

Coagulation analyzers: Recently released and soon to be seen

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January 2015—CAP TODAY's 2015 guide to coagulation analyzers begins here.

Diagnostica Stago last year released rivaroxaban and apixaban calibrators and controls (research-use only) for automated anti-Xa activity assessment. It expects in the coming months to submit them for 510(k) clearance, says Nichole Howard, Stago's communications specialist. The company will soon release the automated ecarin chromogenic assay for dabigatran (RUO).

Stago last fall received FDA clearance for the reagent STA-Liatest D-Di for the exclusion of pulmonary embolism in patients with low or moderate risk. To comply with CLSI guideline H59-A, Stago performed a two-year international prospective study.

The STA-R MAX, the second of the new MAX generation platforms from Stago (not listed in the guide), is expected to launch in the second half of this year. Howard says the STA-R MAX is an analyzer that "provides increased specimen throughput and efficiency, improved ergonomics, and the latest in integrated expert rules technology."

Instrumentation Laboratory, which offered webinars and user-group meetings last year on identifying the optimal test for a variety of clinical applications, has developed assays to measure direct oral anticoagulants, some of which have been commercialized outside the U.S., says Sally McCraven, senior manager of marketing communications at IL. She says IL continues to transition products from a lyophilized to a liquid ready-to-use format, including reagents for APTT, D-dimer, and anti-Xa. IL expects to commercialize a liquid PT reagent shortly, she says.

For information management, IL will soon introduce to customers its myIL, "a customized, single sign-on website experience providing access to all IL Web services, including on-demand webinars, AccuTrak QAP, and ISlweb," McCraven tells CAP TODAY. Also in development is the IL Hemostasis Data Management System.

The companies provided the information displayed on the following pages. Readers interested in a particular analyzer should confirm it has the stated features and capabilities.