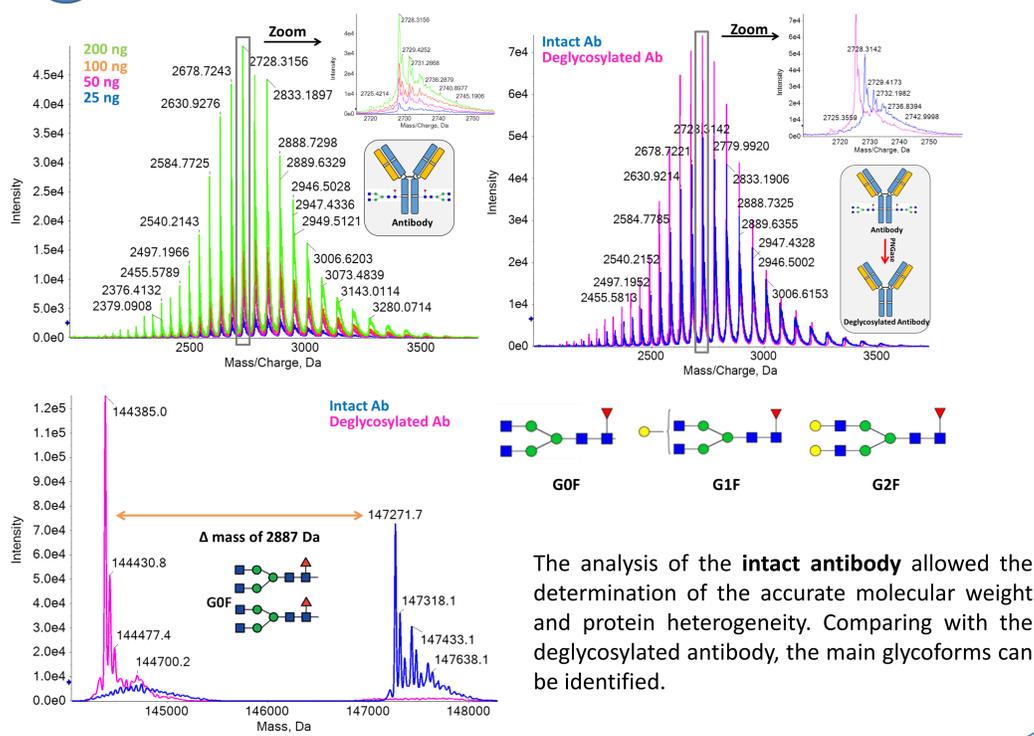


INTRODUCTION

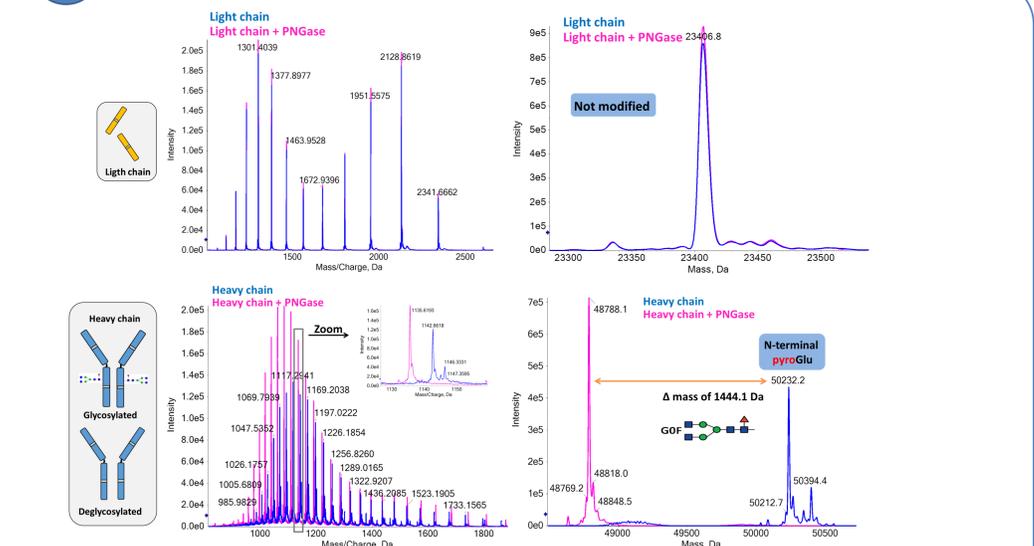
Therapeutic monoclonal antibodies (mAbs) are the dominant product class of the fast growing biopharmaceutical industry. A comprehensive characterization at the molecular level of antibody heterogeneity such as glycoforms, post-translational modifications (PTMs) and sequence variations is of utmost importance. Mass spectrometry (MS)-based approaches are definitely the most powerful analytical strategies to monitor and defined an array of product quality attributes (PQAs) on complex products such as mAbs. In this work, we demonstrate the analytical power of the TripleTOF 6600 MS platform for the analysis of an *in-house* produced mAb.

RESULTS

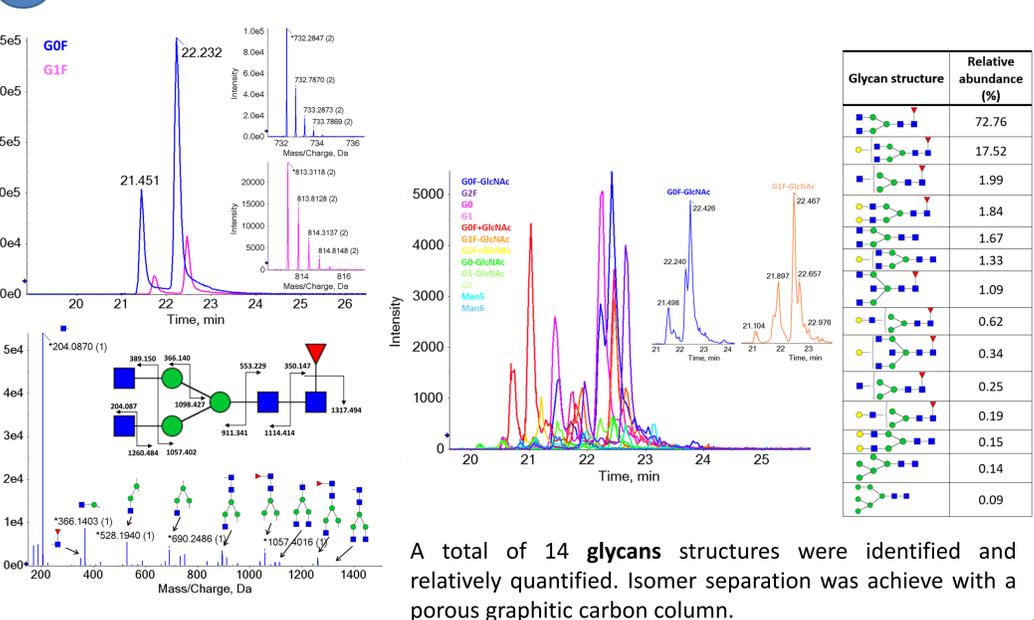
1 Intact antibody analysis



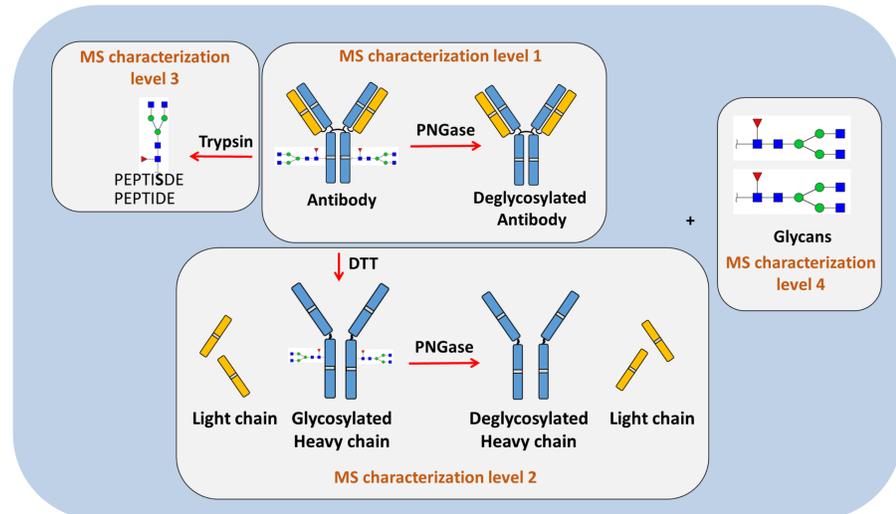
2 Reduced antibody analysis



4 N-glycan analysis

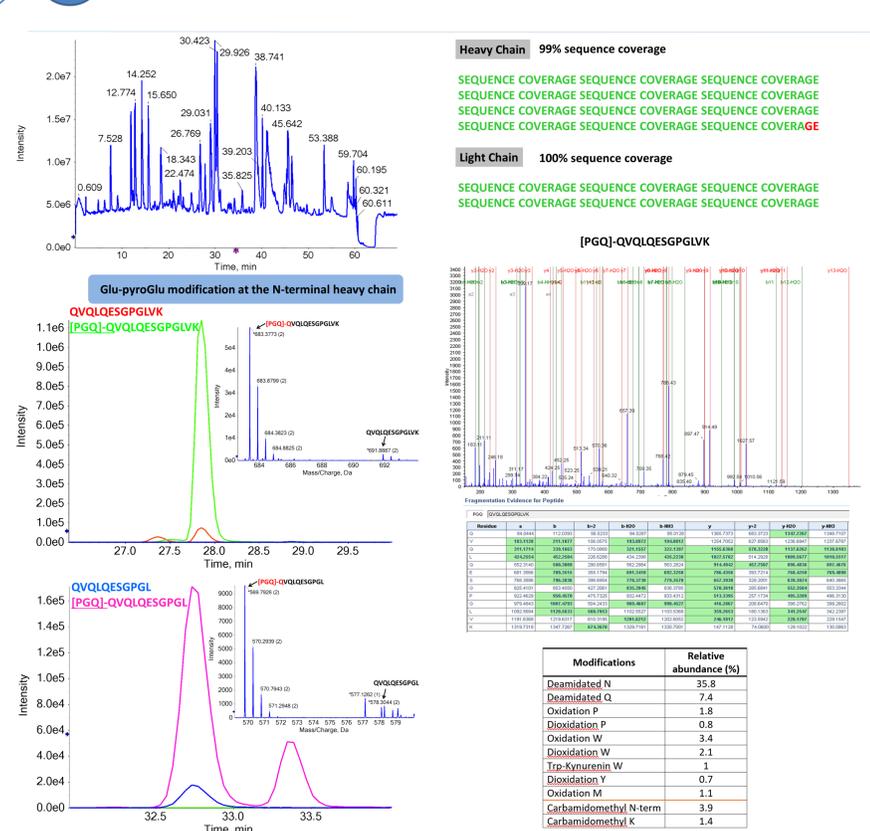


AIMS & STRATEGY



Full characterization was achieved at the **peptide level** with ~ 100 % sequence coverage. The N-terminal Q-pyroGlu modification was confirmed with MSMS data. Several PTMs we also detected and relatively quantified.

3 Peptide analysis



CONCLUSIONS

- Using a single MS platform and a simple sample preparation workflow a detailed and fast mAb characterization was obtained;
- Product quality attributes (PQAs) such as N-glycosylation and other key PTMs were detected and quantified;
- The MS-based analytical strategy explored in this work enables a comprehensive characterization of complex biological products;
- Other PQAs or process related impurities, like host cell proteins, can also be evaluated by this platform.

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