

Services

Glycan analysis for medical research and drug manufacturing

Consistently controlled and well-characterised glycosylation is a subject of concern during biopharmaceutical realisation and is recognised as a **critical quality attribute (CQA)**. It greatly increases drug complexity and heterogeneity, and can significantly influence **drug safety and efficacy**. Moreover, it is typically the single greatest contributor to drug batch-to-batch variability.

Analysis of glycosylation is important not only in biopharmaceutical development and manufacturing but also in **clinical and biological research** where changes in glycosylation have been associated with many states of health and disease providing prognostic and diagnostic information.

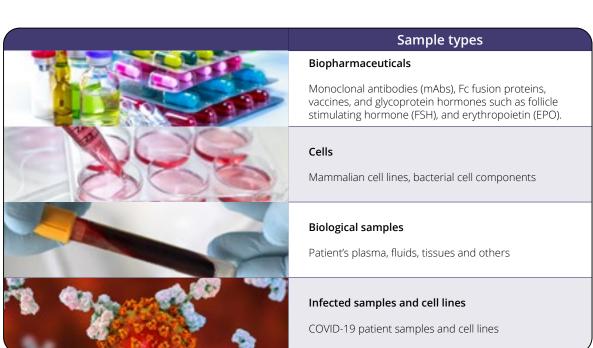
At Ludger, we have **decades of experience with analysing glycosylation** as part of our internal research project, but also we provide our glycan analysis services¹ to world-leading biopharmaceutical and research organizations. We help customers around the globe characterize their drug's glycosylation and provide regulatory authorities with reliable, structured and detailed data.

The following are examples of how our glycan analysis reports are used:

- · in process optimisation
- to support regulatory submissions
- batch quality control during the manufacturing of biopharmaceuticals

Our services include:

- Sialic acid and monosaccharide analysis and quantitation
- N- and O-glycan profiling² and characterisation³
- High-throughput N-glycan screening4
- · Custom method development and validation
- · Method transfer, training and advisory services to get glycoprofiling methods up and running in your laboratories



¹ GMP-compliant modules are also available. ²This includes: HILIC-LC, MALDI-MS, and WAX-LC as well as site specific analysis. ³This includes: Exoglycosidase digestion followed by HILIC-UPLC and/or HILIC-UHPLC-FLR-ESI-MS/MS ⁴ Receive a short report providing information on glycan relative quantitation and identification within two weeks.



Interested in our Glycan Analysis Services?

Write to us and book an initial meeting with our experts, they will guide you through the process and design a glycan analysis workflow tailored to the needs of your organization.

1

Discuss your requirements with our experts We will sign a CDA/MSA if you required





2

Once you are satisfied with your Study Proposal & Quote, place your PO & **send us your samples**





2

Sample Analysis

We offer state-of-the-art methodologies as well as custom solutions for glycosylation analysis using chromatographic and mass spectrometric techniques and a combination thereof. We offer higher sample throughput due to the automation of several processes using a liquid-handling robotised platform. We work up to the GMP standard.





4

Data Analysis

Our glycosylation experts review and process the data, assisted by specialised software tailored to the custom type of analysis. The data is authorised by an independent scientist to ensure consistency.



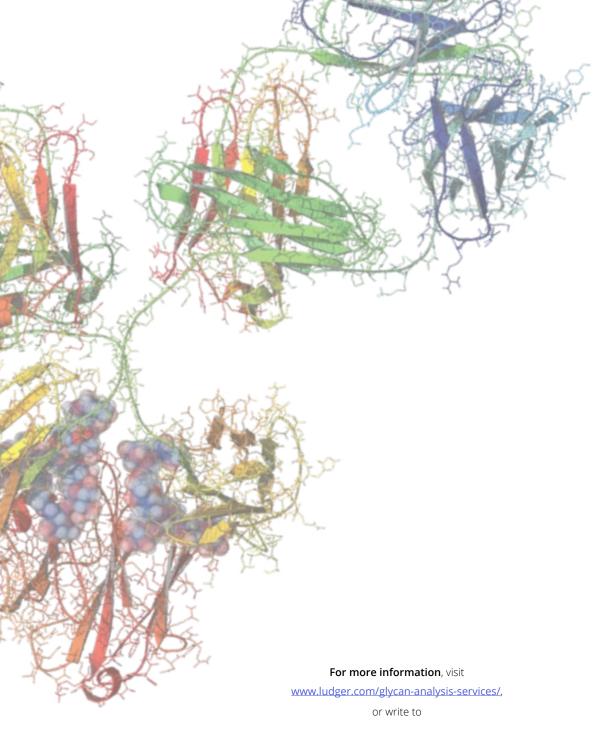


5

Customised Report

We customise each report according to the customer's needs – whether the end goal is a publication or a regulatory submission, we help with sample comparison and data presentation.







Dr. Radoslaw KozakHead of Glycoprofiling
rad.kozak@ludger.com

Ludger Ltd UK headquarters

Culham Science Centre, Abingdon, Oxfordshire OX14 3EB, United Kingdom Tel:+44 1865 408554



Ludger China branch office

Plaza 66, 15/F, Tower 2, 1266 West Nanjing Road, Jing'An District, Shanghai 200040, China