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A company of the LifeScience Foundation

REFERENCE NUMBER
TO 33-00002

RAPID, SIMULTANEOUS AND NON-DESTRUCTIVE BLOOD DIAGNOSTICS USING A MULTI-OMICS NMR PLATFORM

Keywords: nuclear magnetic resonance (NMR), glycoproteins, N-glycans, signal selection, diffusion properties, inflammation, heart disease

INVENTION NOVELTY

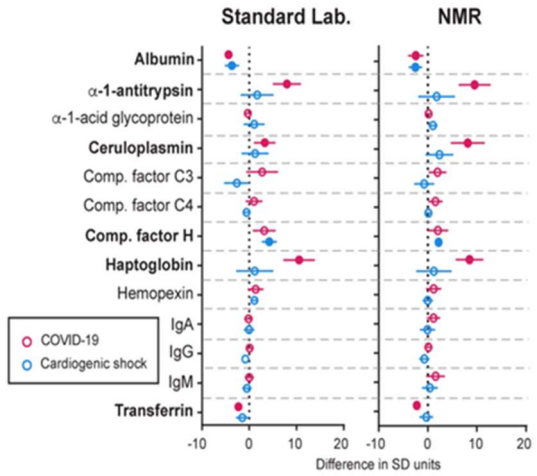
Acute-phase proteins are common components of blood, whose plasma concentrations alters in response to inflammation and/or infection. They play pivotal roles in the immune response, and serve as biomarkers in clinical diagnostics, aiding in monitoring e.g. disease progression and treatment efficacy. Traditional methods for determining serum concentrations of these proteins, such as ELISA, nephelometry, turbidimetry, HPLC or LC/MS, have limitations. They require usually individual tests for each protein, are influenced by protein glycosylation, and destructive to the sample. The invention introduces a novel NMR-based approach that overcomes these shortcomings, enabling the simultaneous quantification and profiling of blood proteins and their glycosylation in a single, swift (10-20 min) measurement. Moreover, the procedure is non-destructive, preserving the sample for further testing. In contrast to other methods, sample analysis is more cost-effective and offers comprehensive insights into protein glycosylation and lipidation; a crucial, yet insufficiently beaconed aspect in comprehending disease mechanisms and formulating targeted therapies.

VALUE PROPOSITION

The invention holds the potential for a breakthrough improvement in the field. By providing a more detailed and specific analysis of acute-phase proteins and their glycosylation status, it enables a more accurate and comprehensive understanding of inflammatory diseases. This enhances diagnostic accuracy, potentially leading to more effective treatment strategies and improved patient outcomes. The method is particularly suitable for diagnosing a wide range of diseases with an inflammatory component, which exhibit pronounced changes in acute-phase protein glycosylation, as evidenced in cardiovascular disease, rheumatoid arthritis, and MASH. Very robust glycoprotein signatures have been observed in various types of cancer and in neurodegenerative diseases.

TECHNOLOGY DESCRIPTION

Previous attempts at NMR-based measurement of acute-phase proteins focused on overlapping resonances in 1H-NMR spectra, known as GlycA and GlycB. However, the exact attribution of these NMR signals to specific glycoproteins and glycosylation types remained unknown. The present invention introduces an innovative NMR-based approach that uses diffusion parameters and various specific NMR properties, along with a robust algorithm, to accurately assign signals to specific glycosylation patterns and predict their respective concentrations (see Figure). This reassignment of glycoprotein NMR signals opens new avenues for medical diagnostics and for differentiating patients with various inflammatory diseases from healthy controls.



Standard deviation (SD) of glycoprotein concentrations in blood serum of COVID-19 and cardiogenic shock patients using either standard laboratory methods or the NMR-based approach (from Mallagaray et al., 2023).

COMMERCIAL OPPORTUNITY

The innovation offers a faster, more affordable and comprehensive method for diagnosing and monitoring inflammatory disease, neurodegenerative disorders, and cancer. It can be integrated into existing platforms or developed into a standalone tool. With the rising prevalence of conditions like diabetes, heart disease, and cancer, the demand for a more accurate and thorough diagnostics is set to grow, providing a major market opportunity. The technology is available for in-licensing.

DEVELOPMENT STATUS

The technology is in an advanced stage of development. It has been extensively validated on serum samples from patients suffering from e.g. inflammatory bowel disease, liver carcinoma, Parkinson's disease. Further validation is underway to evaluate its clinical potential in larger cohorts of patients affected by different inflammatory diseases.

PATENT SITUATION

The German patent DE102023110285.0 has been granted in 2024, and the international application PCT/DE2024/100346 is pending.

FURTHER READING

Mallagaray et al. (2024) Angew. Chem. Int. Ed. 62: e202306154

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Last updated Oct. 2024