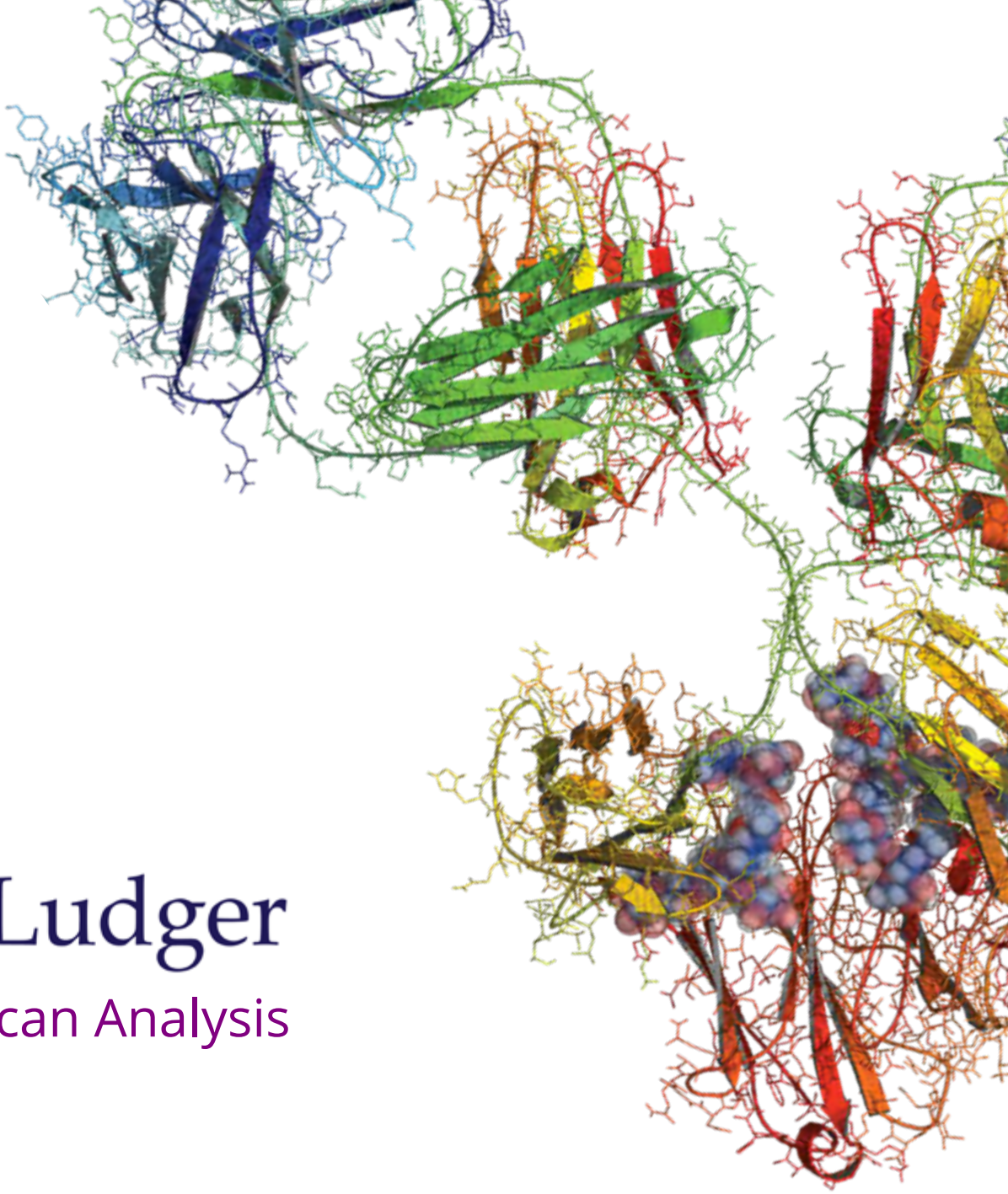


Ludger

Glycan Analysis

Services

Glycan analysis for medical research and drug manufacturing

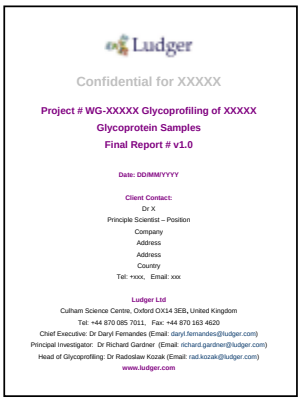
Consistently controlled and well-characterised glycosylation is a subject of concern during biopharmaceutical realisation and is recognised as a **critical quality attribute (CQA)**. It greatly increases drug complexity and heterogeneity, and can significantly influence **drug safety and efficacy**. 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 services[1] 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


Ludger

Confidential for XXXXX

Project # WG-XXXXX Glycoprofiling of XXXXX
Glycoprotein Samples
Final Report # v1.0

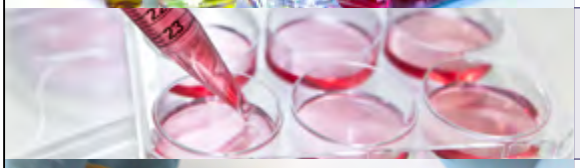
Date: DD/MM/YYYY

Client Contact:
Dr X
Principle Scientist – Position
Company
Address
Address
Country
Tel: +xxx, Email: xxx

Ludger Ltd
Culham Science Centre, Oxford OX14 3EB, United Kingdom
Tel: +44 870 085 7011, Fax: +44 870 163 4620
Chief Executive: Dr Daryl Fernandes (Email: daryl.fernandes@ludger.com)
Principal Investigator: Dr Richard Gardner (Email: richard.gardner@ludger.com)
Head of Glycoprofiling: Dr Radoslaw Kozak (Email: rad.kozak@ludger.com)
www.ludger.com

Our services include:

- **Sialic acid and monosaccharide analysis and quantitation**
- **N- and O-glycan profiling[2] and characterisation[3]**
- **High-throughput N-glycan screening[4]**
- **Custom method development and validation**
- **Method transfer**, **training** and **advisory services** to get glycoprofiling methods up and running in your laboratories

	Sample types
	**Biopharmaceuticals** Monoclonal antibodies (mAbs), Fc fusion proteins, vaccines, and glycoprotein hormones such as follicle stimulating hormone (FSH), and erythropoietin (EPO).
	**Cells** Mammalian cell lines, bacterial cell components
	**Biological samples** Patient's plasma, fluids, tissues and others
	**Infected samples and cell lines** COVID-19 patient samples and cell lines

[1] GMP-compliant modules are also available. [2] This includes: HILIC-LC, MALDI-MS, and WAX-LC as well as site specific analysis. [3] This 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**

3

Sample Analysis

We offer high-throughput and GMP-complaint sample analysis using state-of-the-art methodologies as well as custom solutions using chromatographic and mass spectrometric techniques and a combination thereof

4

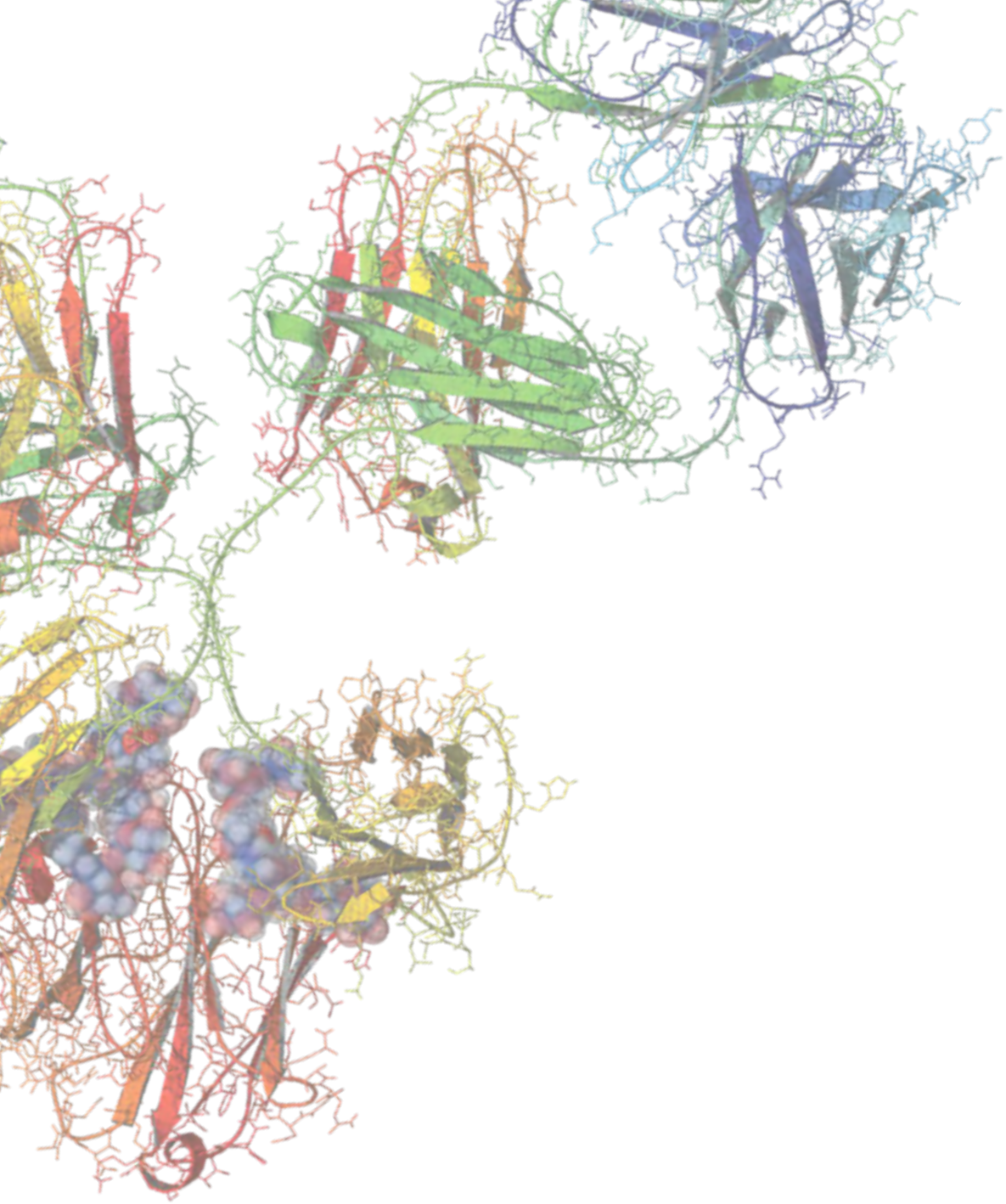
Data Analysis

Data is analysed by our experts using specialised software and peer-reviewed to ensure high-quality standards

5

Customised Report

Whether your report is being used for a publication or regulatory submission, we will make sure it fulfils all your requirements



For more details, visit:
www.ludger.com
or email
info@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