

Q-LINEA ACHIEVES CE-IVD APPROVAL FOR ASTAR

Q-linea AB (publ) (OMX: QLINEA) today announces that the company through very good study results has received a CE-IVD mark for the antibiotic susceptibility system ASTar®. Essential Agreement (EA) was 94.9 percent, Categorical Agreement (CA) 97.6 percent and overall reproducibility 99.6 percent. To achieve CE-IVD approval in Europe, EA and CA must exceed 90 percent. Q-linea can now commercialize ASTar in Europe together with its partner Thermo Fisher Scientific.

“We are very proud of the strong results from our pivotal European study and are now looking forward to initiate the commercialization of ASTar. The study results exceed the previously announced interim results, which is of course very positive. The fact that we have included difficult and important antibiotics such as Colistin in the panel and analysis of fastidious bacteria shows that our technology is well equipped for the future,” said Jonas Jarvius, CEO of Q-linea.

The ASTar® Instrument and ASTar® BC G- Kit offer the broadest combination of antimicrobials and dilution ranges in a single analysis for Gram-negative bacteria*. The analysis also delivers true MIC results.

“I congratulate Q-linea to this important milestone for ASTar. Rapid AST offers the potential to improve patient care and help fighting antimicrobial resistance. I look forward to taking the next steps together with Q-linea with this very exciting product,” said Bernd Hofmann, Vice President Global Marketing at Thermo Fisher Scientific.

EA means giving the same result as the reference method on the concentration of antibiotics that kill or inhibit bacterial growth.

CA means giving the same classification of the bacterium within one of three groups (S.I.R) with respect to susceptibility to antibiotics.

**) Based on commercially available systems market overview, May 2021.*

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About Q-linea

Q-linea is an innovative infection diagnostics company that primarily develops instruments and disposables for rapid and reliable infection diagnostics. Our vision is to help save lives by ensuring antibiotics continue to be an effective treatment for future generations. Q-linea develops and delivers preferred solutions for healthcare providers, enabling them to accurately diagnose and treat infectious disease in the shortest possible time. The company's lead product ASTar® is a fully automated instrument for antibiotic susceptibility testing (AST), giving a susceptibility profile within six hours directly from a positive blood culture. For more information, please visit www.qlinea.com.

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 2021-05-04 19:31 CEST.

Attachments

[Q-linea achieves CE-IVD approval for ASTar](#)