



## Results for Calmark's initial biomarker, bilirubin, are within the expected range - project enters verification and validation phase to obtain CE mark

Calmark Sweden AB (publ) announces today that the development project for the Company's first biomarker, bilirubin, is now progressing to verification and validation. This phase, which is one of the final elements of the process, is estimated to last for approximately eight weeks. When it is completed, regulatory documentation will be compiled in order to achieve the CE Mark approval. This means that bilirubin will obtain its CE mark according to plan.

"Today's decision marks an important milestone for Calmark. We can now ascertain that we can satisfy our technical requirements on measurement accuracy. The results of analysis fall within the expected range when compared to the reference laboratory at Karolinska University Hospital. We are confident to bring the first biomarker, bilirubin, into the final phase of the project," says Anna Söderlund, CEO of Calmark. "Since the reader obtains its CE marking together with each respective biomarker, the initial project is also the most extensive - so I am very happy that we are on our way to achieve this."

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**Calmark Sweden AB** is a medical technology company developing a point-of-care (POC) analysis method with easier and faster sampling of medical conditions in newborns. The unique test platform, which consists of a reader and single-use products, is expected to be ready for launch in 2020 when three important POC tests are introduced. The WHO estimates that 1.5 billion children will be born worldwide by 2030. In the Western world, the introduction of POC diagnostics is resulting in huge savings and shorter healthcare chains. In less developed healthcare systems, the product helps save lives. Calmark aims to become the global leader and ultimately to offer all relevant POC tests for the first period of life, regardless of where in the world a baby is born. Read more about Calmark [www.calmark.se/eng/home](http://www.calmark.se/eng/home).