

Antibody Product Analysis

in Accordance with Regulatory Guidelines

Antibody products should be characterised according to ICH and FDA guidelines. **M-Scan** provides a full GLP/cGMP analysis package for product characterisation and identification of post translational modifications, which include:

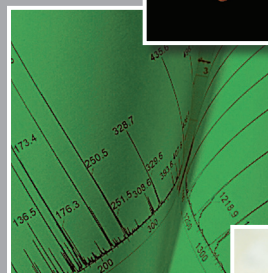
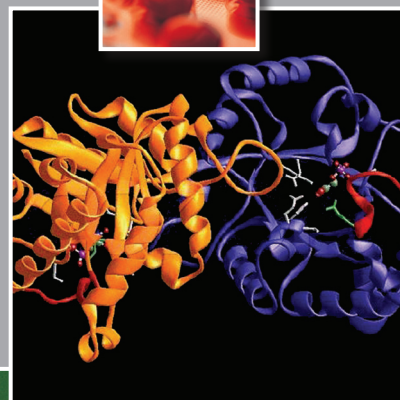
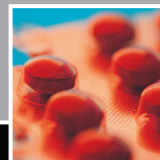
Structural characterisation and confirmation

- Amino acid sequence
- Amino acid composition
- N- and C- terminal sequence
 - N-terminal sequencing (automated Edman)
 - MS/MS peptide sequencing
- Peptide map
- Sulphydryl groups and disulphide bridges
- Carbohydrate structure
 - Monosaccharide composition analysis
 - Oligosaccharide profiling by HPAEC-PAD and MS
 - Linkage analysis
 - Glycosylation site determination
- Deamidation
- Oxidation

Physicochemical properties

- Molecular weight or size
 - Gel electrophoresis
 - MALDI-TOF or ES-Q-TOF-MS
- Isoform pattern
- Extinction coefficient
- Electrophoretic pattern
 - Including CE
- Liquid Chromatographic patterns
 - Reversed Phase
 - Size Exclusion
 - Ion-Exchange profiling
- Spectroscopic profiles
 - Circular Dichroism
 - NMR
- Aggregation
 - Analytical Ultracentrifugation (AUC)
 - SEC/MALLS

Expert Analytical Services

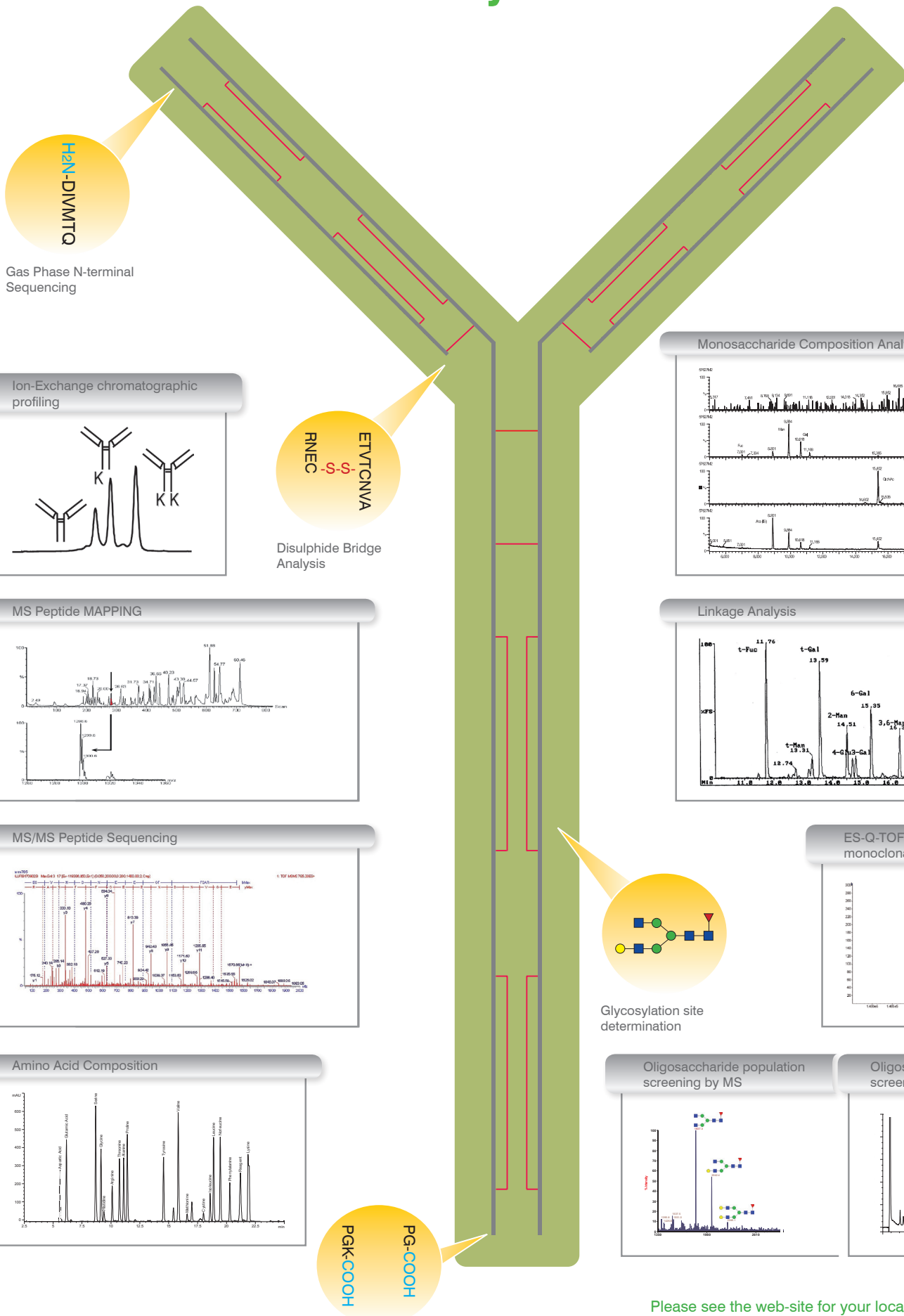


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www.m-scan.com

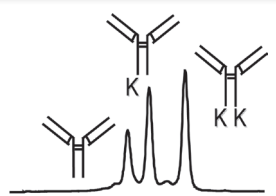
In-depth Analytical Characterisation of Antibody Products



H₂N-DIVMTQ

Gas Phase N-terminal Sequencing

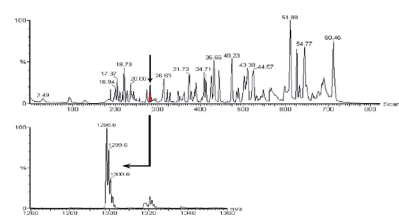
Ion-Exchange chromatographic profiling



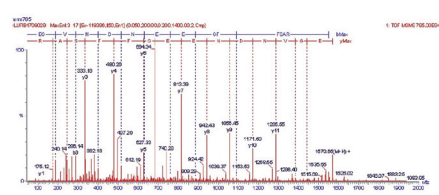
ETVTCNVA
RNEC
-S-S-

Disulphide Bridge Analysis

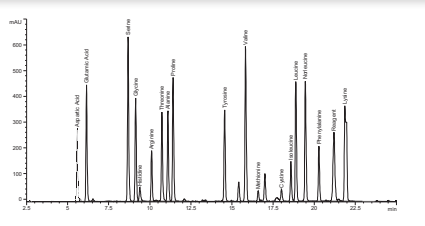
MS Peptide MAPPING



MS/MS Peptide Sequencing



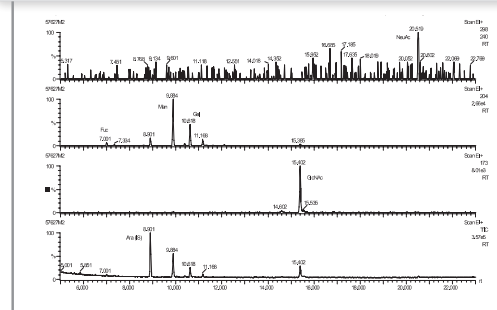
Amino Acid Composition



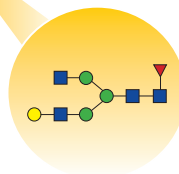
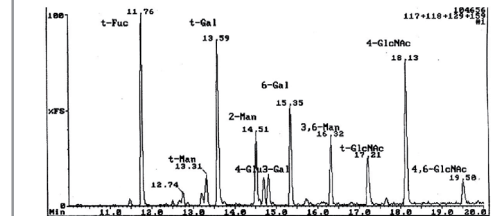
PG-COOH
PGK-COOH

Microheterogeneity at C-terminus

Monosaccharide Composition Analysis

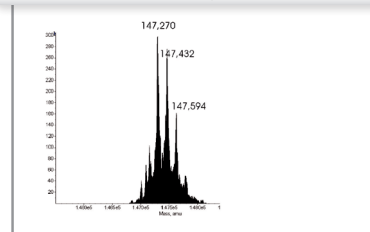


Linkage Analysis

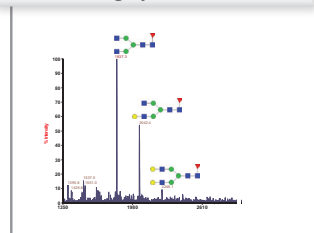


Glycosylation site determination

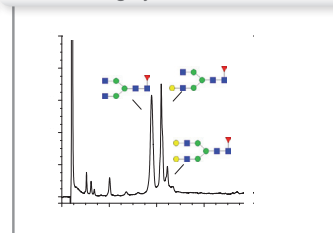
ES-Q-TOF-MS Analysis of an intact monoclonal antibody.



Oligosaccharide population screening by MS



Oligosaccharide population screening by HPAEC-PAD



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