Ludger News

September/October 2015

Glycan Standards

Ludger produces a comprehensive range of purified glycans, including IgG glycans, which are used as standards during the analysis of biopharmaceuticals.

Purity acceptance criteria is 85% as determined by HILIC chromatography of the 2AB labeled glycans. HPAE-PAD chromatography, MALDI mass spectrometry and NMR analysis are also performed as supporting data.

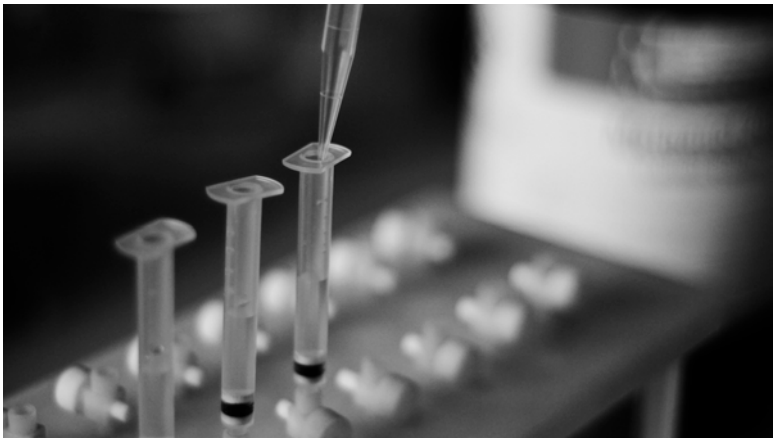
In the examples here we have given their short names and Ludger product names (see table).

For the full list of these and other glycans (unlabeled, permethylated or labeled with 2AB, 2AA, procainamide or APTS), please visit http://www.ludger.com/products.

If you are unsure if we have the standard you are looking for, please contact us at info@ludger.com

Common Short Name	Oxford Notation	Ludger Product
G0	A2	NGA2
G0F	FA2	NGA2F
G1	A2G1	A2G1
G1F	FA2G1	FA2G1
G2	A2G2	NA2
G2F	FA2G2	NA2F

LudgerClean EB10 cartridges for Mass Spectrometry



The use of Mass Spectrometry (MS) to analyse biopharmaceuticals can be enhanced with the use of LudgerClean EB10 cartridges. The cartridges contain a non-porous Electronic Interaction matrix which binds even very hydrophilic glycans. Most salts and detergents either simply pass through the cartridges or bind very lightly and can be washed off before the glycans are eluted. These single use cartridges are suited to MS analysis to reduce the interferences caused by salts and detergents. Detergents can severely affect the performance of mass spectrometry instrumentation and excess salts can form unwanted adducts with analytes or suppress the signal completely. LudgerClean EB10 cartridges are suitable for samples containing a widerange of glycans; typically each cartridge can bind up to 50 μg of N-linked glycans.

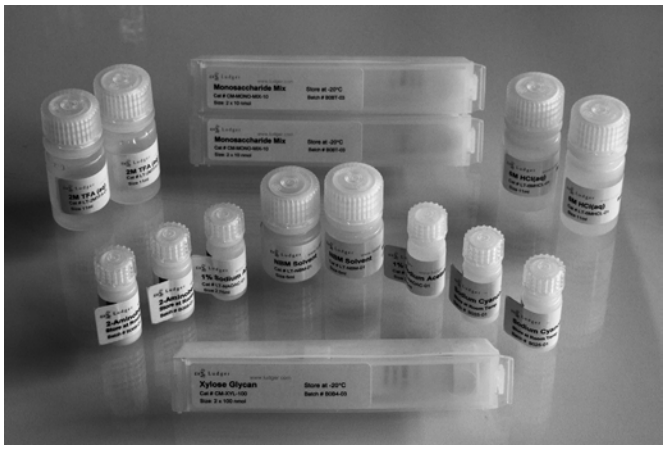
Cat # LC-EB10-A6

NIST Interlab Study

Ludger is participating in an interlab study set up by the U.S. Department of Commerce's National Institute of Standards and Technology (NIST). In this study, a number of laboratories have analysed the glycosylation profile of a NIST mAb reference material. The objective for NIST is to assess the capability of the glyco community to analyze the glycoforms in therapeutic IgGs.

NIST National Institute of Standards and Technology U.S. Department of Commerce

Workflow for Monosaccharide analysis of biopharmaceuticals



Monosaccharide analysis is a regulatory requirement laid out in the ICH Q6B guidelines for characterisation of biopharmaceuticals. This information can be used at all stages of drug development as a method of determining the extent to which glycosylation has occurred. It can also be used to demonstrate consistency between batches for QC lot release during the manufacturing process.

To address this requirement, Ludger provides a workflow for monosaccharide analysis. The LudgerTag™ Monosaccharide Release and Labelling kit provides all that is required to release neutral and amino monosaccharides from up to 96 glycoprotein samples and label them with 2AA. The kit also includes a quantitative standard (monomix) containing 6 monosaccharides (glucosamine galactosamine, galactose, mannose, glucose/dextrose and fucose), enabling instrument calibration in order to quantitatively determine the monosaccharide components in your glycoprotein. In addition we also recommend using the BioQuant glycopeptide standard as a positive control to check the efficiency of glycan release, labeling and recovery.

Samples can be analysed by (U)HPLC using the LudgerSep columns described below using LudgerSep BPT Solvent. Columns for other manufacturers can be used. Please contact us if you would like to discuss this further.

Ludger Products	Cat No.
Release monosaccharides and label with 2AA: LudgerTag™ Monosaccharide Release and Labeling Kit	LT-MONO-96
Positive control: Quantitative glycopeptide standard	BQ-GPEP-A2G2S2-10U
For HPLC analysis: LudgerSep™ R2 HPLC Column	LS-R2-4.6x150
For UHPLC analysis: LudgerSep™ uR2 UHPLC Column	LS-UR2-2.1x50
Solvent : LudgerSep™ R BPT solvent (x10 concentrate)	LS-R-BPTX10