



# Calmark's fully automated production line has been installed and the first batches of test cassettes produced

Calmark Sweden AB (publ) announces today that all the steps in the process validation of the fully automated production line have been completed and the first batches of test cassettes produced with good results.

Calmark's fully automated production line was manufactured by the company Automationspartner in Ramlösa and completed on April 28. It was subsequently relocated to Calmark's production partner Frohe in Tyresö, where it was assembled and installed together with other equipment involved in the manufacturing process for the test cassettes. Staff from Automationspartner, along with staff from Calmark, have trained Frohe's production staff to ensure safe handling and quality.

“I am very happy that the fully automated production line now is up and running. It has been a team effort, and many have contributed. I would like to thank Automationspartner, Frohe and those Calmarkers that have worked side by side to put everything in place,” says Anna Söderlund, CEO of Calmark. “This production update is a prerequisite for selling and delivering to major markets, such as India and China.”

Process validation is the method used to ensure the outcome of a series of production steps that together make up the manufacturing process. As regards medical devices, the process validation comprises the stages IQ (Installation Qualification), OQ (Operational Qualification), and PQ (Performance Qualification), in which the process limits and repetitiveness within production are verified.

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**Calmark Sweden AB** is a medical technology company developing a point-of-care (POC) analysis method with easier and faster diagnostics of medical conditions in newborns. The unique test platform consists of a portable instrument and test cassettes for various biomarkers. The first test, Neo-Bilirubin, was launched to the market in 2020. In the Western world, the introduction of POC diagnostics is resulting in huge savings and shorter care chains. In less developed healthcare systems, the product will offer a decision support which is currently lacking, since the access to hospital laboratories often is limited. Calmark aims to become the global leader in POC diagnostics for newborns and, in the long term, to offer all relevant tests for the first period of life. In addition to products for newborns, Calmark develops a POC test for assessment of COVID-19 disease severity. The B share is listed on the Spotlight Stock Market and is traded under the CALMA B ticker. Read more at [www.calmark.se/eng/home](http://www.calmark.se/eng/home).