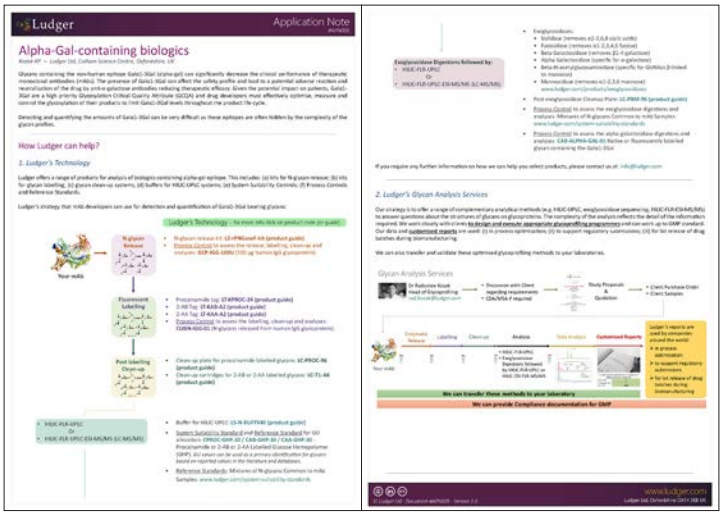
Ludger News

January/February 2020

We would like to wish you all a healthy and prosperous 2020!

How to optimize, measure and control Galα1-3Gal (non-human epitope) on your monoclonal antibody (mAb) therapeutics?

The clinical safety and efficacy of a glycoprotein drug is significantly influenced by its glycosylation. For instance, the presence of terminal α1-3-linked galactose (alpha-gal) can affect the safety profile and lead to a potential adverse reactions and neutralisation of the drug, thus reducing its therapeutic efficacy. Consequently, regulatory authorities are have tightened the requirements for biopharmaceutical companies to characterise, control and monitor their therapeutics glycosylation. However, identification and quantitative analysis glycans can be difficult to achieve due to their complexity and heterogeneity.


Ludger Application Note

Alpha-Gal-containing biologics

How Ludger can help?

Our new application note illustrates Ludger's expertise and the range of glycan analysis services for detection of alpha-gal and how we can assist you with identifying the Glycosylation Critical Quality Attributes (GCQA's) of your glycoprotein drug.

We offer alpha-Gal standards labelled with 2-AB [CAB-Alpha-Gal-01] and 2-AA [CAA-AlphaGal-01]. These standards can be used as positive controls in glycoprofiling sequencing experiments utilising alpha 1-3 galactose specific exoglycosidase.

To enquire regarding glycan analysis please contact rad.kozak@ludger.com or to place an order please contact info@ludger.com

For more information and to view the application note, please visit our webpage on glycan analysis.

Glycan Derivatization

Most methods for protein glycosylation analysis rely on the release of glycans from the glycoprotein. Released glycans lack chromophore or fluorophore properties which restrict their detection and separation by liquid chromatography (LC), mass spectrometry (MS) or a combination of both.

Ludger addresses these challenges by providing several tags which enable glycan detection and separation by LC and enhance ionization efficiency during MS analysis.

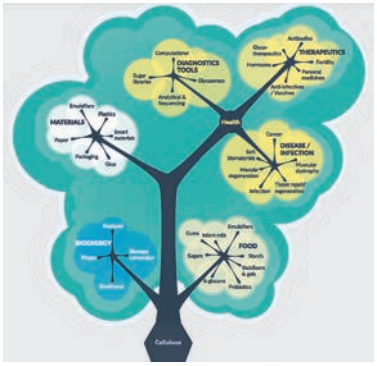
Ludger LudgerTag Labelling Kits	LT-KAB-A2	LT-KAB-VP24	LT-KAB-VP96	LT-KAA-A2	LT-KAA-VP24	LT-KPROC-24	LT-KPROC-VP24	LT-KPROC-96	LT-KDMB-A1	LT-VTAG-24	LT-VTAG-C30	LT-MONO-96	LT-PERMET-96**	LT-PERMET-VP96***
Application:														
N-glycans	✓	✓	✓	✓	✓	✓	✓	✓			✓		✓	✓
O-glycans	✓	✓	✓	✓	✓	✓	✓	✓					✓	✓
GSL glycans	✓	✓	✓	✓	✓	✓	✓	✓					✓	✓
IgG glycopeptides										✓				
Sialic acids									✓					
Monosaccharides												✓		
Release*									included		included	included		
Label	2AB	2AB	2AB	2AA	2AA	Procainamide	Procainamide	Procainamide	DMB	V-Tag	V-Tag	2AA	Permethylation	Permethylation
Reductant:														
Sodium Cyanoborohydride	✓			✓		✓		✓				✓		
Picoline borane		✓	✓		✓		✓							
Analytical platform:														
HPLC analysis	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●		
UHPLC analysis	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●		
LC-ESI-MS analysis	● ●	● ●	● ●	● ●	● ●	● ● ●	● ● ●	● ● ●			●		● ●	● ●
MALDI-MS	● ●	● ●	● ●	● ●	● ●					● ●			● ● ●	● ● ●
Number of samples	24	24	96	24	24	24	24	96	22	24	80	96	96	96

Analytical platform sensitivity range: ● ● (medium) ⟶ ● ● ● (high)
MS signal detection can be affected with sample purity and presence of salt contaminants.
* for release of N-glycans use PNGase F (Cat# E-PNG-xx or LZ-rPNGaseF-kit), for O glycans use LudgerLiberate Orela kit (Cat# LL-ORELA-A2) or hydrazinolysis kit (LL-HYDRAZ-A2), for GSLs use ceramide glycanase (Cat# LZ-CER-HM-KIT), for IgG glycopeptides use protease enzyme e.g. trypsin.
** with Methyl Iodide
*** without Methyl Iodide. This kit can be shipped outside of the UK.

The table above summarizes the applications, type of label, reductant method and analytical platform for each LudgerTag kit.

To view visit our webpage featuring our labelling technology.

Carbomet Workshop – A roadmap for Glycoscience in Europe

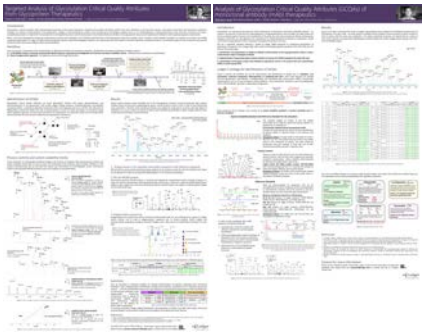


CarboMet held a workshop in Leiden jointly organised by Ludger (represented by Drs Daniel Spencer and Jenifer Hendel) and Leiden University Medical Centre to identify challenges and opportunities in glycoscience covering, biopharmaceuticals, diagnostics/precision medicine, microbiome and sustainable materials. The workshop was attended by 28 delegates from early career to more established researchers representing 10 EU member states.

The stakeholder consultation section of the workshop was led by Dr Daniel Spencer of Ludger Ltd. alongside Professor Sabine Flitsch of the Manchester Institute of Biotechnology and is being followed up by an online consultation to give the wider glycoscience community a chance to contribute to the next European roadmap 'Glycoscience 4.0' (you can view the current roadmap on our news page). We encourage our clients to participate in this consultation.

Please visit the CarboMet homepage to access the survey: https://carbomet.eu/

Ludger poster presentations from BioProduction Congress 2019 and Well Characterized Biologics 2019 now available online



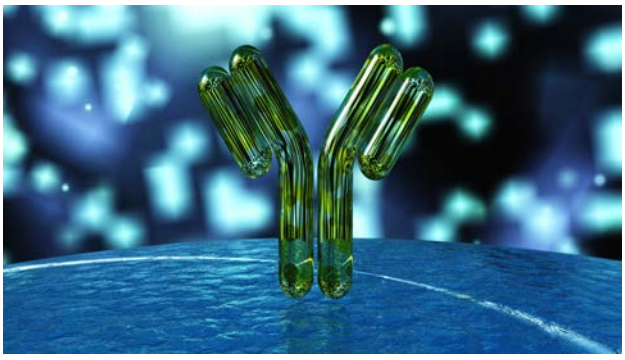
The following Ludger poster presentations are now available to view on the website:

- "Targeted Analysis of Glycosylation Critical Quality Attributes from Glycoprotein Therapeutics" presented by Paulina Urbanowicz (Senior Scientist, Ludger) at BioProduction Congress 2019 in Frankfurt, Germany
- "Analysis of Glycosylation Critical Quality Attributes (GCQAs) of monoclonal antibody (mAb) therapeutics" presented by Radoslaw Kozak (Head of Glycoprofiling and Interim Business Development Lead) at Well Characterised Biologics 2019 (WCB) in Reston (VA), USA.

The posters illustrate the case studies on how to identify and analyse key GCQAs during biopharmaceutical's development and highlight the importance of implementation of process and system suitability standards in glycoanalytical workflows. The posters were well received and we would like to thank everyone who attended both events.

To view these and any of our other posters, please click on the miniatures or visit our Poster webpage.

Publication in Molecular & Cellular Proteomics: Interlab Study on Characterisation of N-glycans from NIST monoclonal antibody



We are proud to announce the successful publication of a manuscript entitled 'NIST Interlaboratory Study on Glycosylation Analysis of Monoclonal Antibodies: Comparison of Results from Diverse Analytical Methods' in collaboration with National Institute of Standards and Technology, United States. Ludger's contribution included:

- Help with the study design and strategy
- Analysis of the N-glycan profile of the reference standard antibody using orthogonal techniques (MALDI, UHPLC and LC-ESI-MS)
- Supporting the visual reporting of structures and nomenclature of glycans identified in the study

The study provided a cutting edge view for glycosylation measurement of biologics and highlighted the need for harmonisation of analytical methods in the world of glycobiology.

Please visit the Ludger Products webpage for more information on our range of glycan characterisation techniques, and for more information about the article visit our Publications webpage.
