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**WERFEN UNVEILS GEM® PREMIER™ 7000 with iQM®3
BLOOD GAS TESTING SYSTEM AT ADLM ANNUAL MEETING**

**— Introducing Hemolysis Detection in Point-of-Care
Blood Gas Testing for the First Time Ever —**

Bedford, MA, July 30, 2024—Werfen today announced the introduction of the GEM Premier 7000 with Intelligent Quality Management 3 (iQM3) at the Association for Laboratory Medicine (ADLM) Annual Meeting (formerly the American Association for Clinical Chemistry), which has received 510(k) clearance by the US Food and Drug Administration. The GEM Premier 7000 with iQM3 represents a breakthrough in blood gas testing, offering hemolysis detection for the first time at the point-of-care (POC).

As the number one source of preanalytical error, hemolysis accounts for up to 70% of all such errors.¹ Despite its prevalence throughout different areas of the hospital, hemolysis is not visible in whole blood, and can go unrecognized. Hemolysis occurs when red blood cell membranes rupture, causing cellular contents to leak into the surrounding fluid, which can elevate potassium results up to 152%.² In samples impacted by hemolysis, low potassium levels can appear normal and normal levels can appear high. Consequences of in vitro hemolysis can include inappropriate patient management, increased length of stay, and increased costs, among others.³⁻⁷

“While hemolysis in point-of-care testing has been widely recognized as a significant problem, and the potential value of its detection tremendous, most have viewed this as an unsolvable challenge—until now. We are exceptionally proud to have solved this challenge with the patented technology in our new GEM Premier 7000 with iQM3 system,” said Remo Tazzi, Vice President Worldwide Marketing and Service at Werfen. “Feedback from our initial customers has been very positive, and we look forward to expanding placements of these new systems throughout the US, and ultimately, the world, to enhance both patient care and efficiency.”

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Werfen Unveils GEM Premier 7000 with iQM3 Blood Gas Testing System at ADLM Annual Meeting

“Every day our clinicians make critical decisions, based on potassium measurements. Knowing whether a blood sample is hemolyzed is crucial for interpretation of potassium results,” said Heather Stieglitz, PhD, D(ABCC), Co-Director of Clinical Chemistry and Point-of-Care Testing, The Ohio State University Wexner Medical Center, Columbus, Ohio. “While we have had the capability to detect hemolysis in a central laboratory, it was missing at the point of care. The GEM Premier 7000 closes this gap, and we are confident that our potassium results will allow clinicians to make safe and rapid decisions for the care of our patients.”

In vitro hemolysis is prevalent throughout the hospital. In neonatal intensive care units, up to half of whole blood samples have been shown to be hemolyzed, while in emergency departments, approximately 20% can be hemolyzed.^{1,8-10} Undetected hemolysis can lead to inappropriate or delayed treatment, unnecessary redraws, increased staff time, and higher costs.³⁻⁷

The system’s hemolysis detection is based upon patented acoustofluidic technology for plasma separation, combined with photometric determination. In just 45 seconds, the GEM Premier 7000 detects hemolysis, while delivering a complete menu of results (pH, pO_2 , pO_2 , sodium, potassium, ionized calcium, chloride, glucose, lactate, hematocrit, total hemoglobin, total bilirubin and CO-Oximetry (tHb, O_2Hb , COHb, MetHb, HHb, sO_2).

iQM3, a real-time, automated, quality management system, continuously ensures sample quality across the most common preanalytical errors, including hemolysis, micro-clots, bubbles and lipemia. It automatically checks sample integrity before, during, and after every analysis, and corrects and documents errors. This helps assure quality results and compliance, 24/7, and informs and expedites critical decision-making.

The all-in-one GEM PAK cartridge automates labor- and skill-intensive processes and offers a variety of menu and test-volume configurations, tailored to the clinical setting. GEMweb Plus 500 Custom Connectivity simplifies control and compliance, enabling comprehensive management of all systems, operators, and data oversight. Its sample handling reports help identify operator competency gaps and training needs, for continuous quality improvement.

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The GEM Premier 7000 with iQM3 system is the latest innovation in Werfen's long line of GEM Premier blood gas testing systems. The most recent, previously introduced model is the GEM Premier 5000 with iQM2, which introduced IntraSpect™, performing continuous quality checks during sampling, in addition to before and after every sample.

The GEM Premier 7000 with iQM3 system is not Health Canada-licensed. It is not available in all countries.

About Werfen's Acute Care Diagnostics Portfolio

The GEM Premier 7000 with iQM3 system is part of Werfen's integrated and comprehensive ACD product portfolio—helping clinicians and laboratorians achieve better patient outcomes, lower total cost of care, assure accreditation compliance and improve operational efficiency in hospital acute care settings. For Whole Blood Hemostasis testing, ROTEM viscoelastic testing systems, the GEM Hemochron™ 100 system, and the VerifyNow™ platelet-reactivity testing system inform key clinical decisions regarding transfusion, bleeding risk and heparin dose adjustment during surgical and interventional procedures along with a clinical assessment of the patient's condition and other laboratory tests. For Blood Gas testing, the GEM Premier systems, including GEM Premier 7000, 5000 and 3500 systems, and the Avoximeter™ 1000 portable CO-Oximeter, simplify POC operations by automating key labor- and skill-intensive tasks, including quality management and system maintenance. From Cardiovascular Operating Rooms and Catheterization Labs, to Intensive Care Units and Emergency Departments, whole-blood, cartridge-based systems with Werfen's integrated data management solutions, help hospitals improve efficiency and enhance patient care.

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Werfen (www.werfen.com), 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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