

# Glycan Assay Services for Cell Line and Upstream Development

## Introduction

Screening for product quality, in particular glycosylation, is becoming increasingly important in cell line and upstream development. It represents a new tool for de-risking projects at an early stage and contributes to accelerating development.

However, traditional technologies are still labor-intensive and require sample purification which makes it impossible to run hundreds of samples in an acceptable time frame. Is it therefore challenging to make the move towards screening more samples in an industrial setting. The turnaround time are typically several weeks even for rather small samples numbers.

The PAIA assay technology provides a fast solution to screen many samples for a limited number of critical glycan features.

Our PAIA technology is now also accessible through Glycan Screening Services which are carried out by the expert staff at PAIA in Cologne/Germany.

These services enable our customers to benefit from the PAIA glycan assay technology and our expertise from multiple projects without having to implement the technology in-house.

The service offering comprises different specific modules which are defined during the initial discussions about the screening strategy for the specific project.

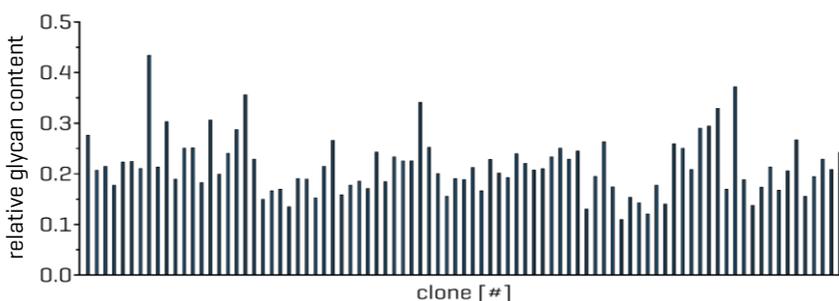
The whole screening project is conducted at PAIA using standardized protocols in a time frame of no longer than two weeks from receipt of samples to final report.

## Highlights

- Supernatant screening
- Hundreds of samples
- Turn-around time: 1-2 weeks
- Small sample volumes

## Applications

- Antibodies, Bispecifics, Fc-fusions
- Minipools and Clone Screenings
- High Mannose
- Galactosylation and Sialylation
- Afucosylation



Results from a clone screening project for a critical quality attribute



## Technology

PAIA has developed a patented technology for streamlining bead-based assays in microplates. This technology has proven to be a powerful screening tool for product glycosylation using carefully selected lectins. Lectins bind specifically to different types of glycosylation, e.g. high mannose, galactosylation, fucosylation and sialylation.

The output of the PAIA glycan screening assay is a lectin binding rate for each lectin and sample. It represents the amount of lectin that has bound to the glycans in the sample. Normalization of the lectin binding rate for analyte concentration therefore allows to rank samples according to that specific glycosylation feature.

Many samples containing the same analyte [e.g. antibody, bi-specific or Fc-fusion protein] are analyzed in a glycan screening project. Each analyte requires some protocol optimization, including sample preparation and assay calibration. Once this is accomplished, several screenings for the same analyte can be run using the optimized protocol.

## Project structure

Each glycan screening project starts with defining the goals for the customer's specific development project and molecule after signing CDA/MTA agreements.

Based on this initial discussion PAIA develops a screening strategy and provides a cost estimate. The project cost depends on the number of samples, number of glycan types to be analyzed and whether the samples need purification.

After scheduling the project and sample transfer to PAIA, the screening will be executed within a maximum of two weeks including the final report to the customer.

An interim report is provided after the assay optimization and before the glycan screening is performed.

Additionally, PAIA offers feasibility studies to first-time customers prior to performing larger service campaigns.

# Glycan Screening. Fast and effective.

For more information, please contact us at [glycans@paiabio.com](mailto:glycans@paiabio.com)