

Q-linea announces FDA submission for expanded claims for ASTar® BC G-panel

Q-linea AB (publ) (OMX: QLINEA) today announces their FDA 510(k) submission for expanded organism and antimicrobial claims on their ASTar BC G- panel, improving the clinical utility of the panel for patients with bacteremia and sepsis by offering more escalation and de-escalation agents as well as increased pathogen coverage.

This submission follows the completion of a clinical trial, conducted at two prestigious US institutions as well as Q-linea's headquarters in Sweden. The intention of the submission is to bring the FDA-cleared version of the panel in line with the successful IVDR panel, currently available in the EU and in use in many clinical settings.

US adoption of the current panel is on the rise, and the second FDA clearance, anticipated in the spring of 2026, is expected to accelerate ASTar's use.

Jim Kathrein, VP of US Commercial Operations, stated, "We are thrilled with the data coming out of this clinical trial and look forward to an expanded menu being FDA cleared in the spring."

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About Q-linea

Q-linea's rapid AST system, ASTar®, accelerates and simplifies the time-sensitive workflows faced during the treatment of patients with bloodstream infections and sepsis. Hospitals use ASTar to vastly reduce the time to optimal antimicrobial therapies and ensure that patients receive the correct treatments sooner — when time matters most. We are helping to create sustainable healthcare, now and in the future, and safeguard the effectiveness of antibiotics for generations to come.

Q-linea is headquartered in Uppsala, Sweden and has regional offices in Italy and the USA, with partnerships worldwide.

ASTar Instrument and ASTar BC G- Consumable kit are CE-IVD marked and FDA 510(k) cleared. For more information, please visit www.qlinea.com

Attachments

[Q-linea announces FDA submission for expanded claims for ASTar® BC G- panel](#)