

PROLIGHT ANNOUNCES POSITIVE DATA FROM PATIENT BLOOD STUDY AT ST THOMAS' HOSPITAL, LONDON

Data from St Thomas' Hospital have confirmed equivalence between whole blood and plasma from patients with elevated troponin levels. The study is a key stepping-stone between the successful biobank study earlier this year and the planned clinical study for product approval.

"These initial results from St Thomas' Hospital are highly encouraging and exactly what we had hoped for ahead of our continued discussions with potential partners. The strong correlation between blood and fresh or frozen plasma on the PsyrosTM platform validates the biobank study carried out earlier this year on frozen plasma samples," said Ulf Bladin, CEO of Prolight.

Data from the first phase of the study on the Psyros platform with fresh whole blood from 25 patients with elevated troponin levels, show a strong correlation between fresh blood and plasma, with a correlation coefficient (R^2) of 0.98. Additionally, the plasma was frozen and retested, giving an R^2 of 0.99 against fresh plasma which reinforces the importance of the biobank study.

Repeat measurements in blood and plasma also show that the assay precision is not compromised in whole blood, which is backed by ongoing experimental data being generated in the Prolight laboratories using fresh blood samples spiked with troponin.

"Successful completion of the first phase of this study marks another milestone as we prepare for our pivotal clinical study. These are the first data that we have generated on fresh whole blood samples taken from patients in a hospital setting. 2025 continues to be an exciting year for Prolight and reaffirms our confidence in the Psyros single-molecule-counting technology," said Steve Ross, CTO at Prolight and Chief Investigator of the study.

The St Thomas' study follows on from the biobank study that was successfully delivered in Q1 of this year. The biobank study demonstrated clinical performance using frozen plasma samples from both chest-pain cohorts and healthy donors. The biobank study demonstrated that the Psyros system is on track to meet the requirements of high-sensitivity troponin.

The next critical step after the biobank study was to demonstrate that the system gives equivalent results in whole blood patient samples when compared to plasma. Whole blood is the sample type that will be used once the system is launched and being used in emergency departments.

A total of 120 fresh blood samples will be tested at St Thomas' Hospital. Additional confirmatory data will be generated throughout 2025 as the Psyros platform goes through cartridge manufacturing process verification and validation at Flex Medical Solutions in Livingston, Scotland.

For further information, please contact:

Ulf Bladin, CEO

E-mail: info@prolightdx.com

Phone: +46 73 582 39 87

Company website: www.prolightdx.com

About Us

Prolight Diagnostics AB develops innovative Point-of-Care systems. These are small, portable instruments and disposable cartridges for performing in-vitro diagnostic (IVD) tests from a drop of blood. We want to offer the foremost POC systems on the market for quick, reliable diagnosis of acute events. Our launch product will be for the measurement of high sensitive troponin, to aid in the rule-in and rule-out of myocardial infarction.

The company's share is traded on the NGM Nordic SME marketplace, under the ticker PRLD.

This information is information that Prolight Diagnostics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-06-16 08:00 CEST.

Attachments

Prolight announces positive data from patient blood study at St Thomas' Hospital, London