

Mannose-6-Phosphate Standard

Many therapeutic glycoproteins contain negatively charged glycans such as sialylated, sulphated and/or phosphorylated glycans that impact their structure, function, safety, and efficacy. Therefore, it is a regulatory requirement to analyse the Glycosylation Critical Quality Attributes (**GCQA**) of these drugs.

For instance, Mannose-6-Phosphate (**Man6P**), a terminal monosaccharide of asparagine-linked oligosaccharides is a key targeting signal for acid hydrolase precursor proteins that are destined for transport to lysosomes and is present in **therapeutic enzymes** (enzyme replacement therapies) developed for treatment of lysosomal storage diseases.

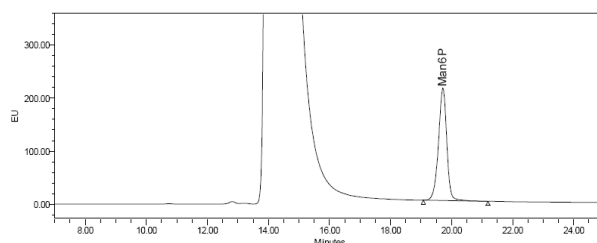


Figure 1. Chromatogram of 2-aminobenzoic acid (2-AA) labelled mannose-6-phosphate

As there was a lack of commercially available Man6P reference standard, Ludger has launched a **Mannose-6-Phosphate** standard (**CM-MAN6P-10**), which is a quantified monosaccharide **reference standard** and has been validated using quantitative NMR. We recommend using this standard to assess the Man6P content while characterising your recombinant therapeutic glycoproteins. For more information on this standard, email info@ludger.com.

Alpha Gal Standards

Glycans containing the non-human epitope Gal α 1-3Gal (Alpha-Gal) can significantly decrease the clinical performance of therapeutic monoclonal antibodies (**mAbs**). The presence of **Gal α 1-3Gal** can affect the safety profile and lead to a potential **adverse reaction** and neutralisation of the drug by anti- α -galactose antibodies reducing therapeutic efficacy. Given the potential impact on patients, **Gal α 1-3Gal** are a high priority **GCQA** and drug developers must effectively optimise, measure and control the glycosylation of their products to limit its levels throughout the product life cycle.

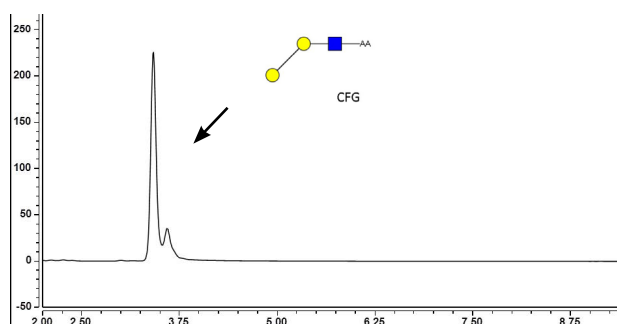


Figure 2. HILIC profile of 2AA labelled Alpha-Gal glycan

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 (**E-AG02**). [Click here](#) for more information or email info@ludger.com.

Pre-launch Announcement of Two N-Glycan Library Standards

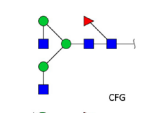
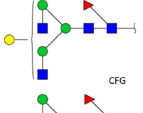

Our **N-glycan libraries** are used both in **FDA**- and **EMA**-approved assays worldwide to ensure compliance with **international guidelines*** throughout the development and **regulatory submission** of new **biotherapeutics** and **biosimilars**.

These glycan libraries are purified from various glycoprotein sources and qualified by **MS**, **HPLC** and **NMR analysis** to meet the high purity and quality standards required by advanced analytical techniques. They can be used as:

- **Reference standard** for therapeutic monoclonal antibodies and biotherapeutics.
- **Process control** to assess the performance of a glycan labelling protocol.
- **System suitability standard** to test analytical platform performance.

1) Monoclonal Antibody Reference Standard (CLIBN-MABMix-10U & CLIBN-MABMix-20U)

Ludger's MAb reference standard contains four N-glycans (see table below) which are found on several **mammalian glycoproteins** including **IgG**, **gamma globulins**, and many **serum glycoproteins**.

Peak	Glycan	Structure
1	NGA2F glycan (FA2, G0F)	
2&3	FA2G1 glycan (G1F)	
4	NA2F glycan (FA2G2, G2F)	

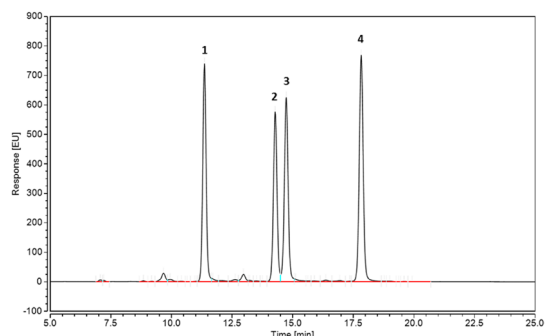
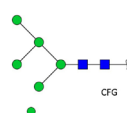
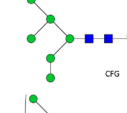
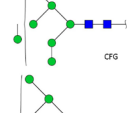
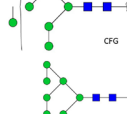
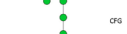


Figure 3. Chromatogram of Procainamide-labelled Mab N-Glycans

2) High Mannose Library Standard (CLIBN-ManMix-10U & CLIBN-ManMix-20U)

Ludger's High Mannose Mix contains five oligomannose N-glycans (see table below) which have **quality control** biopharmaceutical applications such as **half-life monitoring** of biotherapeutics (e.g. **MABs**) and **cell culture health** assessment from truncated glycosylation identification.

Peak	Glycan	Structure
1	MAN-5 (Mannose 5)	
2	MAN-6 (Mannose 6)	
3	MAN-7 (Mannose 7)	
4	MAN-8 (Mannose 8)	
5	MAN-9 (Mannose 9)	

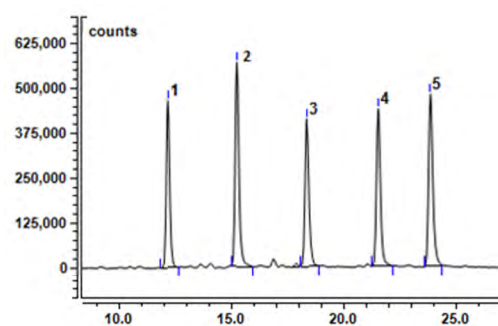


Figure 4. Chromatogram of Procainamide-labelled Oligomannose N-Glycans .

Our standards are supported by complete documentation. The certificate of analysis contains the results from the testing used to characterise the material across a complete range of quality characteristics. The standards are available in 10µg and 20µg quantities.

Subscribe to our newsletter to be the first one to know about these and all future product launches. For more information on these library standards, email info@ludger.com.

* ICH Topic Q 6 B Specifications: Test Procedures and Acceptance Criteria for biotechnological/Biological Products.

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