

PRESS RELEASE

QUALIblood Announces Strategic Partnership with Diagnostica Stago for the Development and Commercialization of the nAPCsr Kit, a Breakthrough in Thrombosis Risk Assessment

Liège, Belgium – February 14, 2025 – **QUALIblood**, a Belgian company specialized in bioanalytical services for preclinical and clinical studies, is proud to announce a strategic partnership with **Diagnostica Stago** to accelerate the development and commercialization of the **nAPCsr** kit, a pioneering diagnostic tool that promises to redefine thrombosis risk assessment. This collaboration will support the performance and clinical validations of the nAPCsr kit in compliance with the In-Vitro Diagnostic Medical Device Regulation (IVDR), ensuring its robust integration into clinical practice.

This ambitious initiative is backed by **Noshaq**, **Namur Invest**, and **private partners** through a convertible bond, alongside funding from the **Région Wallonne**¹, totaling over **€2 million**.

nAPCsr: A shift in thrombosis risk prediction

The nAPCsr (normalized Activated Protein C Sensitivity Ratio) is a revolutionary functional blood test capable of detecting both genetic thrombophilias and acquired prothrombotic states, such as those induced by contraceptive pills. Recent research has demonstrated that implementing nAPCsr-based screening could prevent up to 13,500 venous thromboembolism (VTE) cases annually in Europe, translating into an estimated €1.5 billion in healthcare savings per year. This test empowers clinicians with actionable insights, enabling personalized risk assessment and safer prescribing decisions, potentially guiding millions of women towards best contraceptive approach.

“The nAPCsr assay is a game-changer in thrombosis risk stratification. It bridges the gap between cost-effective screening and personalized. By partnering with Diagnostica Stago, we are not only advancing diagnostic science but also actively reducing the societal and economic burden of thrombosis-related conditions,” said Julie Winand, CEO of QUALIblood.

Regulatory and commercial milestones

QUALIblood has already secured **ISO/IEC 17025:2017 accreditation** for the nAPCsr analysis, reinforcing its scientific validity and compliance with international quality standards. Additionally, a patent filing for this groundbreaking technology is currently underway, securing its position as a leading innovation in thrombosis diagnostics.

“Diagnostica Stago is committed to driving innovation and improving patient care. In collaboration with QUALIblood, we are excited about developing the innovative nAPCsr diagnostic test, designed to enhance quality of life and reduce healthcare costs by preventing thrombosis-related complications. This partnership brings together the best of both worlds—the combined scientific, industrial, regulatory, and commercial expertise of our two companies. We are confident that by uniting our strengths, clinicians will be empowered to personalize treatments and deliver more effective care for women worldwide”, said Manuel Mayer, Executive Director International Business & Customer Support Operations of Diagnostica Stago.

¹ Win4Company - Convention 8943 – HIT24 – Hormone Induced Thrombosis 2024 – The nAPCsr, a predictive biomarker of thrombosis risk in indications and conditions subjected to hormonal changes.

About QUALIBLOOD

QUALIblood is a leading provider of bioanalytical services for preclinical and clinical studies, specializing in precision bioanalysis and biomarker identification. Our multidisciplinary team of pharmacists, biologists, and laboratory technology specialists is committed to provide high-quality, efficient solutions that adhere to regulatory standards. We offer services to pharmaceutical industries, hospitals, and universities to advance medical research and improve patient outcomes through innovative analytical methods and comprehensive study management. The R&D team aims to develop to biomarkers, such as the nAPCsr, to improve patient diagnosis and accelerate healthcare product development. QUALIblood is ISO/IEC 17025 accredited, ensuring the highest standards of quality, accuracy, and precision in all our testing services.

About Diagnostica Stago

Created in 1945, Diagnostica Stago is now a world leading player in the In-Vitro Diagnostics industry. International, independent and privately-owned, Stago group exclusively dedicates its medical expertise to the exploration of Hemostasis and Thrombosis, contributing to the growth and clinical relevance of both disciplines. A close to 2,600 staff comes from a wide range of backgrounds, applying their expertise throughout the value chain to design, manufacture and distribute products and services that improve patient health. Stago offers consistent, high-quality solutions and devotes its research and innovative skills to the development of increasingly effective medical diagnostic products, instrumentation and services

About the nAPCsr

The **normalized activated protein C sensitivity ratio (nAPCsr)** is a measure used in the evaluation of activated protein C (APC) resistance, which is a condition that can lead to an increased risk of blood clots. Higher nAPCsr values indicate greater resistance to APC, meaning the blood is more prone to clotting. This measure is particularly useful in diagnosing conditions like **hereditary APC resistance** (often due to the factor V Leiden mutation) and **acquired APC resistance**, which can be associated with factors such as antiphospholipid antibodies, pregnancy, and estrogen therapy

The team at QUALIblood has developed, standardized, validated and patented a method to measure the nAPCsr in a reproducible and standardized manner. This measure is used in clinical settings to assess the risk of thrombosis and guide treatment decisions marking a significant advancement in personalized medicine, enabling more tailored and effective treatment plans.

With a scalable market reach extending beyond contraceptive safety into broader cardiovascular and thrombosis risk assessment applications, this innovation aligns with public health objectives, ensuring better patient outcomes while significantly reducing healthcare costs associated with preventable thrombotic events. The nAPCsr kit stays at the intersection of healthcare innovation, regulatory compliance, and economic sustainability