Created in 2017 by Dr. Jonathan Douxfils QUALIblood offers a wide range of biological analyses integrating innovative biomarkers.

With 9 scientific experts dedicated to its clients' preclinical and clinical projects and to its internal research projects, QUALIblood has more than 10 years' expertise in haemostasis and biomarkers, with more than 600 biomarkers available in its portfolio. The CRO also has over 100 scientific publications in the therapeutic and diagnostic fields of interest.



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## Expertise in Biomarker Identification

QUALIblood stands out for its expertise in biomarker identification and the development of innovative analysis methods. In 2023, the CRO finished the development a blood test which is now available for the practicians, to assess the risk of thrombosis for women taking the contraceptive pill. Other indications are currently being evaluated: pregnancy, the menopause, breast cancer treatments, etc. The biomarker developed in this context can be used to alert the prescribing clinician to potential unidentified pathologies and enable further investigation (genetic or other tests) if necessary. To date, this test is the only solution that can identify thrombotic risks acquired under estrogen therapy. The test is carried out by QUALIblood laboratory, and partnerships have been set up with analysis laboratories (including Laboratoire Olivier), hospitals and gynaecologists in Belgium to make the test available to the widest possible audience. At the same time, the team is working on the development of a dedicated kit to reduce the cost of

analyses and promote its transferability to analysis laboratories worldwide.

## Technological Advancements

As well as developing new biomarkers, QUALIblood is attentive to the new technologies available, the needs of the market and the demands of new guidelines. With this in mind, the laboratory has acquired Quanterix's Simoa technology, which enables biomarkers to be identified at very low concentrations in the femto molar range (1.10-15 molar). This technological feat eliminates the need to collect cerebrospinal fluid (CSF), since the marker of interest can be detected in the blood. This allows to measure markers of neuronal damage as well as cancerous and cardiovascular markers. This means that pathologies can often be diagnosed earlier, using less invasive sampling techniques. Ultimately, this improves patient care and, above all, enables to better characterise the biological effect of new innovative therapies. At the same time, QUALIblood is working on specific cellular models that have been developed to highlight immune responses to infectious diseases, for example.

## Partnerships and Expertise

Thanks to its partnerships and its team of experts, the laboratory can offer a portfolio of analyses involving more than 10 different technologies for biological haemostasis analyses, identification of known biomarkers, development of new biomarkers, blood biocompatibility assessments, etc. Its project managers are also at the service of its partner customers in defining clinical protocols in order to guide and determine the most appropriate clinical testing strategy in line with regulations. Thanks to their expertise in this field, QUALIblood's experts can advise on the (pre-)analytical methods to be applied and can also manage the samples collected before and after their analysis, using, if necessary, the services of the NAB-X biobank with which they collaborate.

## Versatility and Dynamism

The versatility and dynamism of the team enables QUALIblood to position itself as a partner for companies with product portfolios at an early stage of development. Depending on the client, support can be one-off or more comprehensive, covering the early stages of development right through to submission of the dossier to the authorities, and even beyond, during the post-marketing authorisation (MA) phases. A recent example is the partnership with Mithra in the development of their new contraceptive pill, which has a more favourable safety profile than traditional pills. As part of this partnership, the QUALIblood team developed a biomarker enabling this

characteristic to be highlighted during clinical trials. This biomarker made it possible to prove the safety of the drug without having to wait for the post-authorisation studies normally required for this type of product. The post-marketing studies will, of course, be carried out, but they will be reduced thanks to the test that has been put in place. QUALIblood's support for this product began at a very early stage and continues to this day. In addition to the development and validation of the biomarker, it has included sample management, the completion of clinical files, data analysis and interpretation, and the promotion of the product with the partner.

## Quality and Scientific Support

QUALIblood attaches great importance to quality and the scientific support provided. It operates in accordance with the ISO17025 standard, for which accreditation is currently being sought from BELAC. This demand for quality is also facilitated by the advanced technological platforms used by QUALIblood. SIMOA, HPLC MS/MS, MULTIPLEX, Calibrated Automated Thrombogram, ST-Genesia, STAR-MAX, ACL-TOP, Cell-based NETosis model, Cell-based serological model, Cell-based adenovirus resistance model, etc. These platforms are highly valued by the laboratory's customers: small and medium-sized pharmaceutical companies, universities and hospitals in Belgium and neighbouring countries.

## Commitment to the Circular Economy

Committed to the circular economy, QUALIblood serves mainly Belgian customers and partners. The laboratory is fully aware of the potential of its environment and the levers available to grow and evolve in the sector. In this context, some of its partnerships are established as part of research and development projects subsidised by the Walloon Region or the federal government. That said, QUALIblood intends to extend its range of services to more Belgian and European biotech companies. The laboratory also wants to promote and publicise the nAPCsr test to all gynaecologists in Belgium, France and Europe in general: the risk of thrombosis linked to contraceptive pills does not stop at borders. The QUALIblood team is convinced that it can achieve this objective not only with the medical public, but also with the general public. After all, it's up to patients to choose the style of contraception they prefer. Ultimately, the laboratory plans to strengthen its global service offering by establishing partnerships with other companies with expertise in this field. A winning strategy to strengthen the Belgian value chain and encourage the emergence of innovative therapies in the country.

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