Chemistry and immunoassay testing: Standardizing platforms, ranges, interfaces—panel weighs in

July 2019—*One vendor or two. Automating esoteric testing. The desire for more smart systems. The need for analytics. Seven people spoke with* CAP TODAY *publisher Bob McGonnagle in May about chemistry and immunoassay testing. They are David Alter, MD, DABCC, of Emory University; Nina Babic, PhD, DABCC, of Medical University of South Carolina; Denise Pastore of Siemens Healthineers; Timothy Lenz, PhD, of Randox; Delena Carite of Roche Diagnostics; and Jessica Tubman, MPH, MT(ASCP), and Stephen Ishii, MT(ASCP), of Beckman Coulter. What follows is what they told us.*

CAP TODAY's interactive guide to chemistry and immunoassay systems for mid- to high-volume laboratories.

Dr. Babic, what is a top-of-mind concern for you in your job dealing with the high-volume demand of chemistry and immunoassay in laboratories?

Nina Babic, PhD, associate professor of pathology and laboratory medicine and director of clinical chemistry and point-of-care testing, Medical University of South Carolina: Aside from quality, flexibility and footprint are two important things I consider. By flexibility I mean the adaptability of instrumentation to the size of the laboratory and needs of the patient population. While the MUSC central laboratory is a high-volume, fully automated lab, there are smaller laboratories at associated clinics and hospitals within our system. So we are always looking to consolidate test menus and harmonize tests across different sites. Interoperability between systems and support services, in terms of both IT and instrumentation, are also important.

Jessica Tubman, I believe this is a fairly common concern among the customers Beckman Coulter interacts with, not only in the United States but also around the world, namely they want to be on a single system and they want to have a system that has the flexibility to provide test results in a huge core lab with high volume, but then also to be dispersed within a health system network. Is that correct, and how are you approaching this?

Tubman

Jessica Tubman, MPH, MT(ASCP), global product management, immunoassay, Beckman Coulter: Yes, we hear that quite a bit: the scalability of results, having the same results for your patient and network whether the patient has visited a small or a large hospital, having the same reference range and quality of results no matter what platform is used. At Beckman Coulter, as we pursue new product development, maintaining the same reagent in our immunoassay product line is important. So we are making certain to use the same reagent no matter if the lab uses a small system or a large system within our portfolio. We do believe we have better solutions if we offer low- to high-throughput systems using the same reagents to meet various customer needs.

Dr. Alter, can you give us your reaction to my first questions and the answers?

David Alter, MD, associate professor and director of clinical chemistry, Department of Pathology and Laboratory Medicine, Emory University School of Medicine and Emory University Hospital, and chair, CAP Clinical Chemistry Committee: First, hospital systems can manage multiple platforms and different vendors provided they're savvy enough to keep in mind the way the results are reported. If you're a multi-hospital system that has two or three

different vendors, it's important within the result field to note that this result was performed on this analyzer, and you can standardize reference intervals, but I do think it's important to indicate that even for something as common as a sodium, you want to specify that this sodium was performed on your Beckman and this sodium from hospital B was performed on your Roche Cobas, and so on.

Dr. Alter

However, with certain assays where it's not practical to standardize the reference interval, it forces, I hope, my counterparts and Dr. Babic's counterparts to push their IT departments for separate reporting fields. So if you're in a system that has troponin I and troponin T, or two different troponin Is, you should try to recognize that and to have your vendor A troponin I and your vendor B troponin I reported out separately.

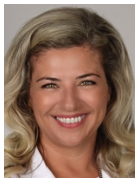
My broader view of the big platforms is that every one of them has pros and cons that cancel each other out, and that when it comes to deciding what to do through an RFP process, the weight falls on the end users, the technical services staff, and what they feel in terms of usability of the instrument and how the vendors respond with service.

I'm sympathetic toward the vendors of the instrumentation because in many cases, they can only do so much and then the customer and instrument vendor end up dealing with IT, and often that's now centralized IT. Delena Carite, how would you deal with this question that Dr. Alter puts so well, which is: We would like to be able to show our physicians and others who've been ordering tests reference ranges that are specific to a particular kind of analyzer. That's not easy to accomplish with centralized IT systems, is it?

Delena Carite, group marketing manager, centralized diagnostics, Roche Diagnostics: I'm not an expert in centralized IT networks from an LIS standpoint, but you can certainly integrate or notate specific parameters about an assay, for reference by the clinician. But I find Dr. Alter's response interesting because we hear the contrary most frequently. Laboratories seek standardized result reporting with common reference ranges for ease of interpretive accuracy and trending of results over time. Therefore, our focus is delivering one result for the physician, hospital, long-term care, nursing home, clinic.

We also continue to see increased interest in standardization beyond common reference ranges and reagents. Specifically, when it comes to software interface, it's important to have a common platform across a health system with one user interface that allows flexibility to shift staff from one lab to another, reducing training time to equip your staff to be confident using a common platform interface, no matter the location. It's certainly a benefit from that perspective.

Dr. Babic, what are your thoughts on this? Do you find yourself in a position where you're sending chemistry or special chemistry technologists to different sites within your network to operate instrumentation daily or weekly?



Dr. Babic

Dr. Babic (MUSC): I would first like to touch briefly on Dr. Alter's comments. Being part of an integrated health system, we do have a situation where two different vendors are used in different laboratories. It's absolutely possible to maintain different vendors for the same tests, and I would argue it's much easier to do so for chemistry assays than immunoassays. This is because immunoassays are not very well standardized and, no matter how hard we try, it's difficult to communicate methodology differences to the physicians. I have encountered numerous situations in which I would speak to a clinician who was not aware that a particular test was performed with different methods, even though it's clearly stated in our EMR.

Regarding staffing challenges, as we are expanding our services and shifting toward an integrated patient-focused model of care, we are opening additional labs with limited test menus and having to rotate technologists between those sites. A limited staffing situation makes platform synchronization and streamlined user training highly desirable.

Dr. Lenz, what are you hearing at Randox as you talk to laboratories?

Timothy Lenz, PhD, regional sales manager, Randox: The lines between chemistry and specialty chemistry are becoming increasingly blurred. We are finding more diversity, especially in larger hospital labs that are starting to function as reference labs for their system. They may be trying to bring tests in-house that are not traditional acute care hospital tests but rather assays that may be ordered by various physician offices within the system—cardiologists or endocrinologists, for example. We are seeing an uptick in labs that are looking to third-party vendors such as Randox for niche reagents and small analyzers as specialty chemistry instruments, to bring some of those more esoteric tests in-house.

Stephen Ishii, can you weigh in on what you've heard?

Stephen Ishii, MT(ASCP), global strategic marketing, chemistry, Beckman Coulter: To the statement Dr. Alter made about having different platforms, it is possible with the information technology that exists today, with the software that's available, to be able to do that in a network situation. But we're also seeing plenty of requests from laboratories that want to be able to standardize reference ranges, assay methodologies, and so forth as much as possible.

Dr. Alter, if you could have your druthers and budget were not a question, would you like to see the Emory network on one platform or do you still believe there's a sort of best-of-breed approach not only in special chemistry or immunoassay but also in chemistry, where you like to have the flexibility of different platforms to optimize individual test results for your patients?

Dr. Alter (Emory): Emory had already standardized automated chemistry prior to my arrival in December 2018. In addition, my prior institution [Spectrum Health, Grand Rapids, Mich.] had, over the last three years, obtained funding through the hospital and put together an RFP to standardize automated chemistry across their entire system. They were able to do so, and it behooved the hospitals not currently on the agreed upon platform to move to the new platform when their current contracts expired. So they now, systemwide, have a common EMR, common chemistry analyzer, and a mostly common hematology analyzer.

I'd like to echo Dr. Babic's comment about immunoassays being harder to standardize. More chemistries than not can be standardized but there are others that cannot be. There are certainly chemistries that can't be standardized very well.

If I'm at a conference and in the coffee queue during a break, I hear people say, "What kind of line do you have?" meaning do you have a Roche line, a Beckman Coulter line, a Siemens line. We're in at least the third generation of lines. Denise, Siemens Healthineers has an important new line, Atellica Solution, but before we talk about Atellica, tell me where we are in the evolution of these high-volume, highly automated lines from your perspective.

Denise Pastore, director, global marketing, lab diagnostics, Siemens Healthineers: You're right: We are in our third generation of automation and our premier product in that line is our Aptio automation line. Featured with the Aptio

automation is our Atellica Solution. They were designed together so they could keep up with the throughput that each laboratory demands.

I agree with Dr. Babic that consolidation and footprint are a need and a priority. In addition, we have to look at the lab requirements for workflow and turnaround time, and to do that you need a rapid transport system, and that's what we can achieve with the Atellica Magline Transport. The Atellica Solution has a lot of flexibility—more than 300 configurations—suitable for a midsize or high-volume or mega-size laboratory, and then we can offer standardization because all of the instruments would use the same reagents, consumables, and hardware.

To meet turnaround times, we make sure stat assays are done within 10 minutes. That would include all cardiac tests such as high-sensitivity troponin I as well as hCG and intact PTH, just to mention a few.

Delena, can you too comment about where we are in generations of lines and how the demands of customers are affecting Roche's approach to these large centralized laboratory lines for immunoassay and chemistry?

Delena Carite (Roche): I agree with much of what Denise said about what customers are saying—they need standardization and common reagents and consumables, and the ability to share that across network and the efficiency of doing so. Roche began the modularity rage in the early 2000s offering laboratories the ability to scale up due to consolidation or scale down when testing is decentralized. 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.

Jessica, can you speak to this question about the need for the large high-volume centralized lines where chemistry and immunoassay are combined? I'm sure you'll agree this is a new demand. What is new in the setups Beckman Coulter is asked to evaluate as you replace new instrumentation or lines or come in for the first time?

Jessica Tubman (Beckman Coulter): Ultimately, we believe laboratories are looking for overall end-to-end productivity to produce repeatable, high-quality results. There is a need for smart systems to free technologist time to focus on high-value–add tasks. They are looking for systems that automate various tasks including quality checks, which account for a significant amount of preanalytical errors. For example, checking the sample label, the sample tube type, and sample volume versus tests ordered to prioritize critical tests and performing serum indices to alert staff when a re-draw is required. Additionally, standardizing workflow—regardless if a stat or routine request—with the ability to manage a large variety of tube types and sample sizes. These steps all add up to drive productivity and efficiency to produce high-quality results and preserve valuable tech time. These are our top priorities as we deliver our next-generation scalable automation systems to bring the benefit of automation to any size laboratory.

Dr. Babic, is there a limit past which we cannot go just with automation?

Dr. Babic (MUSC): We are fairly close to that point where you strike this balance of the technologist's time versus automation. As we are increasingly utilizing artificial intelligence to automate instrument diagnostics and result interpretation and reporting, there will always be exceptions that require human judgment, so there's definitely a limit to what we can automate. To learn and improve, we will still need human intervention.

One area of improvement possible today is preanalytics. To assess specimen integrity and suitability, it would be nice to have a camera installed at the beginning of the automation line to capture the volume and color of specimen before it reaches the analyzer. But how do we solve the problem of add-ons? You still have to have that human intervention where the specimen has to be retrieved and reloaded. Then there is the instrument maintenance. Unless we completely automate that particular process, we will always have to assign a technologist to tend to the instruments. Finally, someone still needs to review calibration and QC data.

What we're seeing now, as our test menu and volumes expand, is the need to add a third party to the automation line, such as, for example, allergy testing or an automated mass spec platform. The need for more flexible and open automation systems is growing. I see that as a challenge in the future.

Dr. Lenz, if we're going to create these large core labs that have all the volume of a network pouring in, and there are esoteric tests that optimally we'd like to have on a line, that almost implies the need for open lines. As you look through your crystal ball at Randox, is that something that's top of mind for you as you plan for the future for labs?

Dr. Lenz (Randox): Absolutely. Our newest and largest chemistry analyzer, the RX Modena, is built to adapt to open line systems. We have not yet implemented this, but it is something we were conscious of when initially designing the system. This also ties into the idea of third-party reagents on open channels or developer channels, depending on the lab's core instrumentation. We are seeing more and more interest in adding third-party assays, which many instrument providers do not offer on their main systems. In that way labs can keep those niche tests automated without having to bring in an additional instrumentation vendor. They just require parameters from the reagent provider for those esoteric tests on their current instrumentation.

Dr. Alter, can you comment on what you've heard and offer insight into what your plans are as you direct these activities at Emory?

Dr. Alter (Emory): I'd like to offer one piece that was not touched on in terms of expanding automation. To the best of my knowledge, none of the major lines have set up good solutions to managing the small-volume tubes and microtainers. It is largely manual and a big issue if you're with a large pediatric hospital.

Looking forward, I hope we stay with one line across the system. It's economically efficient and, in my opinion, is a quality laboratory practice that improves patient care. The holy grail is to be standardized to one platform across the system, and my comment at the beginning of the discussion would reflect that not everybody has the resources to do that.

Isn't that also in some ways a phenomenon of consolidation? In other words, if I'm doing 3 million billed tests a year, I may not have the heft to demand some of the things I can demand if I'm doing 8 or 9 million billables per year. And doesn't that all feed into this sort of nuclear consolidation, you might say?

Dr. Alter (Emory): I would hope so. It depends on how much the administration of your institution values what the laboratory can bring to the table.

I want to end on an important topic that Dr. Alter raised. What is the value of the laboratory? We all live in this world in which there are a lot of pressures—PAMA, the difficulties with health care economics, not only in the United States but everywhere in the industrial world. And an important part of all laboratory enterprises are the results that come out of these automated lines in chemistry and immunoassay. Dr. Alter put his finger on an important point, which is we have to be able to articulate and express the value of these lab results. Denise, how does Siemens help folks in the laboratory articulate the value of what they do?

Denise Pastore (Siemens Healthineers): We're looking at the pressures that are on the laboratory in terms of PAMA and what the reduction in reimbursement means and the way the laboratory can address that challenge so it can remain a profit center versus a cost center. That would be done through our team of consultants. We can work with the laboratory to provide the right solution so we're not overcapitalizing or undercapitalizing, so we can enable them to meet the demands their service has to provide in terms of turnaround time for routine specimens and stats. That has to be seamless and help them meet their metrics daily. We also want to provide consistent quality, so we have to make sure there are checks and balances—that there are built-in reliability metrics, and, for consistency of results, make sure ours are solid. We want to make it as simple as possible to future proof the laboratory. With the more than 300 configurations we offer, we can handle all sorts of specimens.

To get back to a point Dr. Alter made earlier, it's hard to put microtainers and pediatric specimens on an automation line. However, we were able to successfully do that on the Atellica Solution with both tube top sample cups and also microtainers, and all within the same racks. You don't have to have specialty racks, which saves time and labor. And, as a result, there are better outcomes, which is exactly what the lab is meant to do.

Let me invite Jessica and Stephen to talk about the activities at Beckman Coulter, in particular in support of laboratories sustaining and even demonstrating their value to the overall health care system.

Stephen Ishii (Beckman Coulter): We agree it's important that the laboratory be able to show value. We consider ourselves partners with the laboratory in providing products able to do that, in increasing the lab's efficiency, for example. Being able to handle their future desired state is also important, whether it's going to be consolidation or growth. We want to be able to accommodate either one. And to the Siemens point, it is also important to be able to offer the right menu for current health issues. Cost is always an issue, so we'd like to be able to minimize that for the laboratory and address its budget concerns.

Jessica, what would you like to add?

Jessica Tubman (Beckman Coulter): One of the main goals of our organization is to elevate our customers' performance. What can we do to add benefits around automation for laboratories of all sizes, accelerate their care pathways by focusing on the right menu that's going to help in the most critical situations, and help through clinical insights. We talked about informatics as well and how that can tie the whole picture together, and how we can partner with them to do all of that.

Dr. Lenz, what can Randox do to help the labs demonstrate and even improve their value to the system?

Dr. Lenz (Randox): I would echo what the other vendors have said: It is important not just from a financial standpoint but from a clinical standpoint to be able to get reliable results to providers quickly, along with any required interpretation so they can act on that information in a timely manner. Randox is known for providing high-quality reagents and reliable results on our analyzers so that there are no questions about the quality of the results. The ability to expand testing on existing platforms via third-party reagents allows delivery of critical results to patients and clinicians more quickly than when sending those tests out to a reference lab. Even if these may be lower-volume tests, they often provide critical bits of information in diagnosing an acutely ill patient, and time to result can be crucial.

Delena, how is Roche working to help laboratories define and promote their value within health systems?

Carite

Delena Carite (Roche): We strive to help our customers build a sustainable solution for the future. One way is encouraging laboratory professionals to have long-term vision, to create and build a solution in the laboratory that's sustainable for the future. We also focus on enabling the laboratory management team to articulate to its leadership 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—bringing all these different labs together in an integrated health network.

Lastly, Roche is committed to driving the future of digital diagnostics. We offer a suite of software solutions that enable labs and health care providers to drive the future of care delivery, which in turn benefits the patient and demonstrates the value of laboratory medicine to health care.

Dr. Babic, would you like to make a few final comments?

Dr. Babic (MUSC): It's very important that we work as a team in having the robust product, having good manufacturing processes that will minimize variability between different product lots, and optimizing the assays with minimum interference and turnaround time. All of that helps our service, but we are also looking for help with the clinical decision support needs and the capability to educate the clinician and to provide the consultation.

Which tests are appropriate? Which tests are not appropriate? We need real-time data analytics to help us not only monitor our analytical processes but also monitor different trends and be able to come up with predictive pathways to help our clinicians manage the patients and be preventive, not reactive. I've seen attempts and shifts in industry in trying to get this real-time analytics data incorporated, and it's important, because if we are going to make sure we are active participants in clinical care, we do need to have that data and the ability to communicate effectively to a clinician.

Dr. Alter, how would you sum up for us what your thoughts are on these topics?

Dr. Alter (Emory): I can't do better than Dr. Babic, but I have to double down on usability for the technical staff and service from the vendors in real time. I realize communication is key among vendors and that in the corporate universe, it's important not to reveal everything until it has approvals and been verified, but I sometimes have wished over my 20 years that the vendors would have been more transparent regarding an issue identified by the lab by admitting to it and addressing it, as opposed to the standard mantra of "Please recheck your calibration or do another comparison study," or something. I've had handfuls of times across multiple vendors where we've identified issues and pulled our hair out and had to collect reams of data, only to have the scientific staff tell us, "We knew about this issue but we had to validate it from your end."