Q-linea announces FDA clearance of expanded ASTar blood testing menu

Q-linea AB (publ) (OMX: QLINEA) today announces the company has received 510(k) clearance from the US FDA for its expanded ASTar® Gram-negative Blood Culture menu.

The expanded panel represents a significant increase in clinical utility with 93 new bug-drug combinations to a total of 215, approximately 75% more than the Version 1 panel, including key new drugs such as Ceftriaxone, Cefotaxime, Ceftolozane-tazobactam and Ertapenem. In addition, performance has been upgraded with new algorithms for some previous combinations, eliminating many former limitations of the panel.

The Version 2 panel now conforms to all the latest FDA breakpoints, making it the most up-to-date solution available on the market for laboratories and clinicians.

"This menu provides the most comprehensive phenotypic susceptibility data available on the market for physicians deciding on critical therapeutic treatment for patients with Gram-negative blood stream infection and severe sepsis. Reducing time to optimal, targeted antibiotic therapy is crucial to improve individual patient outcomes and minimize the development of novel antibiotic resistance", says Vikas Gupta, Senior Director of Clinical Affairs for Q-linea.

"Our FDA-cleared panel now closely matches what ASTar already provides to patients in Europe and other markets under CE-IVDR clearance", adds Stuart Gander, CEO for Q-linea. "We look forward to providing patients in the US with the full power of the ASTar platform to improve outcomes and reduce costs for healthcare systems."

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About Q-linea

Q-linea is an innovative infection diagnostics company dedicated to saving lives and reducing healthcare costs by developing and delivering solutions for the rapid diagnosis and treatment of infectious diseases. The company's core focus is on rapid Antibiotic Susceptibility Testing (rAST), a critical step in the treatment of sepsis and other severe infections.
Q-linea's flagship technology, ASTar®, is a fully automated instrument designed to deliver rapid phenotypic AST results directly from positive blood cultures in approximately six hours. By significantly reducing the time to answer compared to traditional methods, Q-linea enables physicians to prescribe the optimal antibiotic treatment sooner, improving patient outcomes and actively combating the global threat of antimicrobial resistance (AMR). Founded in 2008 and headquartered in Uppsala, Sweden, Q-linea is listed on Nasdaq Stockholm.

This information is information that Q-linea is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-04-16 08:30 CEST.

Attachments

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