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Press Release

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WERFEN APPLAUDS SIGNIFICANT PUBLICATION URGING ACTION ON THE RISKS OF UNDETECTED HEMOLYSIS

Clinical Experts Issue Special Report Calling for Greater Education, Testing, and Prevention of In Vitro Hemolysis in High-Risk Settings

Bedford, MA, December 11, 2025 — Werfen today announced their commendation for the recent publication of a significant, multi-author Special Report, underscoring the urgent need to address the risks of undetected in vitro hemolysis, a preanalytical error with the potential to negatively impact patient care.[1] The Company congratulates the authors on this important and timely publication.

Published in the *Journal of Applied Laboratory Medicine* (*JALM*)—an international, peer-reviewed publication—the Special Report, "Handling Hemolytic Blood Samples from High-Risk Clinical Areas: A Call to Action," advocates for a coordinated, hospital-wide approach to better detect, prevent, and manage in vitro hemolysis, particularly in high-risk settings, such as emergency departments and intensive care units.[1] The report highlights hemolysis as a significant cause of preanalytical error, with the potential to cause misinterpretation of critical results, most notably potassium.

"This important publication highlights the prevalence and risks of undetected hemolysis in whole blood samples, which can impact test results throughout the hospital," said Annie Winkler, MD, Chief Medical Officer at Werfen. "With innovative technology that detects hemolysis at the point of care in seconds, we can help hospitals expedite decision-making, enhance efficiency, and most importantly, improve patient management."

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As the number one source of preanalytical error, hemolysis accounts for up to 70% of all such errors.[2] Despite its prevalence throughout the hospital, it can often go unrecognized. Hemolysis is the disruption of red blood cells, triggering the release of hemoglobin and other intracellular components into plasma or serum. This can cause an elevation in potassium results, of up to 152%.[3] In samples impacted by hemolysis, low potassium levels can appear normal and normal levels can appear high. At the point of care, this can lead to inappropriate patient management, longer length of stay, unnecessary sample recollection and increased costs, among other consequences.[4-8]

In neonatal intensive care units, nearly half of whole blood samples have been found to be hemolyzed, while in emergency departments, up to 20% may be hemolyzed.[2, 9-11]

This Special Report reinforces the problem of in vitro hemolysis, emphasizes the need for hemolysis detection in whole blood and provides six recommendations as a call to action to address this significant preanalytical error.

Driving Innovation for Faster, More Informed Care

Last year, Werfen introduced the GEM® Premier™ 7000 with iQM®3, the first blood gas testing system that detects hemolysis at the point of care in just 45 seconds,[12] helping to inform appropriate patient management decisions and enhance patient care.[13] The GEM Premier 7000 with iQM3 also helps improve operational efficiency and reduce cost.[13]

For decades, Werfen has been a worldwide leader in Specialized Diagnostics. The Company remains committed to innovation, rooted in real-world collaboration with front-line emergency medicine physicians, ICU clinicians, anesthesiologists, and operating room teams. Incorporating feedback from these integral voices has helped shape solutions that directly address clinical needs and support safer, more effective care, such as blood gas testing that detects hemolysis at the point of care in seconds.

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To read the full Special Report, visit: https://doi.org/10.1093/jalm/jfaf082

Disclosure: Werfen has previously contributed to research funding for one of the authors, and several authors disclosed relationships with Werfen (among many other companies).

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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