

Nexsen Accelerates U.S. Diagnostics Market Entry with MCRA Partnership

Appointment of leading U.S. clinical research and regulatory advisory firm to guide FDA pathway and commercialization strategy

CA, UNITED STATES, November 6, 2025 /EINPresswire.com/ -- Nexsen Limited, a nano-biotechnology company developing next-generation point-of-care diagnostics, today announced the acceleration of its U.S. market entry for its GBS Rapid Sensor and Kidney

Function Diagnostics through the appointment of MCRA, a leading U.S.-based Clinical Research Organization and regulatory advisory firm specializing in medical devices, diagnostics, and biologics.



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MCRA is honoured to support NXN's development of their GBS Rapid Sensor & to play a role in the future of their diagnostic pipeline. We look forward to the continued partnership -exciting times ahead.”

Dr Natasha Griffin, Director of IVD Regulatory Affairs, MCRA

Partnership to Drive FDA Regulatory Strategy and Market Access

Under this new partnership, MCRA will advise Nexsen on its U.S. FDA regulatory pathway and support strategic planning for commercialization, including pre-submission coordination and early engagement with the FDA. The first FDA interaction for Nexsen's GBS Rapid Sensor is expected in early 2026.

The GBS Rapid Sensor is a point-of-care diagnostic designed to detect Group B Streptococcus (GBS) in expectant mothers on the day of labor, providing results within minutes compared to the days required by

traditional methods. This innovation targets a critical unmet need, with over 132 million births globally each year, and aims to reduce preventable complications caused by GBS infections.

Advancing Diagnostic Development Across Global Health Markets

Nexsen's Kidney Function Diagnostics are also advancing rapidly, with MCRA advising on

regulatory strategy to optimize progress toward first approvals. Chronic Kidney Disease affects approximately 700 million people globally, while Acute Kidney Injury impacts 7% of all hospital admissions and 30% of ICU admissions worldwide.

“The appointment of MCRA is a strategic accelerator for Nexsen as we advance towards US regulatory clearance and commercial entry. Their proven track record across FDA submissions and market access for breakthrough diagnostics will be instrumental as we drive the GBS Rapid Sensor and Kidney Function Diagnostics toward first approvals and early market penetration.”

“With our GBS Rapid Sensor clinical data now being collected under the guidance of Prof. Lisa Hui, and a clear regulatory roadmap being developed, we are building strong momentum toward positioning Nexsen as a global leader in rapid, point-of-care diagnostic technology. We are working towards an initial international market access and early sales as soon as the second half of 2026 for our GBS Rapid Sensor.”

— Mark Muzzin, Managing Director, Nexsen Limited

Building Commercial Readiness for Early Market Entry

MCRA's commercial and reimbursement divisions will also advise Nexsen on pricing, distribution, and market access strategies, ensuring the company maximizes first-mover advantage across maternal health and kidney diagnostic markets.

This collaboration follows the commencement of Nexsen's first clinical trial for the GBS Rapid Sensor, led by Professor Lisa Hui, a global authority in maternal-fetal medicine. The data generated will underpin upcoming U.S. and international regulatory submissions.

About Nexsen

Nexsen is a nano-biotechnology company developing a next-generation biosensing platform that combines ultra-bright nanoparticles, high-affinity bioreceptors, and modular lateral flow architecture to deliver Lab-quality diagnostics in a low-cost, user-friendly format. Nexsen's focus is on applications of its platform technology that address a significant unmet need in a globally important market.

Nexsen's lead diagnostic is the GBS Rapid Sensor, a rapid, point-of-care diagnostic tool for detecting Group B Streptococcus in expectant mothers. Other products in development target various applications across human health, ag-tech, and biosecurity.

Learn more at www.nexsen.bio

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