Structural and Physicochemical Testing Services

Characterizing the inherent structural heterogeneity is an essential requirement of the development of a therapeutic monoclonal antibody.

At Sartorius Stedim BioOutsource we offer a comprehensive range of methods to characterize and confirm protein structure, carbohydrate profile, post-translational modifications and impurities. Our state-of-the-art techniques follow ICH Q6B regulatory guidelines to enable an efficient, streamlined development process.

Contact our scientists via our website to discuss your physicochemical and structural analyses requirements.

Structural and Physicochemical methods offered by Sartorius Stedim BioOutsource

Physicochemical Properties	Structural Characterization and Confirmation
Molecular Weight and Size	Carbohydrate Structure
Liquid Chromatographic Pattern (e.g. Size Exclusion Chromatography, Ion Exchange Chromatography)	Amino Acid Sequence
Isoform Pattern	Amino Acid Composition
Extinction Coefficient	Terminal Amino Acid Sequence
Electrophoretic Pattern	Peptide Map
Spectroscopic Profiles	Sulfhydryl groups and Disulphide bridges

Related Services

- Cell Line Development
- Cell Bank Manufacturing
- Bioanalytical Testing
- Biosafety Testing

www.biooutsource.com

A partner you can rely on

Our recently expanded, cutting-edge laboratories are fully equipped, allowing us to continuously support our clients' testing requirements throughout the drug development lifecycle.

Our team of experienced chemists can provide the support and advice required to ensure that appropriate assessments are performed at each stage of the development of a therapeutic antibody.

More information on a selection of our methods

Molecular Weight

The determination of molecular weight is essential for preliminary assurance that the recombinant product is synthesized as expected. Molecular weight measurement can indicate potential sequence variation and provide a high level assessment of post-translational modification, including glycosylation. Our high-resolution LC-MS methods provide accurate molecular weight information on the intact, deglycosylated and reduced monoclonal antibody.

Aggregates and Fragments

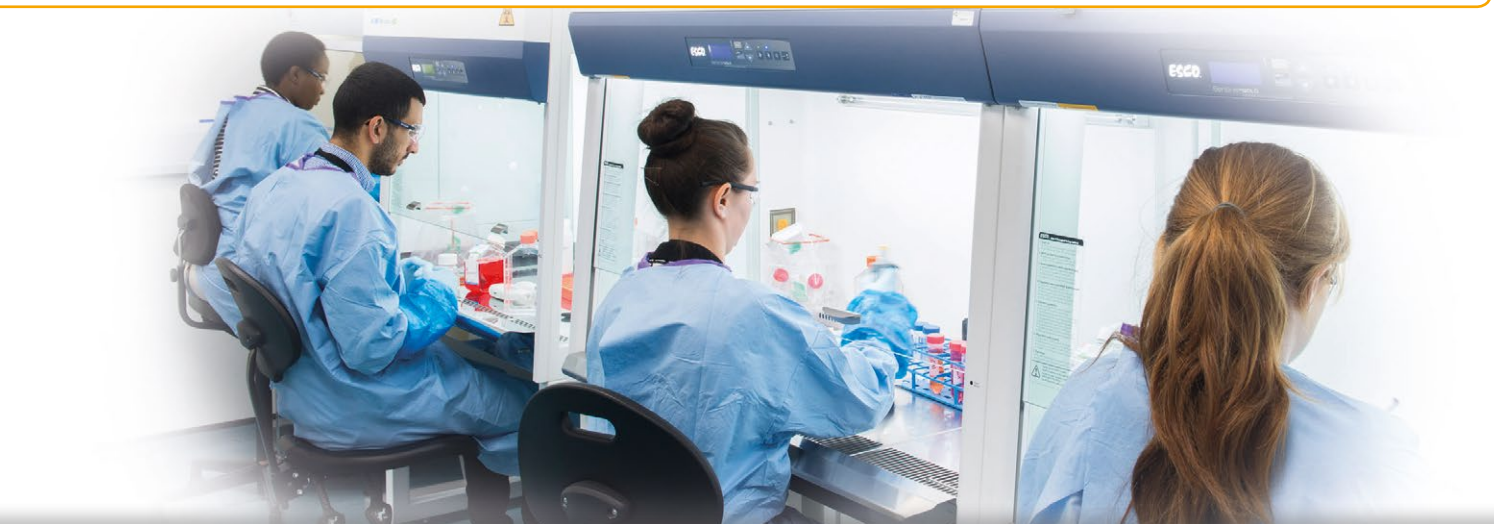
Protein aggregation and degradation products are fundamental characteristics implicated in the stability, biological activity and immunogenicity of a therapeutic monoclonal antibody. We offer low dispersion, high resolution chromatographic methods to separate and quantify high and low molecular weight variants of your monoclonal antibody product.

Charge Variant Analysis

Charge variants of a biological product can have implications on stability and biological function. Charge heterogeneity can be caused by C-terminal lysine clipping, chemical degradation (e.g. deamidation) and post-translational modification (e.g. glycans containing sialic acid). Monoclonal antibodies can be separated according to their isoelectric point using Ion Exchange Chromatography. This powerful technique can distinguish between molecules that have minor differences in the net charge.

Carbohydrate Structure

Characteristics such as effector function, pharmacokinetics and immunogenicity are heavily influenced by the structure of oligosaccharides attached to the monoclonal antibody. Therefore, controlling the glycan profile is a serious challenge to developers of antibody therapeutics. Our Released N-Glycan Assay combines high resolution chromatographic separation with on-line MS detection for confident glycan assignment.



To discuss your testing requirements please contact our experts

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is part of the
Sartorius Stedim Biotech Group