Instrumentation Laboratory
A Werfen Company

Press Release

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INSTRUMENTATION LABORATORY RECEIVES US FDA CLEARANCE FOR NEW GEM PREMIER CHEMSTAT™ TESTING SYSTEM

— Designed for Rapid Basic Metabolic Testing in Emergency Departments and Other Hospital Point-of-Care Settings —

Bedford, MA, Wednesday, March 6, 2019 – Instrumentation Laboratory (IL) today announced the 510(k) clearance of their latest innovation, the GEM Premier ChemSTAT *in vitro* diagnostic (IVD) analyzer with Intelligent Quality Management (iQM®) by the US Food and Drug Administration (FDA). A new and complementary member of the GEM® Premier™ Family, the GEM Premier ChemSTAT system is designed for rapid basic metabolic panel (BMP) testing at the point of care, primarily in hospital Emergency Departments (ED) and the Clinical Laboratory. The system provides laboratory-quality results in less than 70 seconds, from venous or arterial whole blood samples with no preparation required, helping to improve patient management, reduce length of stay and enhance efficiency.

Featuring a complete BMP panel, the system offers three new tests—Creatinine, Blood Urea Nitrogen (BUN) and measured tCO_2—in addition to Sodium, Potassium, Ionized Calcium, Chloride, Glucose, as well as Lactate, Hematocrit, pH and pCO_2. BMP is one of the most widely ordered tests for diagnosing acute conditions, such as kidney failure, insulin shock, respiratory distress, and arrhythmias.

“The addition of the GEM Premier ChemSTAT system to our Acute Care Diagnostics instrument portfolio allows us to offer a more complete menu and extends our reach into the Emergency Department and other clinical settings,” said Giovanni Russi, VP of Worldwide Marketing at IL. “With the flexibility of venous sampling and lab-quality results in 70 seconds, the system will play a key role in prioritizing acutely ill patients, expediting time to treatment, increasing operational efficiencies and enhancing patient care.”

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To assure laboratory-quality results at the point of care, the GEM Premier ChemSTAT system integrates Intelligent Quality Management (iQM), provides a complete picture of quality for each sample—continuously and in real-time—and automated detection, correction and documentation of any action it performs, to ensure the quality of every test result and supporting immediate patient management decisions. No competitive system offers this assurance of sample quality and compliance.

Additionally, GEMweb® Plus Custom Connectivity enables management of all GEM Premier analyzers in a network, including the GEM Premier ChemSTAT system, for complete control of instruments, operators and data oversight from any location. GEM Premier systems, combined with GEMweb Plus 500 connectivity, deliver a complete solution for improved patient care and efficiency.

Like all GEM Premier systems, GEM Premier ChemSTAT analyzers are also exceptionally easy to use. The all-in-one, multi-use GEM PAK cartridge automates the most labor- and skill-intensive processes. No maintenance is needed and all testing components are self-contained, limiting biohazard and infection risk for operators and patients. The PAK is simply replaced every three weeks with no additional handling required.

As the Company continues to receive regulatory approvals in markets around the world in the coming months, commercialization plans for the GEM Premier ChemSTAT system will be announced.

About the IL Acute Care Diagnostics Portfolio

The integrated and comprehensive Acute Care Diagnostics product portfolio helps clinicians and laboratorians achieve better patient outcomes, lower total cost of care, assure regulatory compliance and improve operational efficiency in hospital acute care settings. For Blood Gas testing, the GEM Premier family, including GEM Premier 5000, 4000, 3500 and 3000 systems, and Avoximeter™ portable CO-Oximeters, simplify point-of-care operations by automating key labor- and skill-intensive tasks, including quality management and system maintenance. For Whole Blood Hemostasis testing, ROTEM® viscoelastic testing systems, the Hemochron™ Signature Elite system and VerifyNow™ platelet-reactivity testing system, inform key clinical decisions regarding transfusions, bleeding risk and anticoagulant dose adjustment during surgical and interventional procedures. From Cardiovascular Operating Rooms and Catheterization Labs, to Intensive Care Units and Emergency Departments, whole-blood, cartridge-based instruments with integrated data management solutions from IL address today's healthcare challenges, improving efficiency and enhancing patient care.

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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® Premier™ 5000 system with Intelligent Quality Management 2 (iQM®2), GEM Premier 4000 and 3500 analyzers with iQM, GEMweb® Plus Custom Connectivity, ROTEM® viscoelastic testing systems, Hemochron™ anticoagulation systems, VerifyNow™ platelet function testing system, and Avoximeter™ CO-Oximeters. The IL Hemostasis portfolio includes new ACL TOP® Family 50 Series and ACL TOP Family of Hemostasis Testing Systems, fully automated, high-productivity analyzers, HemoCell™ Specialized Lab Automation and HemoHub™ Intelligent Data Manager. IL also offers the ACL AcuStar®, ACL Elite®, and other Hemostasis analyzers, along with the comprehensive HemosIL® line of reagents.

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