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IL obtains 510(k) clearance for ACL TOP Family 50 Series Hemostasis Testing Systems

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Instrumentation Laboratory (IL) today announced the 510(k) clearance of their latest innovation, the ACL TOP Family 50 Series Hemostasis Testing Systems, by the US Food and Drug Administration (FDA). Designed for mid-to-high-volume clinical laboratories, including those using Lab Automation tracks, the ACL TOP Family 50 Series Systems represent a *true* breakthrough in Hemostasis Quality Management for routine and specialty testing. Commercialization in the US will commence in 2016.

The ACL TOP Family 50 Series systems offer unprecedented pre-analytical quality assurance, risk- management and laboratory accreditation benefits. Automated pre-analytical sample integrity checks identify under-filled sample tubes, abnormal sample aspiration potentially caused by clots, and assay-specific interference from hemolysis, icterus and lipemia. Additionally, the new systems offer enhanced laboratory accreditation tools to automate documentation for compliance with quality standards.

"This is a major milestone for Hemostasis laboratory testing. New ACL TOP Family 50 Series systems are designed to address the key challenges healthcare providers face today: improve patient care, improve patient satisfaction, and reduce total cost of care," said Giovanni Russi, VP of Worldwide Marketing at IL. "Now, IL can offer laboratories a complete and standardized hemostasis testing solution that automates pre-analytical sample checks, and provides greater confidence in test results, lowers risk of clinical errors, and reduces unnecessary patient sample redraws."

The ACL TOP Family 50 Series is a *true* standardized platform comprised of five models: ACL TOP 750 and ACL TOP 750 CTS with closed-tube sampling (CTS) for high volume labs, ACL TOP 750 LAS for lab automation tracks, ACL TOP 550 CTS for mid-high volume labs, and ACL TOP 350 CTS for mid-sized labs. All models offer the same superior performance and usability throughout the entire testing process.

Instrumentation Laboratory Receives Clearance from US FDA for New ACL TOP Family 50 Series Hemostasis Systems in Selected Territories

IL initiated commercialization of the new ACL TOP Family 50 Series systems in Europe upon receiving the European CE IVD Mark, in late 2014. Since then, the systems have been introduced in Japan, South Korea, Australia and other international territories.

The ACL TOP Family remains the most advanced and successful Hemostasis testing platform in the world today. The addition of the new ACL TOP Family 50 Series systems to the IL portfolio will further strengthen their franchise and ensure the Company's leadership position in Hemostasis diagnostics in the future.

Complementing the new ACL TOP Family 50 Series is the Company's comprehensive HemosIL® assay menu. IL offers a complete line of general screening and specialty testing assays for the diagnosis and management of bleeding and thrombotic disorders.

Source:

Instrumentation Laboratory
