

PRESS RELEASE

Gradientech completes clinical sample testing in ongoing FDA 510(k) clinical study

Uppsala, Sweden, July 16, 2025. The diagnostics company Gradientech today announces the successful completion of clinical sample analysis in its ongoing FDA 510(k) clinical study for the QuickMIC® system for ultra-rapid antibiotic susceptibility testing (AST).

Following successful pre-clinical evaluation studies of the QuickMIC® system in the United States and receiving a Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA), Gradientech initiated the 510(k) clinical study last year. The study evaluates the QuickMIC system and its U.S. market-adapted gram-negative panel at three renowned U.S. clinical sites using fresh patient samples.

All patient samples required for the study have now been successfully collected and analysed - both directly from positive blood cultures and from bacterial isolate colonies - marking a significant milestone in the regulatory process.

"This is a fantastic achievement and I'm deeply grateful to all the dedicated professionals at our clinical sites who support Gradientech in this important collaboration," says Sara Thorslund, CEO and co-founder of Gradientech. "Reaching this milestone is a decisive step toward bringing QuickMIC to the U.S. market, where it has the potential to make a meaningful impact on healthcare and improve outcomes for sepsis patients with its first-in-class precision and rapid time to result."

QuickMIC® and its gram-negative panel are CE marked and commercially available in Europe. QuickMIC is classified as a Breakthrough Device by the U.S. Food and Drug Administration and available for Investigational Use Only in the U.S., but not 510(k) cleared.

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About Gradientech

Gradientech is a leader in ultra-rapid antibiotic susceptibility testing, developing next-generation diagnostics for infectious disease medicine. Our innovative diagnostic solutions aim to save lives, reduce healthcare costs, and combat the spread of antibiotic resistance - one of our greatest global health threats. Gradientech is headquartered in Uppsala, Sweden. Visit www.gradientech.se for more information.