

Octet[®] Sialic Acid (GlyS) Kit

High-Throughput Glycan Screening of Crude and Purified Samples



Key Features

- No sample purification or digestion required; reduces preparation time by up to 3 hours
- Screen for samples with desired sialylation levels – high, medium or low
- Combine titer data with sialic acid data for more informed decisions

Overview

Glycosylation is considered among the most important post-translational modifications when developing new biologics. Having a significant impact on product performance and variability, glycosylation is a critical quality attribute (CQA) influencing product safety and efficacy. Protein glycosylation can affect isolation and purification steps (process consistency), pharmacokinetics (half-life) properties and *in vitro* stability (product shelf-life). Sialic acid content is especially important as it can impact the stability and clearance of a protein.

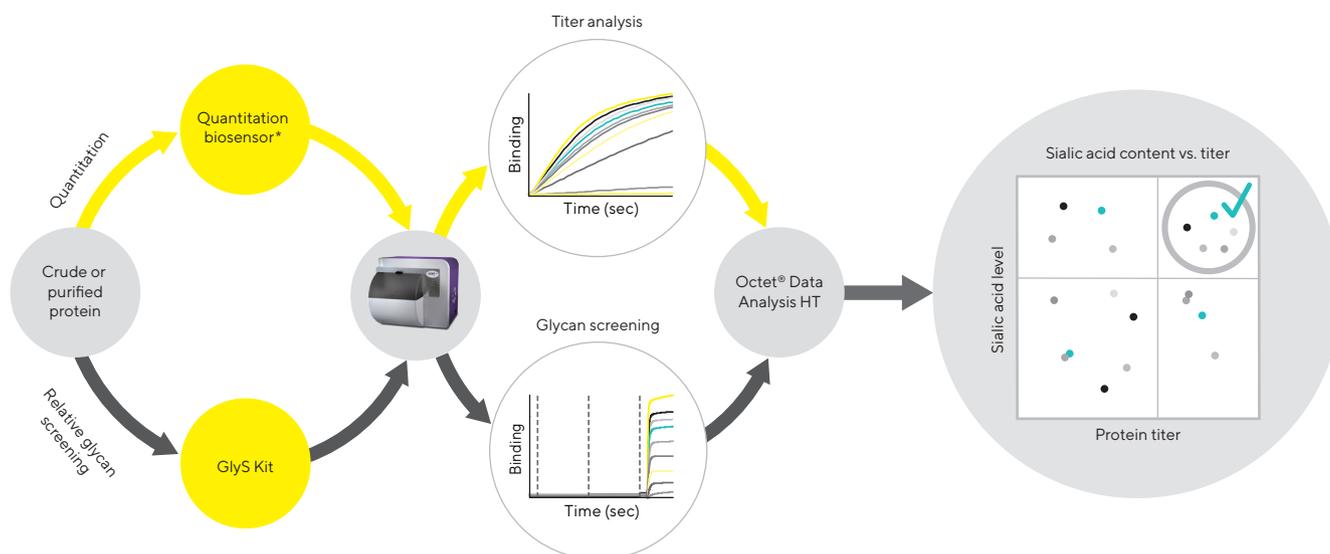


Figure 1: Typical workflow of CQA analysis on the Octet® platform. Titer is measured using a ProA, HIS1K, ProG or other quantitation biosensor* and relative screening of terminal sialic acid is performed using the Octet® GlyS Kit. Octet® Analysis Studio Software can then combine both data files to view sample representation with CQAs in one file and create reports for export. *Not included with Octet® GlyS Kit.

Work Directly with Cell Culture Samples

The Octet® GlyS Kit does not require sample purification or digestion, allowing analysis of crude samples. Screening to identify ideal candidates and those that fail can be done much faster and earlier in the process.

Screen for Optimal Sialylation

The Octet® GlyS Kit uniquely enables high-throughput relative sialic acid screening of crude samples. It is designed as a complementary tool for cell line development groups to screen for samples that have desired sialylation levels, allowing more time to be spent focusing on the samples that matter for the specific project.

Combine CQA Data for More Informed Decisions

Octet® Analysis Studio Software[†] allows titer data to be combined with sialic acid content data. The ability to view and choose from desired titer and sialylation levels at the same time provides more in-depth knowledge that facilitates more informed decisions. The software also supports creation of reports with these combined CQAs that can be exported directly into Microsoft® PowerPoint® and other programs.

How It Works

The Octet® GlyS Kit is designed to enable use of crude cell culture samples without any purification or digestion. For human monoclonal antibody (mAb) or human Fc-fusion proteins, the kit includes anti-human detection Ab that binds only to the protein-of-interest (POI) and not to host cell proteins (HCP). A secondary amplification step increases the signal from POI. This amplified signal negates the minimal signal from HCP to confidently relative rank the sialylation levels. For non-human POI, anti-POI Ab is required.

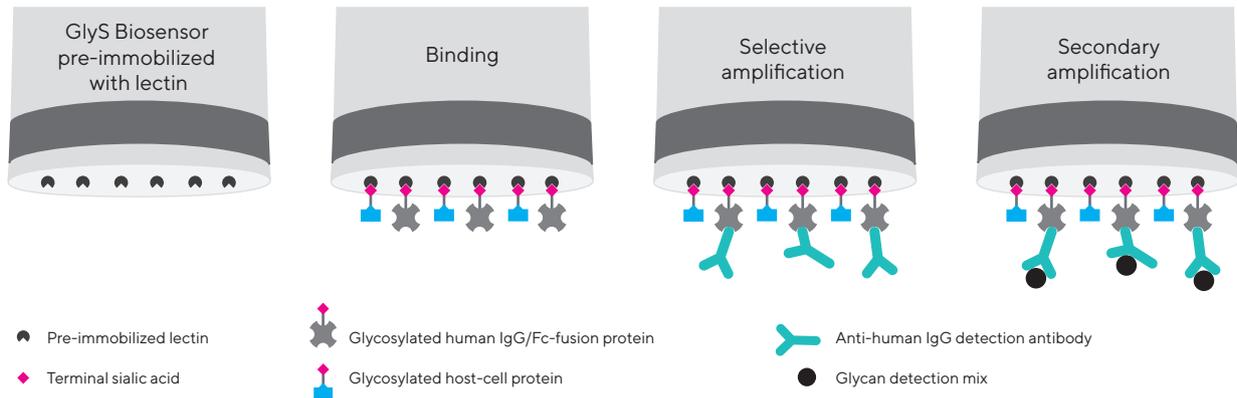


Figure 2: Example assay workflow for human IgG or human Fc-fusion proteins. Selective amplification of signal is from the protein of interest and not from host-cell protein (HCP).**

Ordering Information

Part No.	Name	Description
18-5135	Octet® GlyS Kit**	Includes 1 Octet® GlyS Biosensor Tray (96 biosensors) and 1 Octet® GlyS reagent kit containing Glycan Buffer A, Glycan Sample Prep Buffer, Anti-hlgG Detection Ab, Glycan Detection Substrate, Glycan Detection Buffer and Glycan Wash Buffer.

** Please refer to the Octet® GlyS Kit user guide for other assay workflows and additional materials required.

† Requires Octet® BLI Discovery and Analysis Studio Software version 11.1 or higher.

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