

# On-demand assay for heparin-induced thrombocytopenia, 10/16

## **At the AACC show 2016**

**October 2016**—Instrumentation Laboratory introduced several innovations in hemostasis at the meeting, including the FDA 510(k)-cleared HemosIL HIT-Ab(PF4-H) assay for use on ACL Top Family Hemostasis Testing Systems. The fully automated, on-demand assay for heparin-induced thrombocytopenia detects antibodies associated with HIT on a hemostasis testing system. The liquid, ready-to-use immunoassay delivers results in minutes, allowing clinicians to make timely, well-informed therapeutic decisions.

“We are proud to remain at the forefront of hemostasis testing solutions with this major milestone, marking the first FDA clearance of a fully automated HIT antibody assay that delivers results in minutes,” Remo Tazzi, director of worldwide hemostasis marketing at IL, said in a statement.

Other products highlighted at the meeting were the ACL Top Family 50 Series Testing Systems, the HemoHub Intelligent Data Manager, HemoCell Specialized Lab Automation, and HemosIL ReditPlastin Assay. The ACL Top Family 50 series offers preanalytical quality assurance and risk-management and laboratory accreditation benefits. Automated preanalytical sample integrity checks identify underfilled sample tubes, abnormal sample aspiration potentially caused by clots, and assay-specific interference from hemolysis, icterus, and lipemia. Additionally, the systems offer enhanced laboratory accreditation tools to automate documentation for compliance with quality standards.

HemoHub Intelligent Data Manager connects all ACL testing systems and allows users to manage workflow, monitor quality control, and provide clinical decision support from a single workstation. It is scalable for an unlimited number of patient files and analyzer connections and features a KPI-configurable dashboard and configurable statistical report formats.

HemoCell centralizes control of hemostasis testing. Integrating the Thermo Scientific TCAutomation Laboratory Automation Solutions, ACL Top 750 LAS system, and HemoHub Intelligent Data Manager, HemoCell is designed to improve throughput and reduce turnaround times and preanalytical issues. Additionally, operator exposure to biohazards is reduced.

HemosIL ReditPlastin is a prothrombin time assay that offers high sensitivity and low ISI  $\approx 1.0$ . The analytical performance of the assay is comparable to the HemosIL RecombiPlastin 2G assay. Acclimation time and pipetting are not required, which reduces manual reagent handling. Recombinant human tissue factor and synthetic phospholipids components provide lot-to-lot consistency. The assay is fully validated for use and stable for 10 days in original vials on ACL Top Family and new ACL Top Family 50 Series Hemostasis Testing Systems.

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