## **Press Release**

A Werfen Company

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### INSTRUMENTATION LABORATORY LAUNCHES HEMOSIL® ACUSTAR ADAMTS13 ACTIVITY ASSAY IN EUROPE AND OTHER INTERNATIONAL MARKETS\*

### ---- The Only Automated, On-Demand Test to Aid in the Diagnosis and Monitoring of Thrombotic Thrombocytopenic Purpura ----

**Bedford, MA, Thursday, September 19, 2019** – Instrumentation Laboratory (IL) today announced commercialization of the HemosIL AcuStar ADAMTS13 Activity Assay in the European Union and other international markets. For use on the ACL AcuStar<sup>®</sup> Hemostasis Testing System, this fully automated, chemiluminescent immunoassay offers clinicians rapid, on-demand ADAMTS13 activity testing to aid in the diagnosis and monitoring of Thrombotic Thrombocytopenic Purpura (TTP), with first results produced in approximately 30 minutes. The first and only automated, on-demand assay for the measurement of ADAMTS13 Activity, the HemosIL AcuStar ADAMTS13 Activity Assay measures the only biomarker specific for TTP, a lifethreatening, hematologic disease.

When plasma exchange (PLEX), the standard of care in the treatment of TTP, is promptly initiated, mortality can be reduced from approximately 90% to 10-20%. Because current laboratory methods, including enzyme-linked immunosorbent assays (ELISA) and fluorescence resonance energy transfer (FRET), require specialty lab testing with turnaround times up to three days, PLEX is frequently initiated without confirmation of TTP diagnosis. However, of suspected TTP patients, approximately 66% test negative for the disease.<sup>1</sup> Now, with the HemosIL AcuStar ADAMTS13 Activity Assay, informed patient management decisions can be made in minutes, potentially eliminating days of unnecessary PLEX treatment and associated adverse events, saving significant cost and improving care in the majority of suspected patients.

"Our new HemosIL ADAMTS13 Activity Assay is a true reflection of our mission to enhance patient care through innovation. With significantly faster results, it offers tremendous improvements in the diagnosis and treatment of TTP," said Remo Tazzi, Director of Worldwide Marketing Hemostasis at IL. "We are very proud to introduce this important assay to clinicians who manage critically ill patients."

1 of 2

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# Instrumentation Laboratory Launches HemosIL<sup>®</sup> AcuStar ADAMTS13 Activity Assay in Europe and Other International Markets

Like all reagents on the ACL AcuStar System, the HemosIL AcuStar ADAMTS13 Activity Assay is ready-to-use, cartridge-based and available on-demand, 24/7. Chemiluminescence extends linearity to quantify extremely low levels of ADAMTS13 activity (linear range  $\geq$ 0.2%) and is traceable to the World Health Organization ADAMTS13 Activity First International Standard, ensuring results accuracy.

### About the ACL AcuStar Hemostasis Testing System

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, complete testing results in as little as 25 minutes, with no special training required.

### About Thrombotic Thrombocytopenic Purpura (TTP)

TTP is a rare (1:1,000,000), life-threatening, hematologic disease, in which platelet-rich thrombi form in the microvasculature due to ADAMTS13 deficiency (a von Willebrand factor protease). It requires immediate evaluation and management to provide life-saving treatment. While the standard of care is PLEX, this treatment may be unnecessarily administered in the absence of ADAMTS13 results.

#### **Reference**

1. Kim CH, et al. ADAMTS13 test and/or PLASMIC clinical score in management of acquired thrombotic thrombocytopenic purpura: a cost-effective analysis. *Transfusion*. 2017;57(11):2609–18.

\*Not available in all countries. Not saleable in the United States and Canada.

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. Based in Bedford, MA, USA, IL operates Technology Centers there, as well as in Orangeburg, NY, USA, San Diego, CA, USA, and Munich, Germany. IL is a company of Werfen, based in Barcelona (Spain). IL Acute Care Diagnostics product offerings include the new GEM<sup>®</sup> Premier<sup>™</sup> ChemSTAT system with Intelligent Quality Management (iQM<sup>®</sup>), GEM Premier 5000 system with iQM2, GEM Premier 4000 and 3500 analyzers with iQM, GEMweb<sup>®</sup> Plus Custom Connectivity, ROTEM<sup>®</sup> viscoelastic testing systems, Hemochron<sup>™</sup> systems, VerifyNow<sup>™</sup> platelet-function testing system, and Avoximeter<sup>™</sup> CO-Oximeters. The IL Hemostasis portfolio includes new ACL TOP<sup>®</sup> Family 50 Series and ACL TOP Family of Hemostasis Testing Systems, fully automated, high-productivity analyzers, HemoCell<sup>™</sup> Specialized Lab Automation and HemoHub<sup>™</sup> Intelligent Data Manager. IL also offers the ACL AcuStar<sup>®</sup>, ACL Elite<sup>®</sup>, and other Hemostasis analyzers, along with the comprehensive HemosIL<sup>®</sup> line of reagents.

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