kiechle, MD, consultant, clinical pathology, Cooper City, Fla.; Maria Crisostomo, senior sales product manager, Bio-Rad Laboratories; and Edward Gilligan, technical marketing manager, Roche Diagnostics.

We invite readers and the companies to share their thoughts about the following product guide by telling us what works and what can be improved. Send comments to Kristen Eberhard at keberha@cap.org.

Readers interested in a particular analyzer should confirm it has the stated features and capabilities. —Amy

