Press Release



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WERFEN COMMERCIALIZES ACL TOP® FAMILY 70 SERIES HEMOSTASIS TESTING SYSTEMS IN NORTH AMERICA

-Delivering Optimized Workflow Across the Hemostasis Laboratory Network with a Powerful Combination of Quality and Efficiency-

Bedford, MA, March 31, 2025—Werfen today announced the commercialization of ACL TOP Family 70 Series Hemostasis Testing Systems in North America, following 510(k) clearance by the US Food and Drug Administration and licensure by Health Canada. These systems represent the next generation of market-leading ACL TOP Systems, building upon Werfen's established legacy of quality and innovation in Hemostasis testing, with enhanced efficiency and connectivity across an entire laboratory network.

To streamline and optimize workflow, ACL TOP Family 70 Series systems offer centralized QC and performance verification management. When connected to HemoHub[™] Intelligent Data Manager, synergistic integration allows uniform application of a laboratory's Quality Management System, across multiple instruments and sites, from one centralized location; transcription errors are eliminated, and report generation and storage automated. Performance verification studies (required, for example, with new lots of reagents) that today involve a fivestep manual process, are reduced to a two-step automated process, saving significant staff time, improving quality and reducing costs.

"The ACL TOP Family 70 Series clearly demonstrates Werfen's commitment to innovation and continuous quality improvement in Specialized Diagnostics. Built upon an incredibly strong foundation, our new systems offer even greater efficiency and quality to hospital laboratories, where test volumes continue to grow, while resources decrease," said Remo Tazzi, Vice President Worldwide Marketing and Service at Werfen. "Feedback from initial customers has been very positive, reinforcing the value ACL TOP 70 Series systems deliver. We look forward to expanding placements of these new systems throughout North America and globally, bringing the best in Hemostasis testing to hospital and patients around the world."

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Werfen Commercialized ACL TOP Family 70 Series Hemostasis Testing Systems in North America

The broadest portfolio of truly standardized Hemostasis systems, five ACL TOP Family 70 Series models accommodate a range of testing needs from low- to medium-volume (ACL TOP 370) to medium- to high-volume (ACL TOP 570), up to the highest-volume, fully automated labs (ACL TOP 770, ACL TOP 770 S, ACL TOP 770 LAS). All models offer the *same* quality results, intuitive software, reagent portfolio, features, usability and training, for superior performance, flexibility and scalability throughout the testing process. To ensure security and uninterrupted functionality, cybersecurity and privacy-by-design are integrated.

ACL TOP Family 70 Series systems feature automated preanalytical checks, first introduced as a breakthrough, by predecessor, the ACL TOP Family 50 Series. Detecting and flagging samples that exceed assay-specific thresholds for Hemoglobin, Icterus and Lipemia, as well as underfilled sample and those with clots, the systems assure quality results.

ACL TOP Family 70 Series systems are not available in all countries.

About Werfen's Hemostasis Complete Solution

ACL TOP Family 70 Series systems are part of Werfen's Complete Solution for Hemostasis testing. A comprehensive panel of HemosIL[®] assays for routine to specialty testing offer complete disease statement management. For even greater productivity, HemoCell[®] Specialized Lab Automation, customized for each lab, optimizes testing workflow. HemoHub Intelligent Data Manager provides central management of Hemostasis laboratory networks. And Werfen's award-winning* Service and Support teams partner with customers to ensure optimal instrument operation, and provide training and 24/7 Technical Support.

Werfen (<u>www.werfen.com</u>), founded in 1966, is a worldwide developer, manufacturer and distributor of specialized diagnostic instruments, related reagents, automation workcells, and data management solutions for use primarily in hospitals and independent clinical laboratories. The Company's clinical areas of focus include Hemostasis, Acute Care, Transfusion, Autoimmunity, and Transplant. Werfen's Acute Care portfolio includes the new GEM Premier 7000 with iQM3, the GEM[®] Premier[™] 5000 with iQM[®]2, GEM Premier 3500 system with iQM, GEM Premier ChemSTAT[™] system, ROTEM[®] viscoelastic testing systems, Hemochron[™] systems, VerifyNow[™] platelet function testing system, and Avoximeter[™]1000 CO-Oximeter, GEMweb[®] Plus 500 Custom Connectivity and GEMweb Live. The Hemostasis portfolio includes ACL TOP[®] Family 50 Series and ACL TOP Family Hemostasis Testing Systems, ACL AcuStar[®] system, ACL Elite[®] systems, HemoCell[™] Specialized Lab Automation, HemoHub[™] Intelligent Data Manager, along with the comprehensive line of HemosIL[®] assays.

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