

ANTIBODIES

Demonstrating Biosimilarity

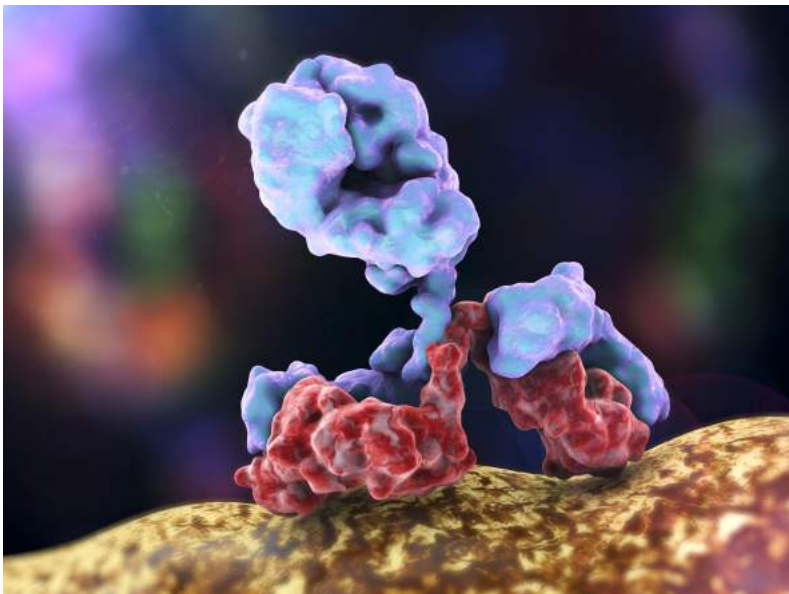


Expertise in Antibody Characterisation

Proteomics International (PI) has extensive experience in providing physiochemical and structural analysis of antibody products. Whether there is a need for antibody analysis to support drug discovery or the drug manufacturing process, PI offers tailored analyses based on the projects specific requirements.

PI will map a biosimilar product to determine whether there is a fingerprint-like similarity profile compared to the reference product. The data generated is provided in accordance to **FDA**, **EMA** and **ICH Q6B** test procedures and guidelines.

Comprehensive structural and functional characterisation



Comparability analysis includes:

- Intact mass analysis by LCMS
- Peptide mapping analysis
- N/C-terminal analysis
- Disulphide bridge analysis
- Amino acid analysis
- Glycosylation analysis
- Impurity profile and characterisation
- CD analysis
- Aggregation analysis
- Electrophoretic patterns

Proteomics International

Founded in 2001, PI is a specialist testing facility operating in Australia under the Asian time zone.

As the world's first company to receive ISO 17025 laboratory accreditation for proteomics services, PI provides specialist analytical testing services for the pharmaceutical and biotechnology industries.



A trusted partner for demonstrating biosimilarity for global regulatory approvals

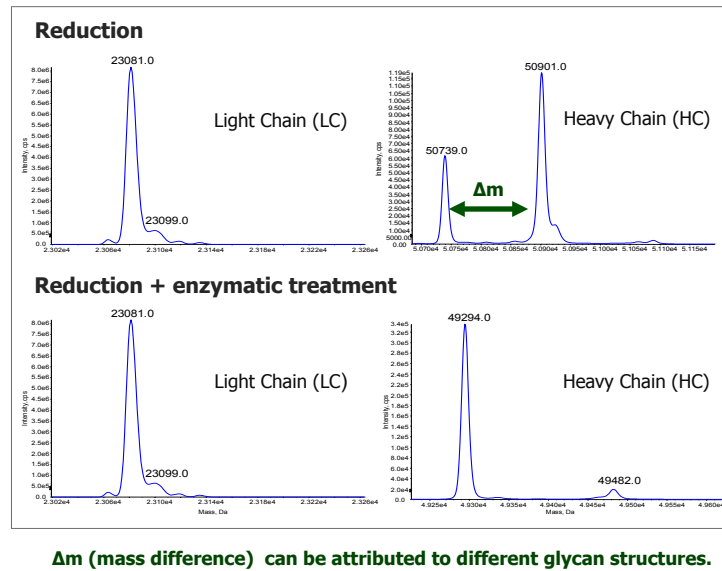
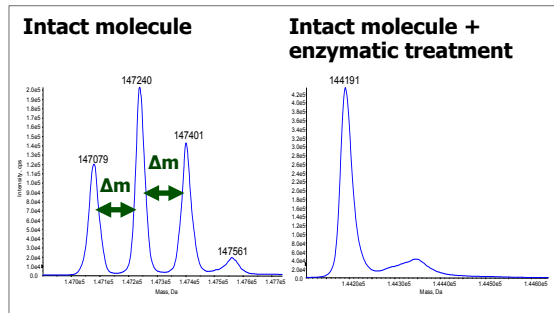
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Antibody Characterisation

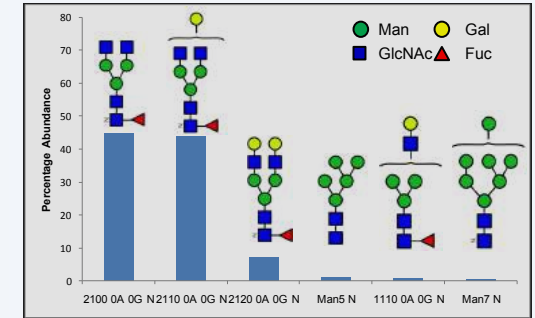
Intact mass analysis determines the correct mass and any heterogeneity of the recombinant antibody.

The analysis is conducted by ESI-LC mass spectrometry (MS) for both the intact and reduced heavy and light chains. Additionally these analyses are performed after enzymatic release of the glycans.



Δm (mass difference) can be attributed to different glycan structures.

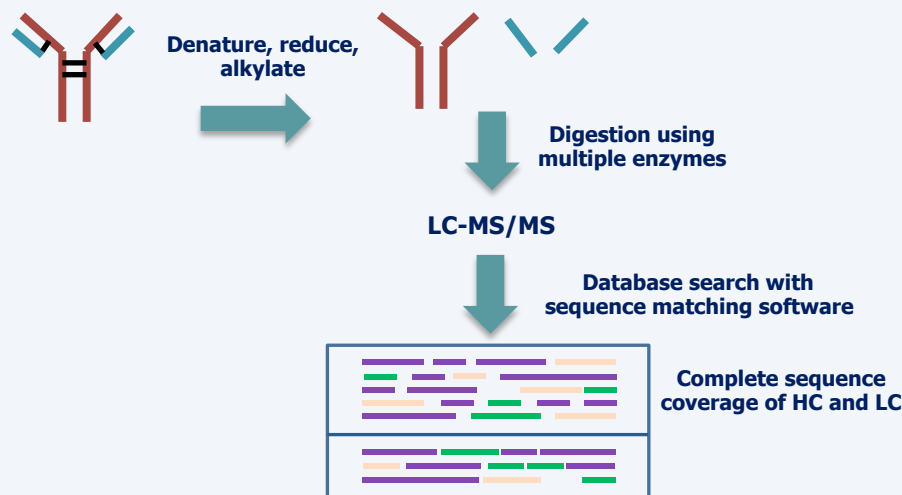
N-linked glycan analysis using mass spectrometry (MS). The analysis is conducted with the mAb-Glyco chip LC-MS system. This identifies and quantifies glycans based on their m/z values, retention time and isotopic patterns.



The relative glycan abundances detected.

Peptide mapping analysis confirms the complete primary sequence of the antibody product by mass spectrometry (LC-MS/MS) using a multi - enzyme digest strategy. The sample spectra are compared to the theoretical sequence to assess protein coverage using Mascot sequence matching software [Matrix Science].

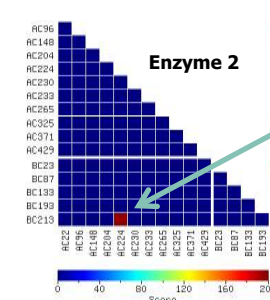
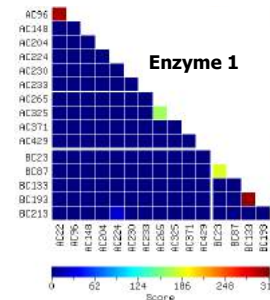
Peptide mapping workflow



Disulphide bridge analysis

The analysis determines disulphide linked peptide fragments following multi-enzyme strategy digestion of the antibody. The antibody sample is processed through different reduction and alkylation conditions followed by LC-M/MS analysis. These conditions provide the data necessary for a complete assessment of disulphide bridges and any free thiols within the antibody. The data analysis is conducted by using:

- Software to automatically assign protein disulphide bonds (intra- and inter- linked) from mass spectrometry data.
- Missing disulphides (e.g. complex disulphides involved in an antibody hinge region) are manually sequenced and annotated.



Change in color represents disulphide linked peptide

Scoring profiles show the identified disulphide linked peptides of the antibody for two different enzyme digestions.