Calmark's LDH test for assessment of COVID-19 enters the verification and validation phase of the CE marking process – analytical results are within the expected range

Calmark Sweden AB (publ) announces today that the development project for the Company's product COVID19-LDH now moves to verification and validation. This phase is one of last steps in the process, with an estimated duration of approximately five weeks. Thereafter, the product will move into production, and CE mark certification can take place.

CE conformity marking and the development of medical devices follows a seven-step process, where the first three steps involve requirements capture and development. The product is then verified against the prescribed requirements and validated by would-be users (steps four and five). The development project is then closed, moving to production in step six. In the final and seventh step, the product formally obtains its CE marking.

The CE certification of Calmark's tests for children requires the product to be validated with blood from new-born infants in step five. In these cases, Calmark has to work with hospital research entities to finalize validation. The LDH test for COVID-19 will be used for adult patients, which means that Calmark can conduct both verification and validation on its own account in accordance with the directives applied by the Company.

"We can today announce that the COVID-19 product complies with our technical requirements. The analytical results fall within the expected range when compared to the reference laboratory at Karolinska University Hospital," says Anna Söderlund, CEO of Calmark. "We feel comfortable moving to the final phase of the project. This is the result of a development effort carried out at unprecedented speed, and I would like to thank my remarkable team for their good work!"

For more information about Calmark Sweden AB, please contact:

Anna Söderlund, CEO
Telefon: +46 70 214 98 93
E-post: anna.soderlund@calmark.se
www.calmark.se

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.