Instrumentation Laboratory
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Press Release

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INSTRUMENTATION LABORATORY RECEIVES US FDA CLEARANCE FOR NEW HEMOSIL® HIT-AB(PF4-H) ASSAY

—First Fully Automated On-Demand Assay for Heparin-Induced Thrombocytopenia—

Bedford, MA, July 26, 2016 —Instrumentation Laboratory (IL) today announced the 510(k) clearance of the HemosIL HIT-Ab(PF4-H) assay for use on ACL TOP® Family Hemostasis Testing Systems, by the US Food and Drug Administration (FDA). The first, fully automated, on-demand assay for Heparin-Induced Thrombocytopenia (HIT) on a Hemostasis testing system, HemosIL HIT-Ab(PF4-H) detects antibodies associated with HIT.

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-Ab(PF4-H) is a liquid, ready-to-use immunoassay that delivers results in minutes—on-demand, 24/7—allowing clinicians to make timely, well-informed therapeutic decisions, essential in critical scenarios.

"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," said Remo Tazzi, Director Worldwide Hemostasis Marketing at IL. "Our mission is to develop products that enhance patient care while enabling greater efficiency in the laboratory. The HemosIL HIT-Ab(PF4-H) assay is an exemplary achievement of this goal."

Management of HIT involves cessation of heparin therapy and initiation of expensive alternative anticoagulants. Delays in diagnosis caused by prolonged test turnaround time can lead to speculative treatment, increasing bleeding risk for the patient and increasing drug costs, if replacement anticoagulant therapy is used unnecessarily. Conversely, if patients with HIT remain on heparin while awaiting laboratory confirmation of diagnosis, they may develop more serious complications leading to increased morbidity and mortality. Therefore, the availability of on-demand HIT antibody testing plays a critical role in better managing HIT, providing results when treatment decisions are needed, and ultimately minimizing patient risk and reducing costs.[1,2]

More About HIT

HIT is one of the most common 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.[3] 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.

ACL TOP Family of Testing Systems*

The ACL TOP Family of instruments remains the most advanced and successful Hemostasis testing platform in the world today. A complete line of analyzers, all designed with the same high standards of operation and functionality, the ACL TOP Family offers a truly standardized platform for routine or specialty testing in mid- to high-volume labs, for efficiency and enhanced patient care.

*ACL TOP Family is comprised of ACL TOP 300 CTS; ACL TOP 500 CTS; ACL TOP 700; ACL TOP 700 CTS; ACL TOP 700 LAS models.

References

1. Caton, S, *et al*. Assessing the clinical and cost impact of on-demand immunoassay testing for the diagnosis of heparin-induced thrombocytopenia. *Thromb Res.* 2016 Apr;140:155-62. http://dx.doi.org/10.1016/j.thromres.2016.01.025
2. Warkentin, TE. Demand on-demand testing for the diagnosis of heparin-induced thrombocytopenia. *Thromb Res.* 2016 Apr;140:163-4.. http://dx.doi.org/10.1016/j.thromres.2016.02.015
3. Warkentin TE. New approaches to the diagnosis of Heparin-Induced Thrombocytopenia. *CHEST.*2005; 127:35S–45S.

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