

# A Novel LC-MS System Solution for High Performance Routine Characterization of Protein Biopharmaceutical

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## ABSTRACT

- All too often high performance combined with routine analysis methods result in a compromise in system performance. This work will illustrate how one can obtain high-performance in a routine manner without compromises.
- This LC/MS system and methods will be demonstrated with intact proteins and peptide maps from antibodies and recombinant proteins. The value to a work-flow of an optimized LC, columns, MS, and software for data analysis will also be presented.

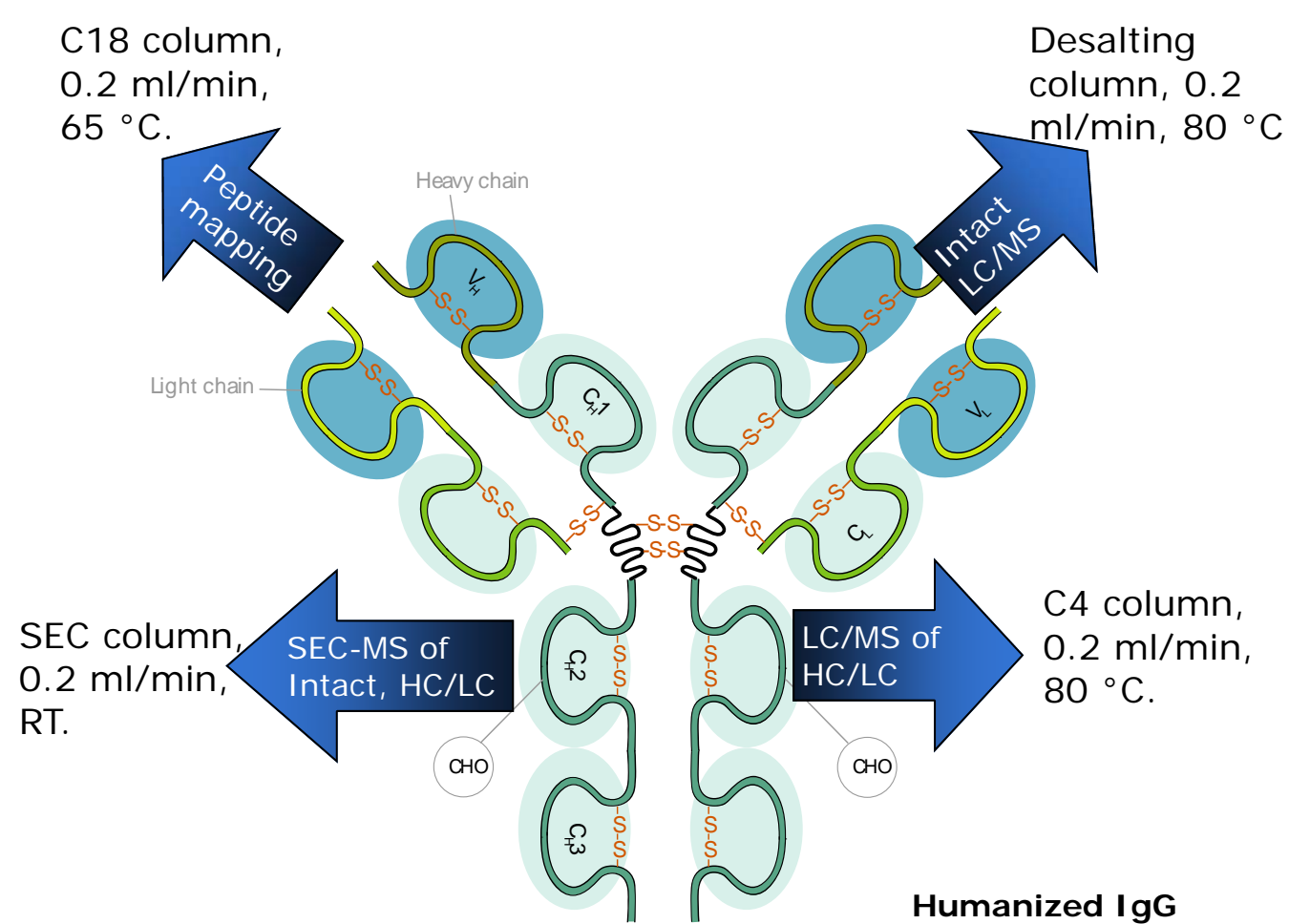
## INTRODUCTION

- Comprehensive characterization of biopolymers as drug candidates is a requirement for safety and regulatory agencies.
- LC/MS of proteins and peptides is a powerful method for characterization.
- The ability to reproducibly generate and interpret high quality LC/MS data in a timely manner is challenging. This is often hindered with the lack of tools addressing a complete work flow.
- This poster outlines a complete set of work flow tools for time efficient high performance LC/MS and SEC-MS characterization of proteins and peptides.

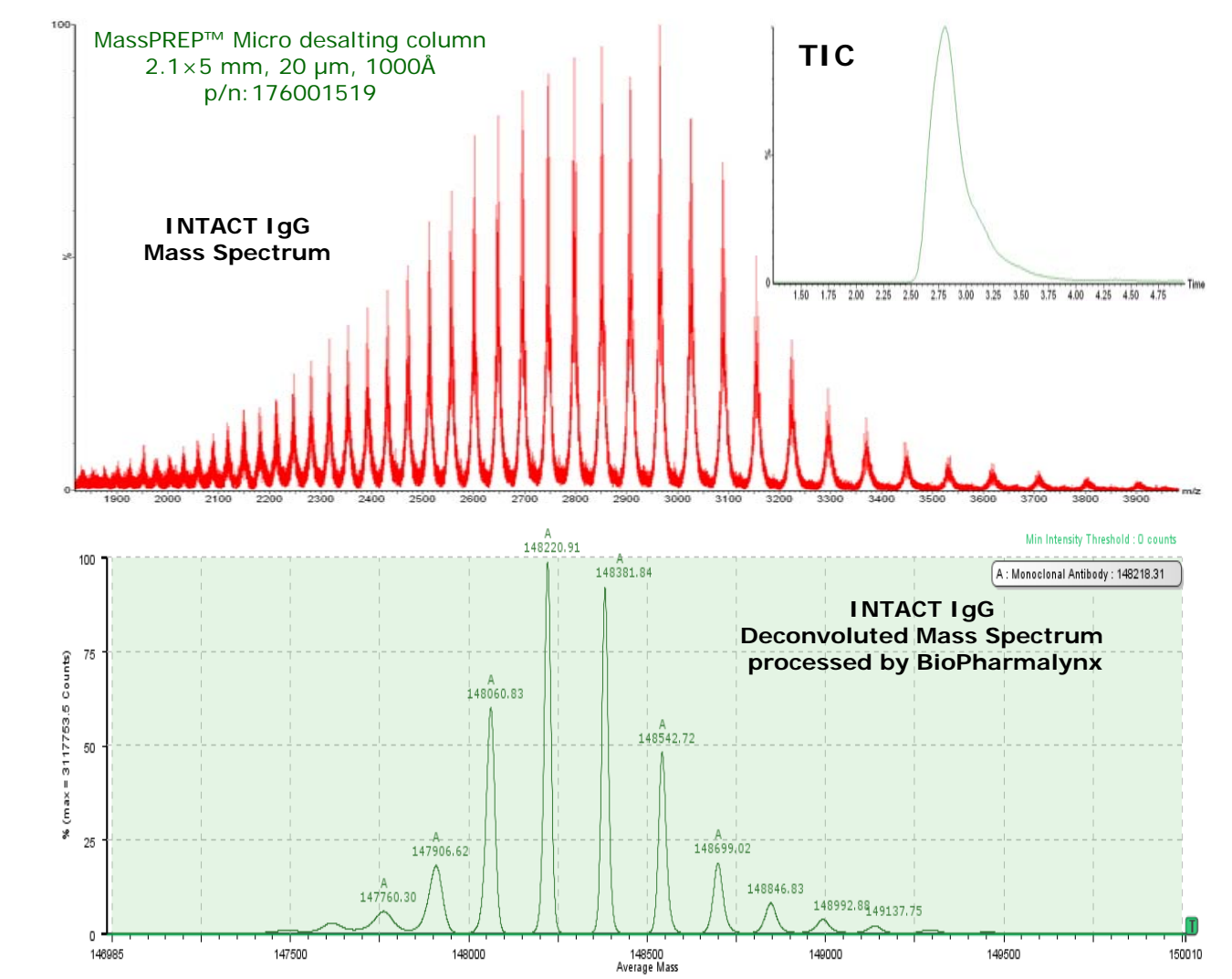


Waters biopharmaceutical LC/MS system: ACQUITY UPLC® LC and Xevo™ G2 QToF MS

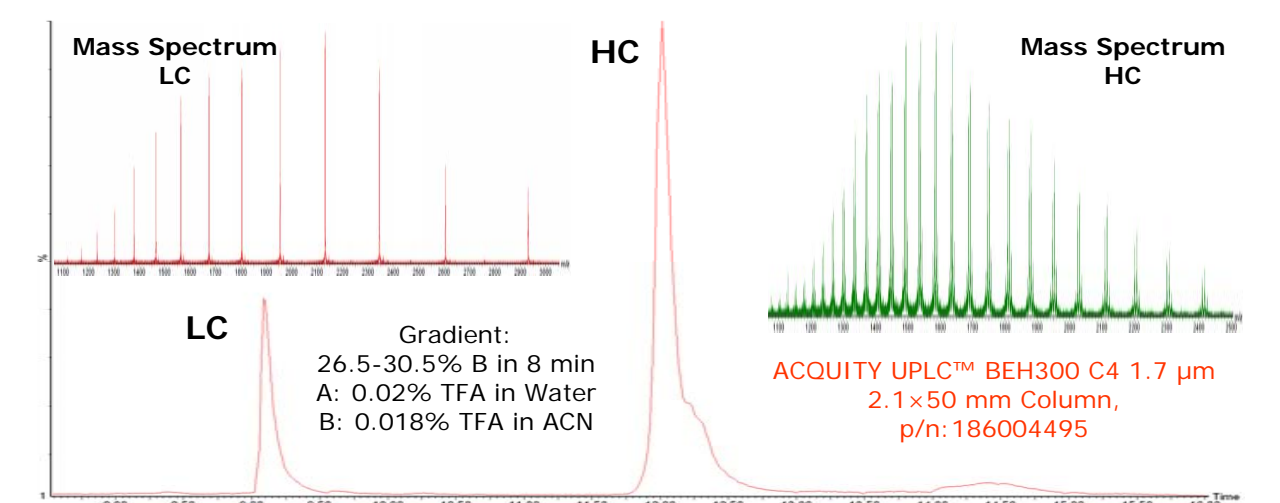
## EXPERIMENTAL



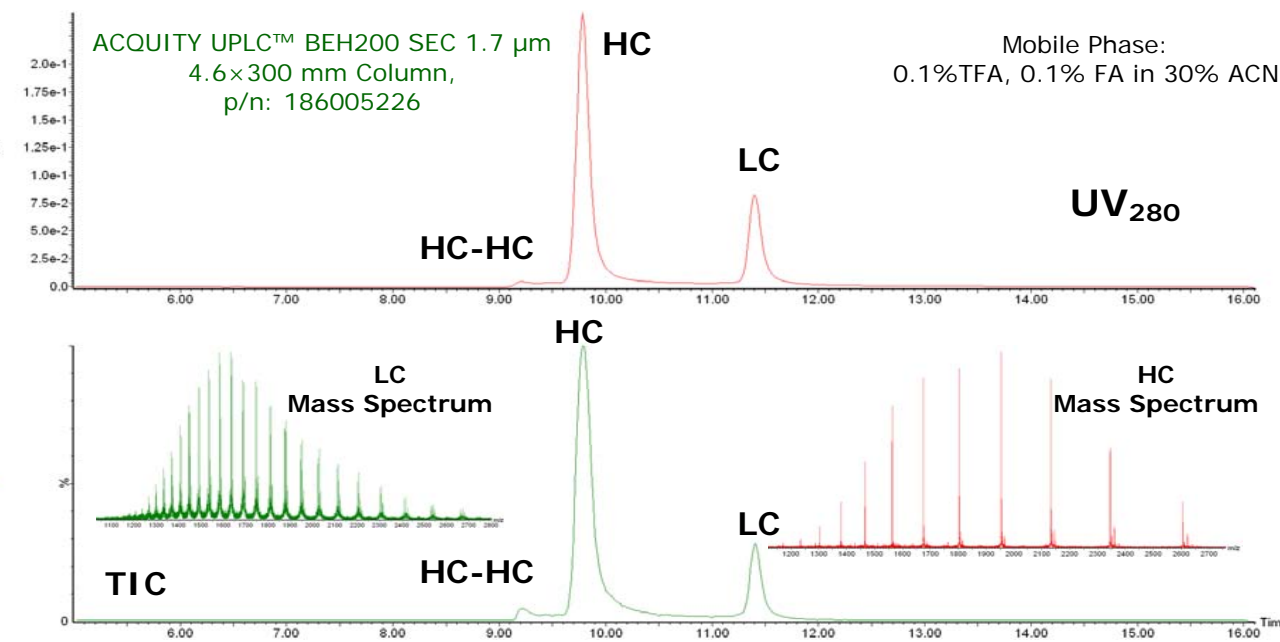
## INTACT LC/MS of IgG



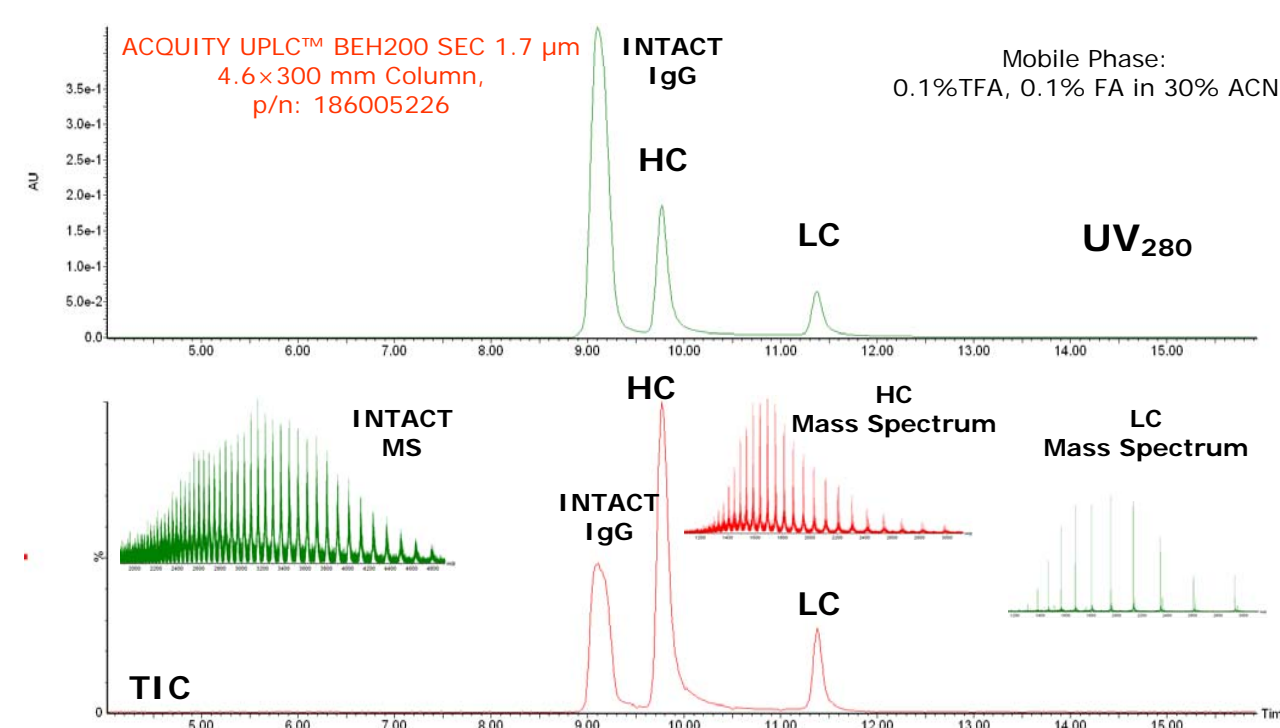
## Reduced LC/MS of IgG



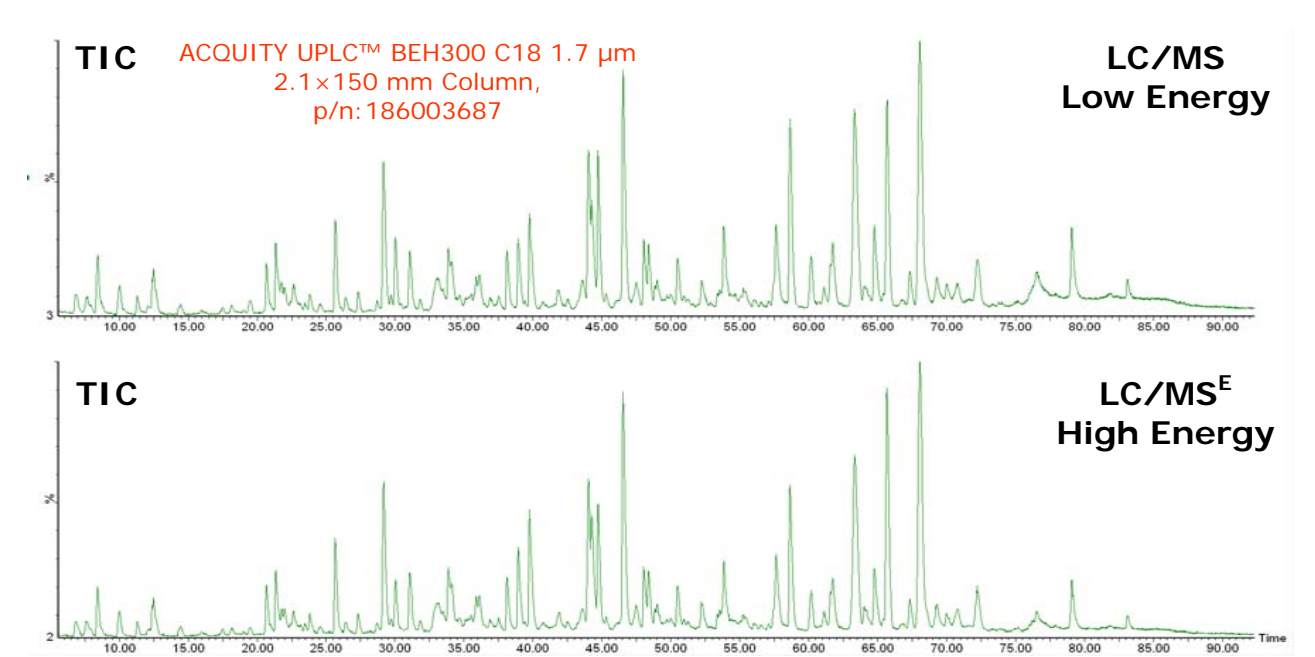
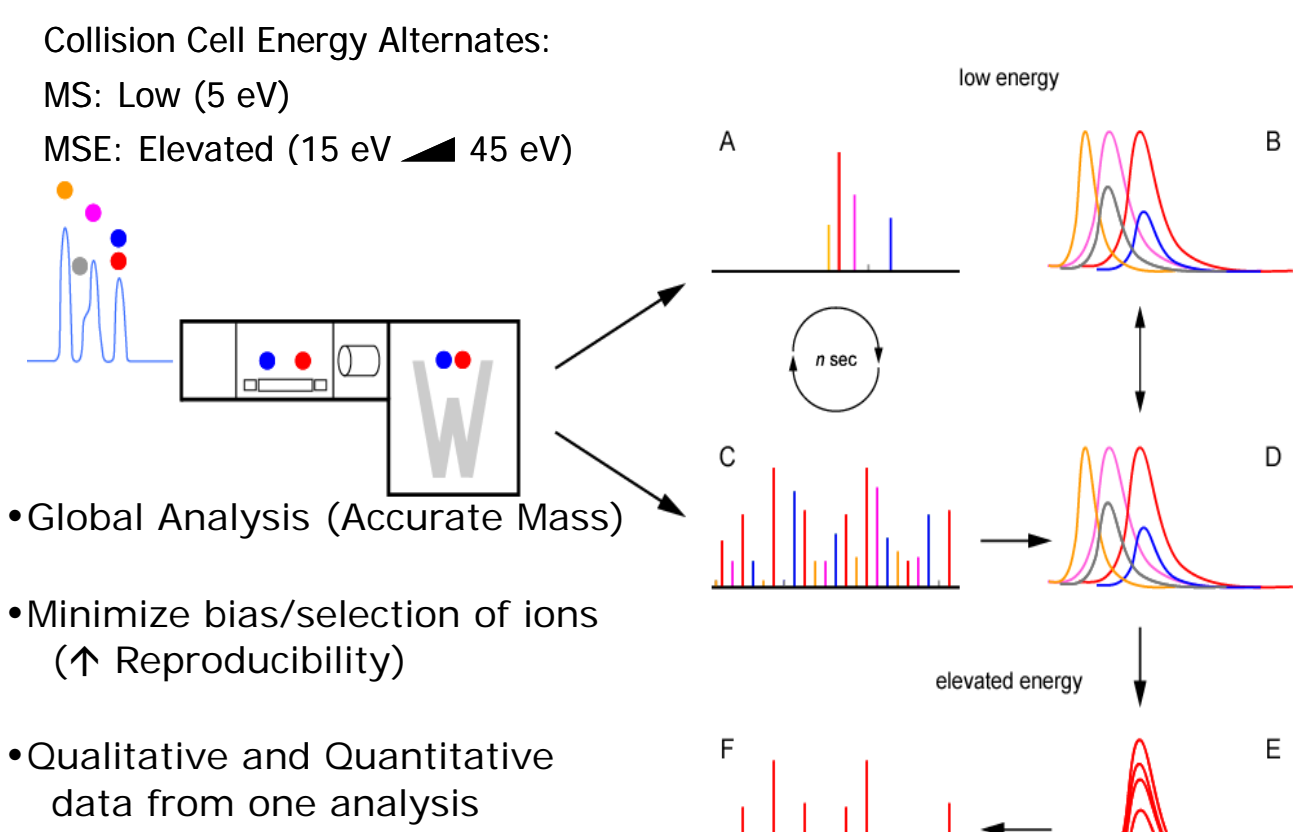
## Reduced SEC/UV/MS of IgG



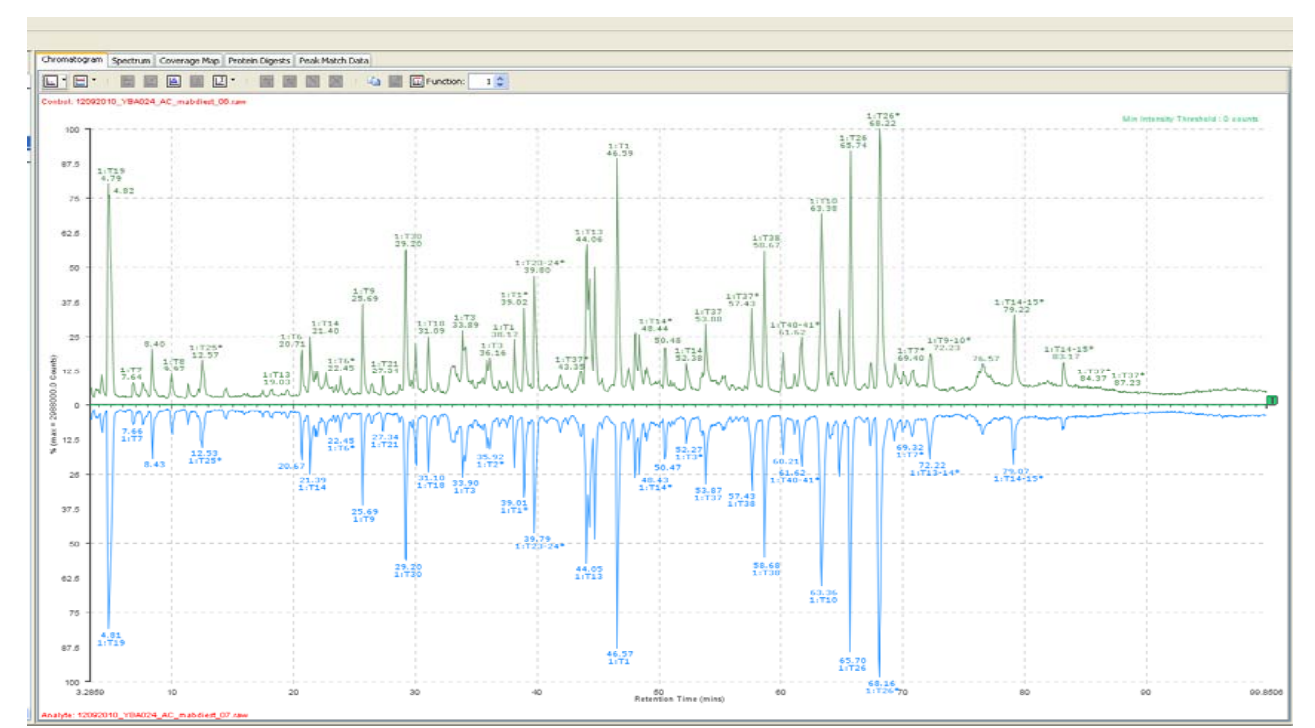
## SEC/UV/MS of IgG Intact and Reduced Mixture



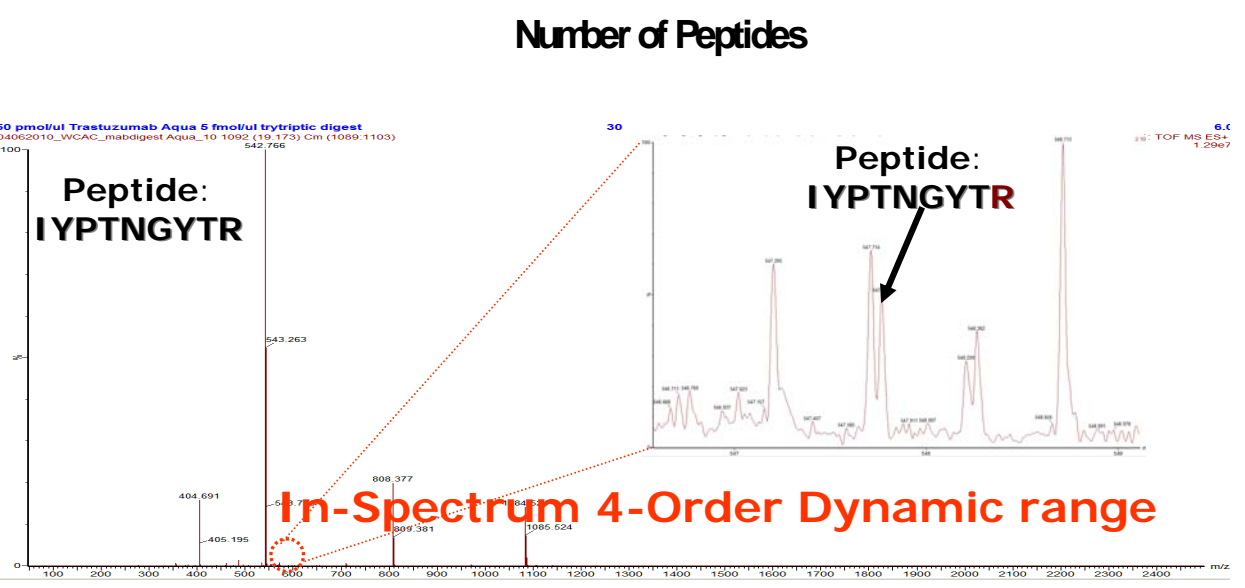
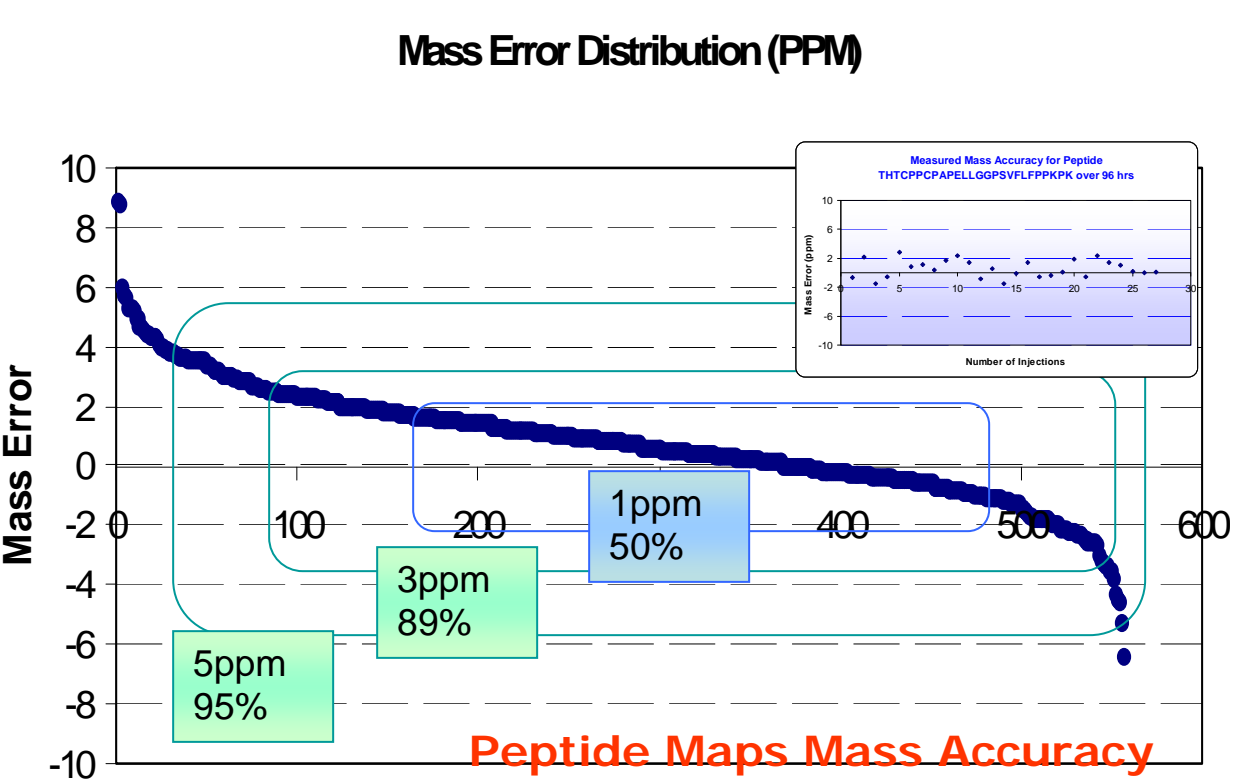
## LC/MS<sup>E</sup> PEPTIDE MAP



LC/MS<sup>E</sup> Tryptic Peptide Map of humanized IgG showing TICs of low and elevated energy channels.



BiopharmaLynx processed Peptide Maps showing automated annotation of chromatographic peaks.

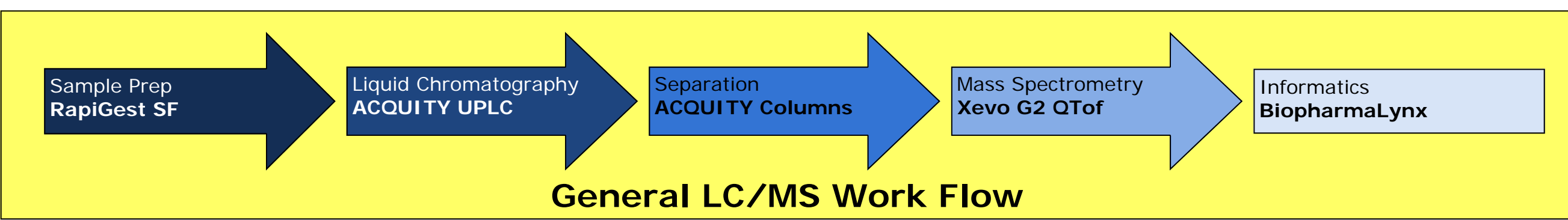


## CONCLUSION

- High performance routine characterization of intact proteins and peptide maps
- No compromise LC/MS performance
- *Featuring*
  - Waters ACQUITY UPLC® LC System
  - ACQUITY UPLC Columns (1.7µm particles)
  - ACQUITY BEH200 SEC, 1.7 µm x300 mm
  - Xevo™ G2 QToF Mass Spectrometer
  - BiopharmaLynx™ informatics
- Ideal for characterization of:
  - Intact Proteins
  - Peptide Mapping



- Advance characterization of peptides with MS<sup>E</sup> enabled with BiopharmaLynx
- Complete solution (work flow) tightly integrated



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