# Calmark's LDH test for assessment of COVID-19 disease severity is estimated to be ready for launch in Q1 2021

Calmark Sweden AB announces today that the product development of an LDH test for assessment (triage) of COVID-19 is proceeding according to plan; the test is now projected to obtain CE conformity marking in Q1 2021. The project has now successfully completed the chemical impregnation in Calmark's recently installed BioDot machine, which will be used in the production line.

CE conformity marking and the development of medical technology products follows a seven-step process, where the first three steps involve identification of requirements specification and development to cover them. The product is then verified against the prescribed requirements and validated by potential end users (steps four and five). The development project is then closed, and design transfer to production is done in step six. In the final and seventh step, the product formally obtains its CE mark approval.

Tests for LDH in adults, which have been diagnosed with Covid-19, will be a part of the assessment of the development of the disease course. Studies indicate that the occurrence of increased levels of LDH in early onset of Covid-19 improves the possibilities of identifying patients at risk, assess severity and start the clinical intervention and monitoring. Doing that the prognosis improves and the possibility of recovery increases for the patients. Thus, LDH is an important biomarker for fast triage of patients with Covid-19.

*"It is good to see that the project is moving forward,"* says Anna Söderlund, CEO of Calmark. *"The installation of our BioDot machine was a great stride forward and we can nowsee that the recipe for our LDH chemistry is working well in a large-scale production environment."*



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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 reader and single-use products. The first tests are being launched in 2020. WHO expects 1.5 billion children to be born worldwide prior to 2030. 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 decision-making 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. 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.