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**INSTRUMENTATION LABORATORY RECEIVES US FDA CLEARANCE
FOR HEMOSIL[®] ACUSTAR HIT-IgG_(PF4-H) ASSAY AND CONTROLS**

— First Fully Automated Chemiluminescent Assay for Heparin-Induced Thrombocytopenia—

Bedford, MA, October 16, 2017 —Instrumentation Laboratory (IL) today announced the 510(k) clearance of the HemosIL AcuStar HIT-IgG_(PF4-H) Assay and HemosIL AcuStar HIT Controls by the US Food and Drug Administration (FDA). The HemosIL AcuStar HIT-IgG_(PF4-H) Assay is the first on-demand, fully automated, chemiluminescent reagent on a hemostasis testing system for the qualitative detection of platelet factor 4 (PF4)-heparin complex IgG antibodies associated with Heparin-Induced Thrombocytopenia (HIT). It provides enhanced detection of HIT antibodies on ACL AcuStar[®] Hemostasis Testing Systems in specialty and hospital Hemostasis laboratories. Chemiluminescent technology offers analytical excellence through an expansive working range for high analytical sensitivity and precision.

“Now hospitals and specialty labs can perform HIT testing 24/7 on the ACL AcuStar Testing System with no special training required”, said Giovanni Russi, Vice President of Worldwide Marketing and Service at IL. “The HemosIL AcuStar HIT-IgG_(PF4-H) assay is an important complement to our latex-based HemosIL HIT-Ab_(PF4-H) assay, expanding the IL portfolio for this critically important test. These assays enable faster and more effective patient management, reducing expensive and unnecessary therapeutic changes.”

HIT is a severe immunologic adverse reaction to a Heparin complex that paradoxically causes blood clots to form, leading to venous and/or arterial thrombosis, and can be fatal. Diagnosis of HIT is key to positive patient outcomes and may prompt initiation of alternative anticoagulants. Unlike existing manual processes, HemosIL HIT-IgG_(PF4-H) is a liquid, ready-to-use IgG antibody isotype specific immunoassay that delivers results in minutes—on-demand, 24/7—allowing clinicians to make timely, well-informed therapeutic decisions, essential in critical scenarios.

HemosIL HIT-IgG_(PF4-H) joins the HemosIL HIT-Ab_(PF4-H) assay, which received 510(k) clearance for use on the IL ACL TOP[®] Family of Hemostasis Testing Systems in 2016.

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About ACL AcuStar Hemostasis Testing Systems

ACL AcuStar Systems bring full automation to specialty testing that, until now, has required time-consuming manual processes and highly technical skills. Chemiluminescent technology, designed specifically for the Hemostasis lab, allows superior range and analytical sensitivity compared to ELISA or immunoturbidimetric assays. Advanced assay technology, complemented with end-to-end automation, provides a quantum leap in simplicity and throughput, while ensuring uncompromised results.

About HIT

HIT is one of the most common of all adverse drug effects, due to the sheer volume of patients receiving heparin therapy. Approximately 0.2–2.0% of patients treated with heparin (over 12 million patients/year in the US, alone) develop HIT. In most cases HIT is caused by IgG antibodies specific to PF4-Heparin complexes binding and activating platelets. If HIT is untreated, risk for serious sequelae (eg, stroke, pulmonary embolism, death) increases significantly. Positive outcomes depend on early and accurate diagnosis and prompt initiation of alternative anticoagulants.

Instrumentation Laboratory (www.instrumentationlaboratory.com), founded in 1959, is a worldwide developer, manufacturer and distributor of in vitro diagnostic instruments, related reagents and controls for use primarily in hospitals and independent clinical laboratories. The Company's product lines include Critical Care, Hemostasis and Patient Blood Management products and services. The IL Critical Care portfolio, includes the new GEM Premier™ 5000 system with Intelligent Quality Management 2 (iQM®2), GEM Premier 4000 and 3500 analyzers with iQM, GEMweb® Plus 500 Custom Connectivity, Hemochron®, VerifyNow® and Avoximeter® systems. The IL Hemostasis portfolio includes new ACL TOP® Family 50 Series Hemostasis Testing Systems and the original ACL TOP Family of Systems, fully automated, high-productivity analyzers. IL also offers the ACL AcuStar®, ACL Elite®, and other Hemostasis analyzers, along with the comprehensive HemosIL® line of reagents. In Patient Blood Management, IL offers the ROTEM product line. IL is based in Bedford, Massachusetts, USA.

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