PRESS RELEASE

Gradientech presents QuickMIC® clinical study results

Uppsala, 17 May 2022. **The diagnostics company Gradientech, developing QuickMIC® for ultra-rapid antibiotic susceptibility testing, today announces decisive results from the completed clinical performance evaluation study of QuickMIC and its gram-negative panel. The results exceed the regulatory requirements to achieve a CE-IVD registration.**

The clinical performance evaluation study of the QuickMIC system is completed with promising results to form the basis for a CE-IVD registration of QuickMIC following the IVD Directive. The study includes 473 bacterial strains of species common in sepsis, whereof 64 are patient samples collected from the clinic during the on-going study. The study results are based on more than 3,800 drug-bug combinations with an overall Essential Agreement (EA) of 94.7%. The overall Categorical Agreement (CA) was similarly 94.7% and the reproducibility of the QuickMIC system was high with 99.1%. Regulatory requirements for a CE-IVD approval are an EA exceeding 90% and a reproducibility exceeding 95%. Both EA and CA are comparison values where the same bacterial strain is tested with the test device and the reference method, and results shall agree.

The average time to results for all drug-bug combinations in the study was just below 3 hours and 20 minutes, proving that the QuickMIC system is a class-leading device as the until now first ultra-rapid AST system for sepsis approaching the market.

"We are of course more than thrilled about the clinical study results, and in addition to meeting the regulatory requirements we also prove the uniqueness of QuickMIC regarding the exceptionally short time to results and unprecedented precision. I would also like to highlight the degree of challenge in the strain collection with more than 35% multi-drug resistant strains included in the study," says Sara Thorslund, CEO of Gradientech.

The three external clinical study sites will continue to collect and run patient samples to further increase the number of clinical samples in the study. This is to meet the increased requirements towards a CE-IVD approval following the new IVD Regulation. Gradientech does not foresee any negative impact on the study results with extended number of clinical samples.

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About Gradientech
Gradientech is leading the field of ultra-rapid antibiotic susceptibility testing. We develop next-generation diagnostics in infectious disease medicine. Our product QuickMIC allows patients with sepsis to quickly receive specific guidance on the right antibiotic in the right dose. It saves lives, reduces healthcare costs and limits the spread of antibiotic resistance – one of the greatest global health threats of our time. Gradientech is headquartered in Uppsala. Visit www.gradientech.se for more information.