

Excellent clinical results from large commercial evaluation

Q-linea AB (publ) (OMX: QLINEA) - Q-linea today announces the results from the commercial evaluation performed by Thermo Fisher Scientific™ and supported by Q-linea during the summer 2021. The overall Essential Agreement (EA, meaning reaching the same results as the reference method) was 96,6%, thus exceeding the results from Q-linea's pivotal CE-IVD study. ASTar® could also provide results for 98,7% of all organisms analyzed.

The study was performed by Thermo Fisher Scientific at several sites in Europe during the summer of 2021. Several types of hospital laboratories participated, with a mix of extended hour and 24/7 operation to cover different possible customers. The study included almost 500 routine clinical samples. ASTar's performance was very robust, with only one service intervention throughout the study.

ASTar Instrument and ASTar BC G-Kit already deliver the broadest answer regarding the combination of the number of antibiotics and the number of double dilution steps of each antibiotic, in a single analysis for gram-negative bacteria*). The test enables the analysis of gram-negative bacteria, including difficult-to-grow so-called fastidious bacteria, which satisfies the need for rapid and comprehensive results to support optimal treatment decisions.

"This is truly excellent and illustrates the importance of a broad panel coverage since our goal has always been to provide actionable results for as many patients as possible. To see results that surpass our earlier CE-IVD study is of course also positive, and that the system performed robustly. I look forward to the future and our collaboration with Thermo Fisher Scientific," said Jonas Jarvius, CEO of Q-linea.

"We share Q-linea's commitment to improving patient outcomes through innovations that deliver simplified workflows and faster results. As the commercial partner for the ASTar, we look forward to bringing this proven solution to more labs and hospitals." said Romain Lecomte, Sr. Director Clinical Product Marketing at Thermo Fisher Scientific.

ASTar Instrument and ASTar BC G- Kit are CE-marked but not FDA 510(k)-cleared and not available for sale in the United States.

*) Based on commercially available systems market overview undertaken by Q-linea - 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.

Attachments

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