

## PRESS RELEASE

### **Gradientech Receives FDA Feedback on 510(k) Submission for QuickMIC®**

*Uppsala, Sweden, February 10, 2026. The diagnostics company Gradientech today announces that it has received feedback from the U.S. Food and Drug Administration (FDA) regarding the company's submitted 510(k) premarket notification for its QuickMIC® system for ultra-rapid antimicrobial susceptibility testing (AST) of bacterial isolates.*

Following submission of the 510(k) application and an initial period of interactive review, the FDA has issued a hold letter requesting additional information related to the application. The requested clarifications primarily relate to cybersecurity aspects of the system, as well as limited additional performance testing. Gradientech is working closely with the FDA and has initiated activities to address the requested information as part of the ongoing review process.

"This constructive feedback represents an important step in our regulatory journey in the U.S.," says Sara Thorslund, CEO and co-founder of Gradientech. "We continue our dialogue with the FDA and are focused on completing the remaining requirements to support an FDA clearance of QuickMIC® for the U.S. market."

QuickMIC® is currently the fastest phenotypic AST system on the market, delivering results within 2-4 hours directly from positive blood culture samples. This enables same-day optimisation of antimicrobial therapy for patients with sepsis, representing a significant improvement compared to traditional methods that often require up to two days. The system is used today in routine clinical diagnostics at a growing number of European hospitals.

*QuickMIC® and its gram-negative panel are CE marked and commercially available in Europe. In the U.S., QuickMIC® has been granted Breakthrough Device designation by the FDA and is available for investigational use only; it is not yet 510(k) cleared.*

#### **For further information, please contact:**

Sara Thorslund, PhD, CEO

Tel: +46 736 29 35 80

[sara.thorslund@gradientech.se](mailto:sara.thorslund@gradientech.se)

#### **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 [gradientech.se](http://gradientech.se) for more information.*