

In coag, all eyes on new anticoagulants and new systems, 1/13:12

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The newer oral anticoagulants are top of mind not only inside coagulation labs but also for the companies committed to creating coagulation testing solutions.

"The rapid introduction of the new oral anticoagulant drugs and expanded indications for existing drugs are driving an urgent need for laboratory testing in cases of unexplained bleeding and surgery," says Diagnostica Stago's director of marketing, Hamid Erfanian, who reports that Stago is responding with research-use-only calibrators and controls for several of these drugs to enable rapid, automated testing.

Instrumentation Laboratory, too, is developing assays to meet this need, says director of marketing for North America commercial operations Venita C. Shirley. There are "a number of references in the literature that suggest certain situations, such as renal or hepatic insufficiency, might warrant understanding what the circulating concentrations of the new oral anticoagulants are," she says. And, says Siemens Healthcare Diagnostics' senior marketing manager, Jackie Hauser, MT(ASCP), increased use of such anticoagulants "will drive labs to look for easy ways to determine the presence or monitoring of these agents."

In addition to identifying needs related to the new oral anticoagulants, each of the three aforementioned companies in 2012 released a new platform, all of which are featured in this month's coagulation analyzers product guide. They are IL's ACL TOP 300 CTS hemostasis testing system, Siemens' Sysmex CA-600 systems, and Stago's STA Compact Plus.

The STA Compact Plus, released in July, incorporates the mechanical clot detection technology used in Stago's STA Compact analyzer and simultaneously performs clotting, chromogenic, and immunological assays in true random access, Erfanian says. The system's Coag ConneXion software, which standardizes patient and quality control results, was recently updated with expert rules that facilitate "greater compliance with current College of American Pathologists guidelines on factor assays," Erfanian says. The rules also allow for automatic detection of nonspecific inhibitors, addition of dilutions, selection of the appropriate results to report, and reruns of outliers, he adds.

In addition to its new system, Stago in 2012 introduced "manufacturer-recommended adaptations" of reagents to expand testing on its Destiny Max coagulation analyzer, which is also in the product guide. They are STA Liatest vWF for automated antigenic determination of von Willebrand factor, STA Stachrom protein C for automated chromogenic determination of protein C activity, and STA Liquid anti-Xa for automatic determination of unfractionated heparin and low-molecular-weight heparin. Also released to measure rivaroxaban levels were research-use-only calibrators and controls, which are to be used with STA Liquid anti-Xa.

IL's ACL TOP 300 CTS for low- to medium-volume labs, launched in June 2012, "offers complete standardization" with the company's ACL TOP family of hemostasis testing systems, Shirley says. It uses the same reagents, consumables, and software; has the same features; and yields the same results as the ACL TOP 500 and 700 systems, which are also in the product guide. The ACL TOP 300 performs clotting assays at a 671-nm wavelength and reports clotting assays on samples with low fibrinogen. Also launched in June was the HemosIL D-dimer HS 500 assay, which is approved for use, in conjunction with a pretest probability assessment model, to exclude deep venous thromboembolism in outpatients suspected of DVT and pulmonary embolism, Shirley says. In October, IL released the HemosIL protein S activity assay, which has an onboard stability time of six hours.

Siemens' Sysmex CA-600 automated hemostasis analyzers are designed to handle routine and specialty testing for low- and high-volume labs, Hauser says. The CA-620 model is for labs that conduct basic clotting tests. The CA-660 performs routine clotting tests as well as chromogenic and immunoassay tests, which include Siemens' Innovance antithrombin, D-dimer, and vWF assays.

At Helena Laboratories, hemostasis/point-of-care division global marketing manager Dave Pearman reports that use of his company's AggRAM platform continues to grow worldwide. Early this year, he says, the company will release an updated version of the analyzer's HemoRAM software with enhanced search features, improved instrument startup time, an expanded LIS output stream, and more. Helena also continues to offer its Cascade M and M-4 coagulation systems, he says.

Finally, Bio/Data Corp. last year introduced for its Platelet Aggregation Profiler 8E (PAP-8E) a telephone-guided calibration verification service called Tele-Check. With Tele-Check, says vice president and CSO William M. Trolio, a company service technician guides labs through the PAP-8E calibration verification process. A Bio/Data quality control representative later reviews the results generated. If the results are acceptable, the company issues and sends to the lab a certificate of testing and calibration verification and calibration sticker. Later this year, Trolio says, Bio/Data will introduce Collagen SRP, a research-use-only synthetic agonist for platelet function testing.

CAP TODAY's coagulation analyzers product guide includes systems from the aforementioned companies and from American Labor/Lab A.C.M., Cepheid, Chrono-Log Corp., and LABiTec GmbH. The companies supplied the information listed. Readers interested in a particular analyzer should confirm it has the stated features and capabilities.

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