Lab needs driving coagulation analyzer market

Valerie Neff Newitt

January 2018—Customer wish lists help to define every generation of coagulation analyzers, test menus, and related technologies. That's evident in the recent and upcoming launches and the ongoing work of the companies whose analyzers are profiled in this issue in the 2018 coagulation analyzer product guide.

At Helena Laboratories, "We hear demands for easier connectivity, smaller sample sizes, greater availability of more specialty tests, like low-molecular-weight heparin and direct thrombin inhibitors," says Theresa Peveto, BSCLS, MT, hemostasis product manager. "And everyone wants a good activated partial thromboplastin time point-of-care test that is as reliable as an in-laboratory test." Toward that end, Peveto says Helena Laboratories is well into the development of a new analyzer with an especially broad platform that will include "new assays not normally seen."

For instrumentation, the smaller the better. "We will see the industry move toward smaller devices, something like a glucometer—quick, smaller sample sizes, smaller strips, less dependent on technique and technology," Peveto predicts.

Maria Peluso-Lapsley, MBA, senior product marketing manager in North America for Siemens Healthineers' chronic disease portfolio, notes that many customers are expanding and gaining more oversight of their hospital-affiliated offices and clinics. "They need simple solutions that don't require a lot of training. They want small analyzers that can transmit data, directly or indirectly via middleware, into their hospital information system and ultimately into their electronic medical record systems. Additionally, they want technology that does not disrupt flow, be it patient flow or workflow in an office or clinic."

For the health care networks that want to standardize equipment across the network, "our customers want an end-to-end enterprisewide solution," Peluso-Lapsley says.

At Instrumentation Laboratory, "We have asked customers, 'What do you need and what would make your life better?'" says Venita Shirley, MBA, MT(ASCP), director of hemostasis marketing in North America. One answer, she says, is time-saving convenience. "In response we have reengineered many reagents to be liquid, ready to use with robust stability, eliminating reconstitution time, acclimation time, and repetitive manual pipetting." HemosIL ReadiPlastin for prothrombin time testing on ACL Top and ACL Top Family 50 Series systems, for example, has onboard stability of 10 days, she says.

William Trolio, MBA, MT, vice president and chief scientific officer, of Bio/Data, says shortening processing time is paramount to his customers. "Specimen processing time is one of the more frustrating parts of platelet testing," he says. "Platelets are only good for about four hours. . . . And you may beat up the platelets so much during the preparation that you won't get the right results due to platelet activation or compromised sample conditions—icterus, hemolysis, or lipemia."

Trolio

Bio/Data is working to modify the centrifugation process "to minimize the amount of g-forces applied and shorten

the time so that labs get decent samples," Trolio says. "Right now people tend to do very slow spins to begin with—20 minutes or longer—and that is only to prepare half the sample. Then they have to spin it for another 20 minutes to get the blank. But we are now down to a time frame of under 10 minutes to have the two different samples that are needed. Since platelets are what we do, centrifugation is getting a lot of attention from us." He expects the new centrifuge will come to the market as a second-generation unit in the first part of this year.

"The health care industry is consolidating, hospitals are forming groups, groups are joining together and reconfiguring, purchasing is in a constant state of flux," says Susan L. Taylor, MS, MT(ASCP), director, STA marketing, Diagnostica Stago, "and it is all changing how the laboratory must respond. Labs, now recognized as business units, are expected to be centers of value."

"'Easy-to-use, reliable, high-throughput equipment that promotes efficiency and flexibility' cannot be a sales pitch," Taylor says. "Whereas we used to demonstrate the skills and the attributes of an instrument, now we must also demonstrate how they actually serve a specific customer in their work environment, in real time, and with their lab team. That is very different for us, but customers have a right to expect it."

Siemens launched in 2016 its first
point-of-care PT/INR device. The Xprecia Stride is a handheld coagulation analyzer that mimics the look of a smartphone and provides results in 60 seconds or under, Peluso-Lapsley says. "While the handheld concept is not new to the industry, what is new is that this device uses the same reagents for PT/INR that are used in the large analyzer portfolio. This feature ties into customers' desire to standardize equipment and reagents and better correlate results."

Another example of coagulation innovation is preanalytical checks, which "have been on chemistry analyzers forever," Taylor says. "Now coagulation analyzers are starting to respond in kind." Diagnostica Stago has developed a module that's in the presubmission stage with the FDA; the company is aiming for a 2019 entry into the market. The checks, which will run on the company's STA Max generation instruments, will detect hemolysis, icterus, and lipemia (HIL).

Taking a somewhat different approach, the ACL Top 50 Series systems from Instrumentation Laboratory identify and measure the allowable threshold for HIL. "With the ACL Top 50 Series systems," Shirley says, "HIL is measured against a 510(k)-cleared method for HIL, referencing a value. HemosIL products reference allowable HIL thresholds and the ACL Top 50 Series systems can accurately compare the HIL from patient samples to allowable thresholds. Using this method, the lab doesn't have to validate anything."

Company research has found that technologists and technicians over-reject samples, erring on the side of caution. "That is a big problem if those samples are from outpatient or critically ill patients," Shirley says. "This preanalytical system allows coagulation labs to automatically execute their policy on sample acceptance and rejection. When you automate your policies, you know they are being done correctly."

Capacity flexibility has become important in the past year or two, Taylor says. "Within some of these large hospital systems you might have a remote clinic that does a few tests, versus a large reference lab in the group that does the great bulk of testing. But both want to work off the same lot number of reagents. So in order to improve the management of the quality control results, and the normal ranges reported within a group's patient population, we are ready to offer flexibility in reagent packaging—multiple packaging with the same lot. This isn't something we have all done in the past."

This year Diagnostica Stago will introduce multiple package sizes—10 mL and 20 mL—for reagents used for PT/INR testing within a laboratory group. She expects this flexibility will affect not only efficiency of reagent use but also QC workflow and management of quality results, as well as the costs to manage those quality results.

The company aims in the next two months to improve workflow flexibility with the introduction of remote alarms and alerts on coagulation analyzers. They will be delivered via its expandable Coag Expert software system,

currently resident on its Max generation instruments.

Taylor describes a likely scenario: “Imagine you have set up all of your coags before dinner and then you go to the cafeteria. Suddenly your instrument has lost communication with your LIS. No worries, because this system will text your phone or send you an email. It will also manage onboard reagents, let you know if they are running low and if you need to intervene. It will also let you know if there is an alarm on the system of which you need to be aware, in the event you are somewhere else in the lab.” Taylor foresees this being particularly helpful for evening and night shifts running multiple departments or multiple instruments within a department.

Another new capability to be added to the Coag Expert software will enable connectivity, via a user-enabled portal, allowing technicians at Diagnostica Stago to “remote into an instrument for troubleshooting and fixes from our hotline,” Taylor says. “We also will be able to track levels of inventory from our site and let a user know if it is time to place an order for new reagent.”

Improved connectivity has a marked impact on information flow and overlaps into areas of prime concern such as QC. When, for example, devices throughout an enterprise can connect, directly or through middleware, compliance officers will be able to oversee QC at multiple sites from a stationary position.

One hospital-group customer has a single compliance officer who oversees 32 sites across a wide area, Taylor says. “People don’t want to manage QC by Excel spreadsheets coming from all over the group. Being able to connect one instrument to another and then to a monitor on that person’s desk is a benefit and something we will be introducing in the next year.” Taylor adds, “One person could remotely oversee QC at various other locations, review control results from all of the network-connected sites, create peer groups for the purpose of comparing data within all of the groups, all on their office monitor.”

Providing flexible connectivity is a shared goal, as evidenced by the Siemens acquisition last year of Conworx Technology, a Berlin-based developer of POC device interfaces and data management solutions. The result is Siemens’ expansive middleware open solution for connectivity, POCcelerator and UniPOC. Peluso-Lapsley explains, “This allows POC devices to send data to the middleware and beyond, to over 150 devices in spaces where Siemens does not necessarily have a presence. Open, enterprisewide connectivity is really where the market is headed.”

Siemens champions the integration of barcode readers because its utility goes beyond sample, test, and patient identification uses, Peluso-Lapsley says. “Integrated barcode readers can record a great deal of pertinent information. Think about what that could mean enterprisewise if a system is ever in an audit situation. If an auditor wants you to take patient sample XYZ and detail how it moved through the entire process, our integrated barcode reader has recorded the date of the test, the operator ID, which analyzer serial number ran it, patient identification, and the reagent and consumable lots used to run that patient result.”

Helena’s Peveto says everyone is hoping for a good point-of-care APTT test. “Most of the APTTs we see for POC are not as reliable as laboratory tests. There is a discrepancy between the two,” she says, “and that makes health care providers wary.”

Trolio of Bio/Data trumpets the need for better platelet testing. “People in the industry are realizing that platelets cause a lot more problems than typical coagulation factors, and they are figuring out ways to add platelet testing technology to their instrumentation.”
The von Willebrand factor activity assay is one that falls into the same realm of under-development, he says. “About a quarter of all hysterectomies performed to control heavy bleeding should not be done,” he says. “Patients may actually have one of the milder types of von Willebrand’s disease that can be easily treated.”

While most coagulation analyzers “do a pretty decent menu of coagulation tests,” Trolio says, “none of them had the ability to do platelet function tests until very recently.” He tips his cap to other companies, “particularly Siemens and Instrumentation Laboratory, for trying to fill those gaps.”

In the meantime, Bio/Data is developing a test for dual antiplatelet therapy. No good test exists to measure the effect of aspirin and Plavix independently, for example, primarily because the patient takes the two drugs at the same time and it is hard to separate them in the plasma, Trolio says. “We are working on a synthetic reagent that has the ability to recognize each independently.” The test will not only measure how a person metabolizes the drugs but also whether the drug is being taken as prescribed. “It would alert a physician as to whether the drug is in a patient’s system, as well as if it is working.”

Stago’s Taylor, too, speaks to the recognition of antiplatelet antibodies. “Heparin-induced thrombocytopenia has been a very hot topic, brought to the forefront of our clinical customers by our friends at Instrumentation Laboratory. We have to commend them.”

Instrumentation Laboratory launched HemosIL HIT-Ab(PF4-H) last March. It is the first on-demand, fully automated qualitative assay for the detection of anti-PF4-H antibodies, commonly associated with heparin-induced thrombocytopenia. “When the assay is used within the context of the 2013 ASH guideline, the negative predictive value is 99.6 percent,” Shirley says. “Patients with a negative result may safely remain on heparin therapy instead of being transitioned to alternative anticoagulants, which are expensive and pose a higher risk of bleeding.”

For laboratories in buying mode, Peluso-Lapsley offers her own checklist to consider. “Look for technology that allows for multi-parameters to be tested on a single platform, delivers efficiency, lowers total cost of ownership, utilizes a simple interface so technologies can be deployed with lower training costs, locks out unqualified operators, imposes a smaller footprint, allows devices to be location agnostic, and connects seamlessly.” She looks to the industry to miniaturize these technologies and develop wireless solutions that will allow data to move quickly. “That is where the future of coagulation is headed.”
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