

Thermo Fisher S C I E N T I F I C

Separation Science Built for Biopharma

Pharma & Biopharma Tours | 2016

Overview

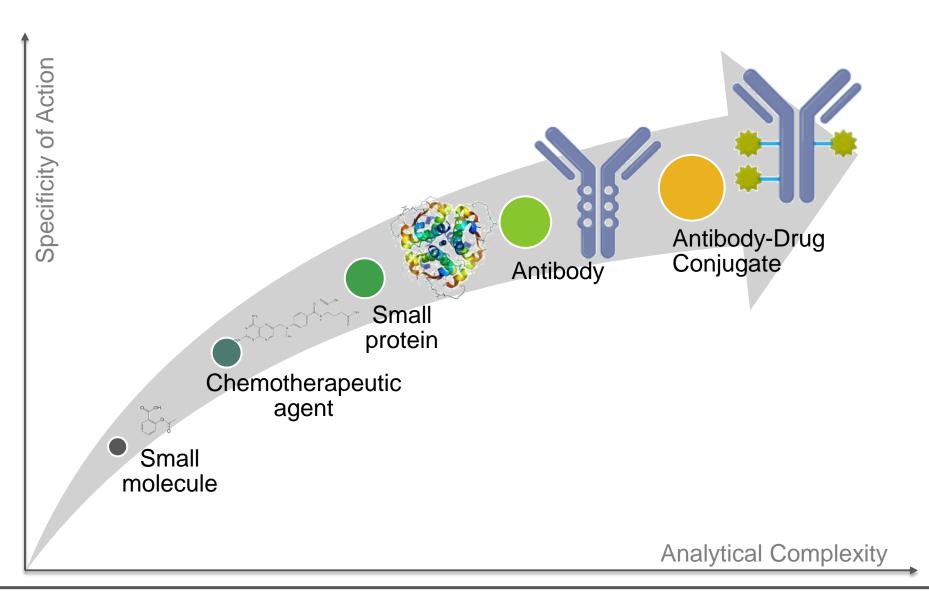
- 1. Evolution of UHPLC built for biopharma
 - Meet the family
- 2. What makes Vanquish different?
 - Key features and benefits
- 3. Biopharma workflows
 - 5 fundamental workflows



Evolution of UHPLC Built for Biopharma



Why Focus on Biopharmaceuticals?



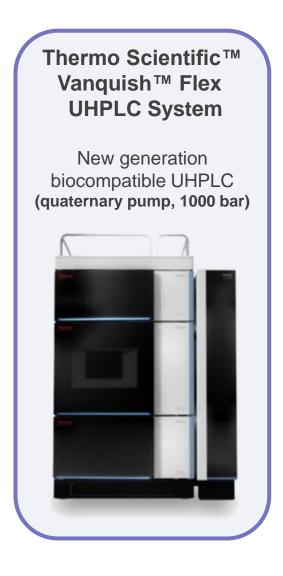


We Listened...



Meet the Family

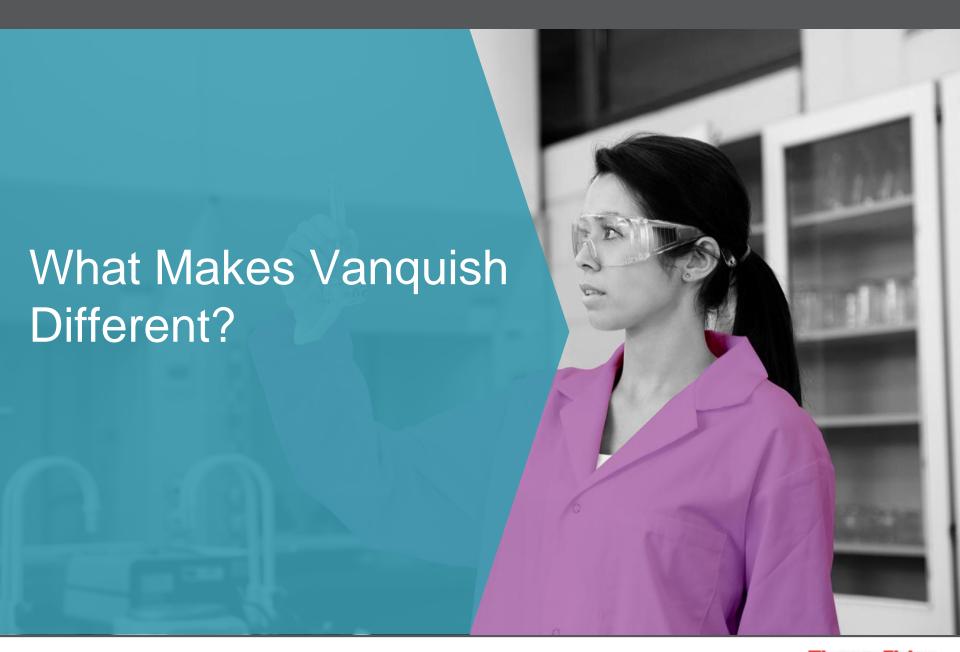




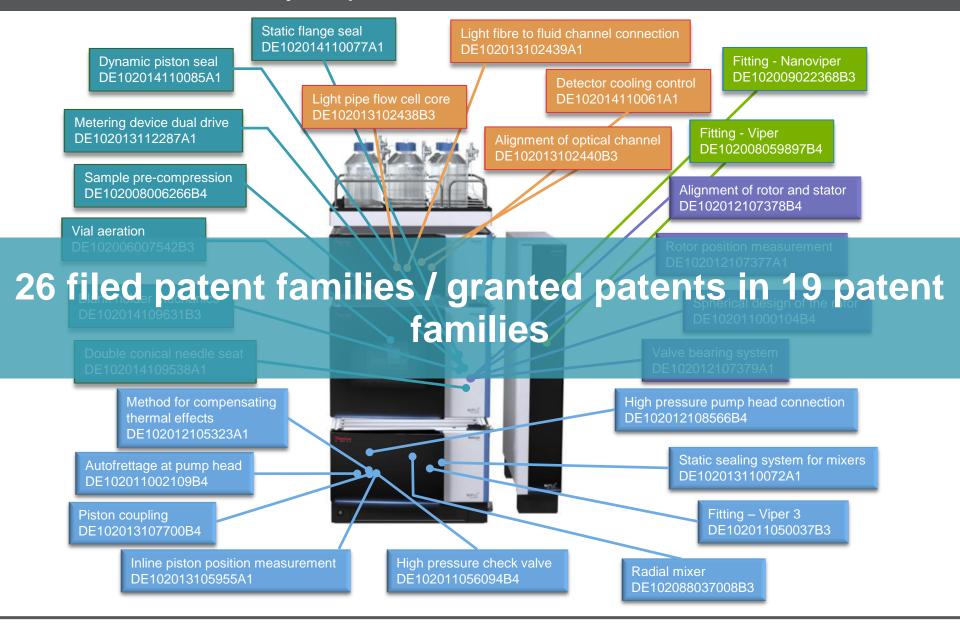
Thermo Scientific™ Vanquish™ UHPLC System New generation

New generation biocompatible high-end UHPLC system (binary pump, 1500 bar)





Innovation in Every Aspect





- Tool-free fluidics
- Compact footprint
- Intuitive fluidic layout
- Easy switching of modules/ maintenance

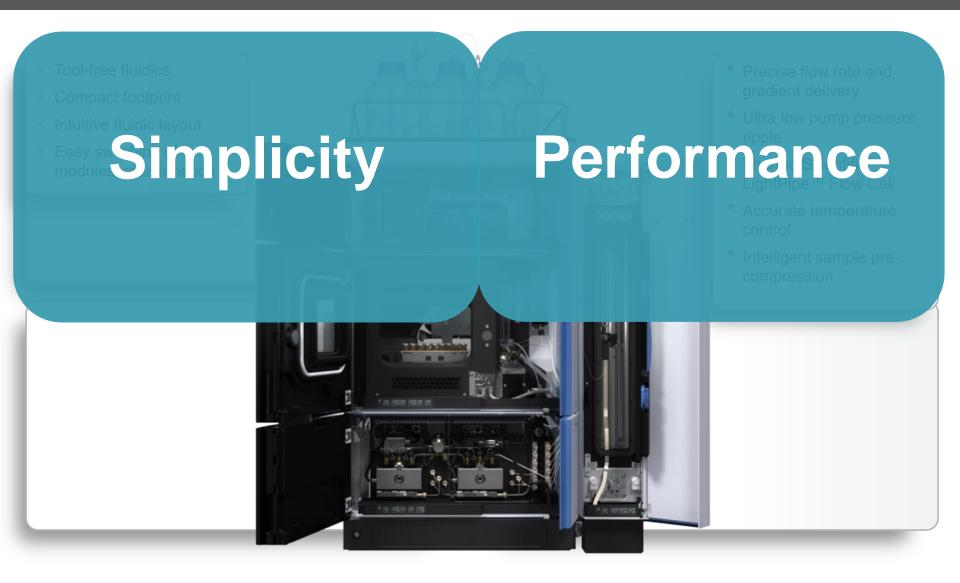








- Precise flow rate and gradient delivery
- Ultra low pump pressure ripple
- Thermo Scientific™
 LightPipe™ Flow Cell
- Accurate temperature control
- Intelligent sample precompression



- Tool-free fluidics
- Compact footprint
- Intuitive fluidic layout

Simplicity

- Precise flow rate and gradient delivery
- Ultra low pump pressure

Performance

- Accurate temperature control
- Intelligent sample pre compression

- Customizable gradient delay volume
- Multiple heating modes
- Large sample capacity
- Broad flow rate and temperature range
- 4 x detectors and simple MS integration
- Supports long column capacity & all major chemistries





- Simplicity

Performance

- Versatility





- Tool-free fluidics
- Compact footprint
- Simplicity

- Performance
 - Accurate temperature control
 - Intelligent sample precompression

- Customizable gradient delay volume
- Multiple heating modes
 - Versatility
- 4 x detectors and simple MS integration
- Supports long column capacity & all major

- Barcode reader
- Dry-air sample cooling
- Precision
- Thermo Scientific™
 Dionex™ Chromeleon™
 Chromatography Data
 System (CDS) Software



Simplicity Performance **Biopharma** Versatility Confidence

Integration in Your Laboratory

- AppsLab application library
- Columns, Prep and Thermo Scientific[™] Viper[™] finger-tight connections
- Thermo Scientific™
 Dionex™ Chromeleon™
 Chromatography Data
 System (CDS) Software
- Fully integrated mass spectrometry solutions
- Seamless method transfer



Chromeleon





... Increase productivity

- Industry-leading Operational Simplicity and throughput with eWorkflows
- Faster data processing, visualization, and reporting with dynam updating and Intelligent Functionality built-in



... Control all your instrumentation

- Thermo Scientific LC/IC/GC/ (quant) MS plus >300 third-party modules
- · Customizable instrument ePanels for consistent look and feel



... Achieve regulatory compliance

- Flexible to support research and compliant laboratories
- Comprehensive user management and eSignatures



.. Simplify administration

- Centralized or distributed data storage
- Scales from workstation to large global networks



... Connect your laboratory

- Easily interface with other laboratory software (e.g. LIMS)
- Download ready-to-run applications from AppsLab Library

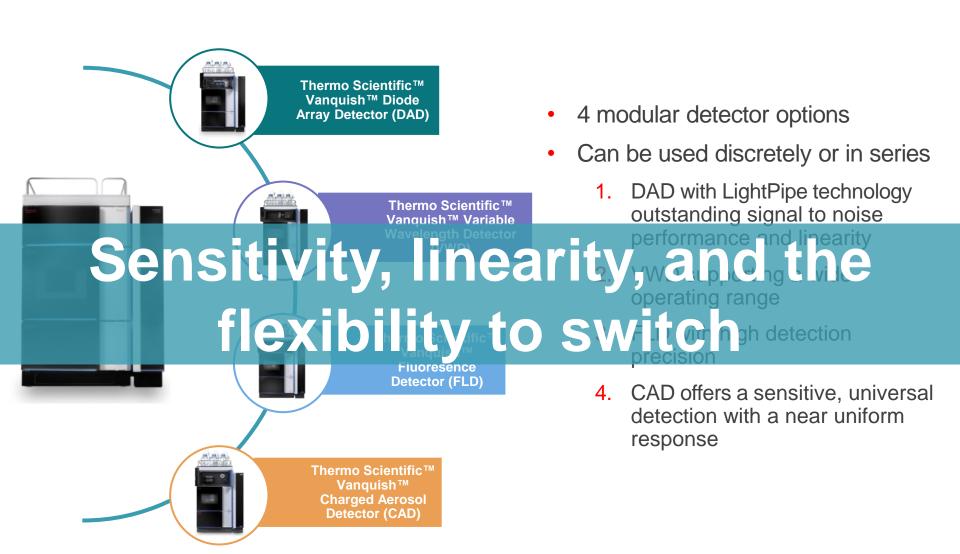


Range of Detectors



- 4 modular detector options
- Can be used discretely or in series
 - DAD with LightPipe technology outstanding signal to noise performance and linearity
 - 2. VWD supporting a wide operating range
 - 3. FLD with high detection precision
 - CAD offers a sensitive, universal detection with a near uniform response

Range of Detectors



Fully Integrated MS Solutions



- Dedicated connection kit connects the LC to the MS
- The column compartment can be located at either side of the LC instrument for optimal flow paths
- Control and processing depending on user preference
 - Thermo Scientific[™]
 Xcalibur[™] (with Thermo
 Scientific[™] SII)
 - Chromeleon CDS
 - In both cases data can be exported for processing with other MS software packages

Fully Integrated MS Solutions

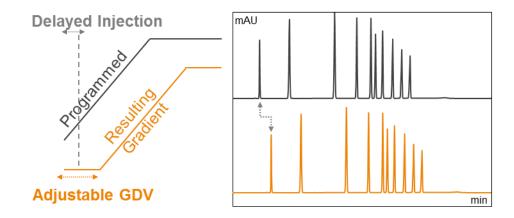


- Dedicated connection kit connects the LC to the MS
- The column compartment can be located at either side of the LC instrument for optimal flow paths
- Control and processing depending

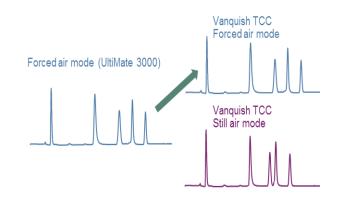
- Chromeleon CDS
- In both cases data can be exported for processing with other MS software packages

Simple Method Transfer

- Gradient delay volume (GDV) adaption
 - Adjustable metering device idle volume
 - Mixer and Viper capillaries
 - Delayed injection



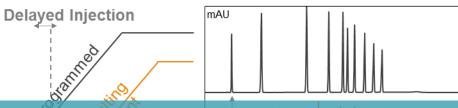
- Match the thermostatting mode
 - Forced and still air mode give different results
 - Mimic thermal conditions used in existing systems
 - UltiMate 3000 column compartments or that of other (U)HPLC systems





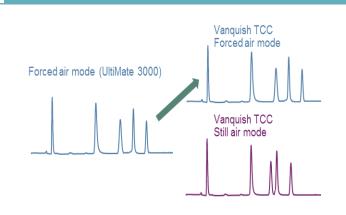
Simple Method Transfer

- Gradient delay volume (GDV) adaption
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Easy, fast method transfer & method development

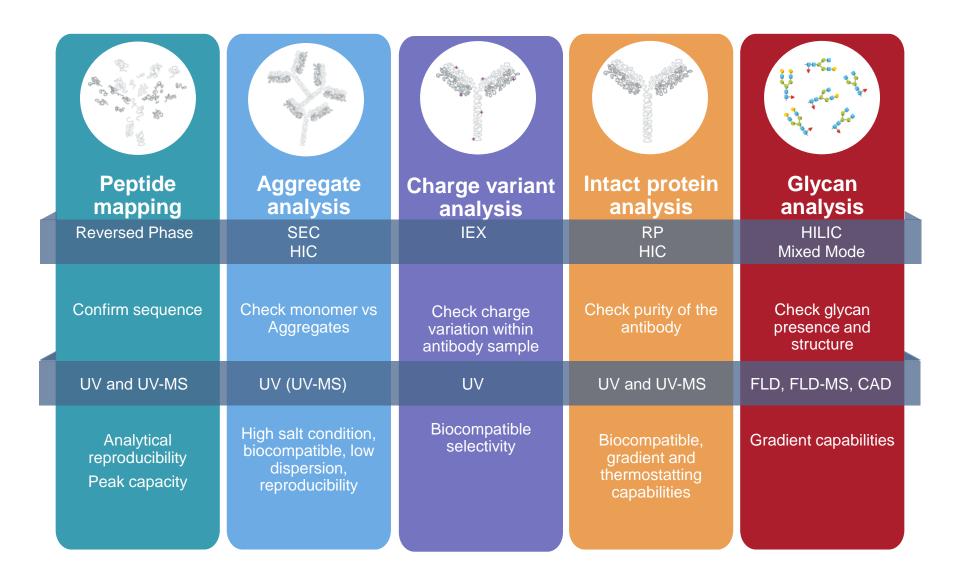
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5 Fundamental Workflows

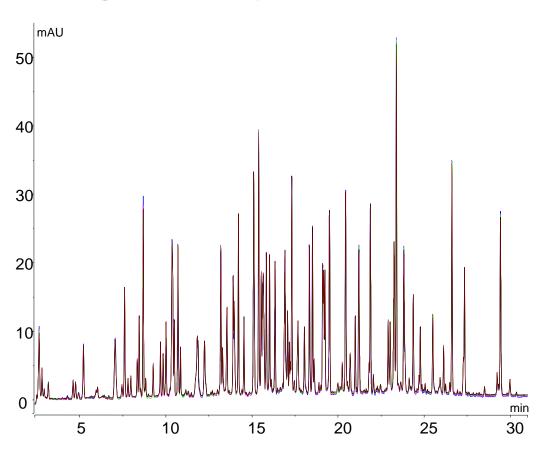




1. Peptide Mapping



High retention time precision with the Thermo Scientific™ Acclaim™ column (n=5)



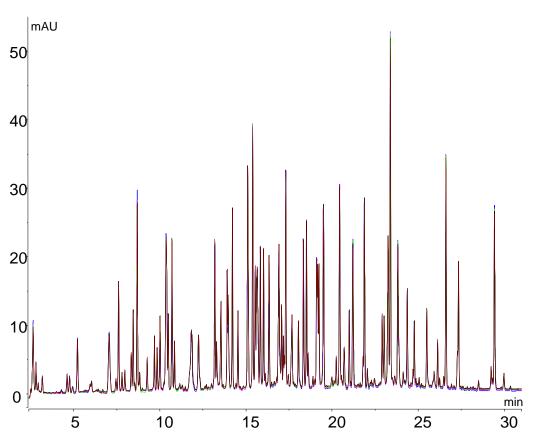
- Very high precision of both retention time and peak area
- Excellent separation in 30 minute gradient
- Active eluent pre-heating to avoid any thermal mismatch

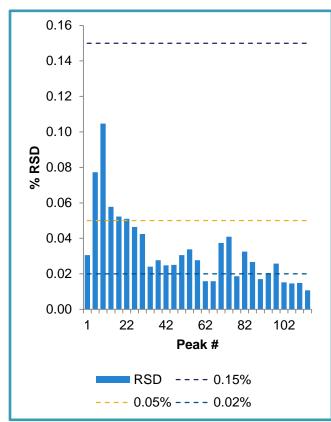


1. Peptide Mapping



High retention time precision with the Thermo Scientific™ Acclaim™ column (n=5)



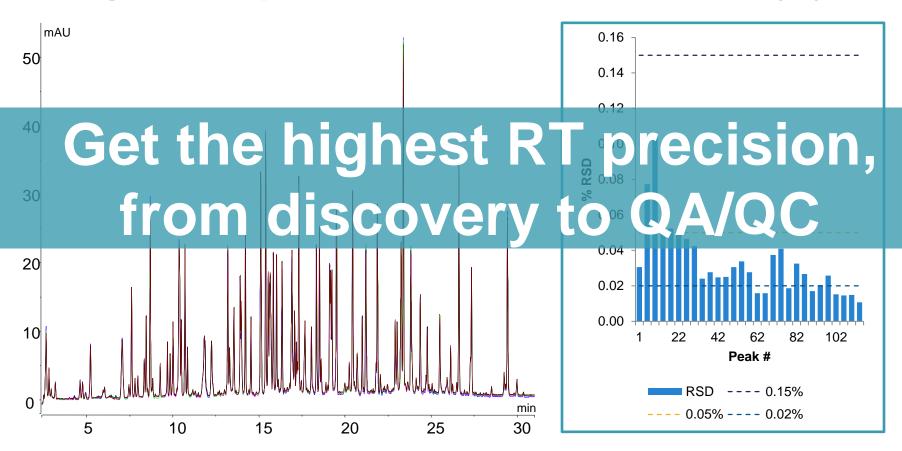




1. Peptide Mapping



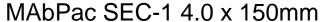
High retention time precision with the Thermo Scientific™ Acclaim™ column (n=5)

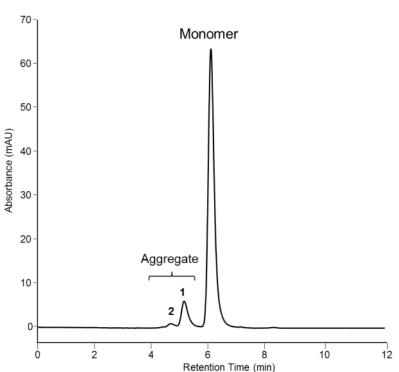


2. Aggregate Analysis

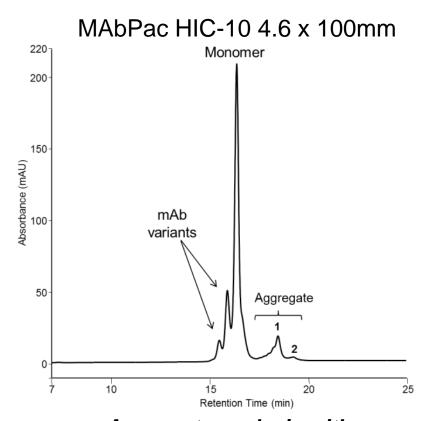


Aggregate separation of a mAb on the Thermo Scientific™ MAbPac™ SEC-1 and HIC-10 columns





Fast aggregate analysis



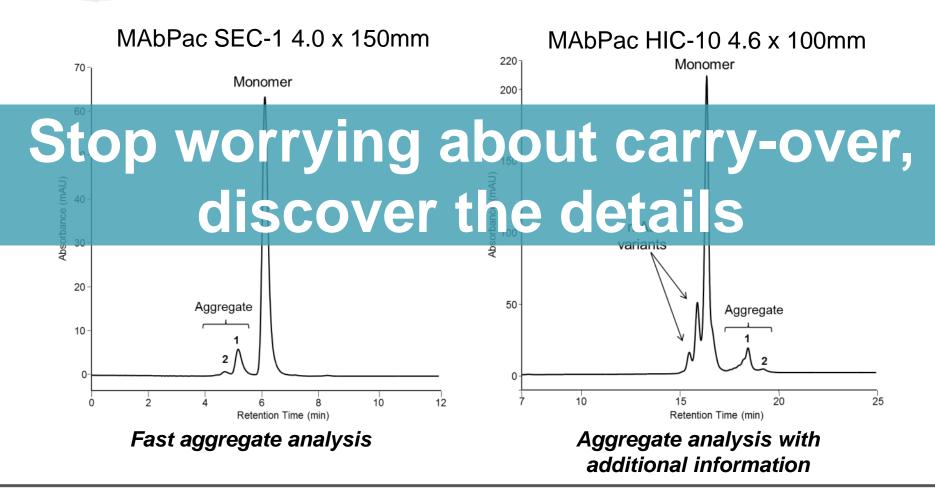
Aggregate analysis with additional information



2. Aggregate Analysis



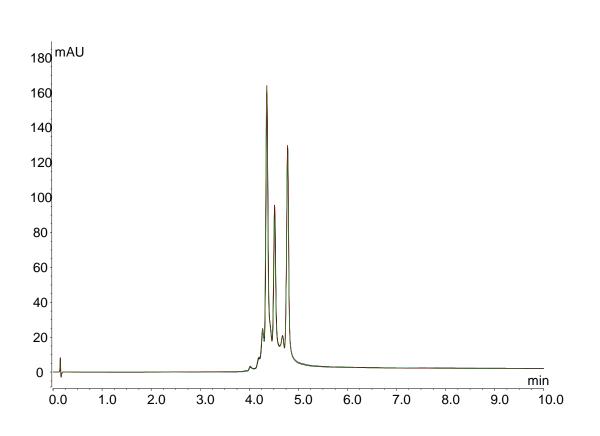
Aggregate separation of a mAb on the Thermo Scientific™ MAbPac™ SEC-1 and HIC-10 columns



3. Charge Variant Analysis



Charge variant analysis of a mAb by pH gradient on the Thermo Scientiifc™ MAbPac™ SCX column (overlay of six runs)

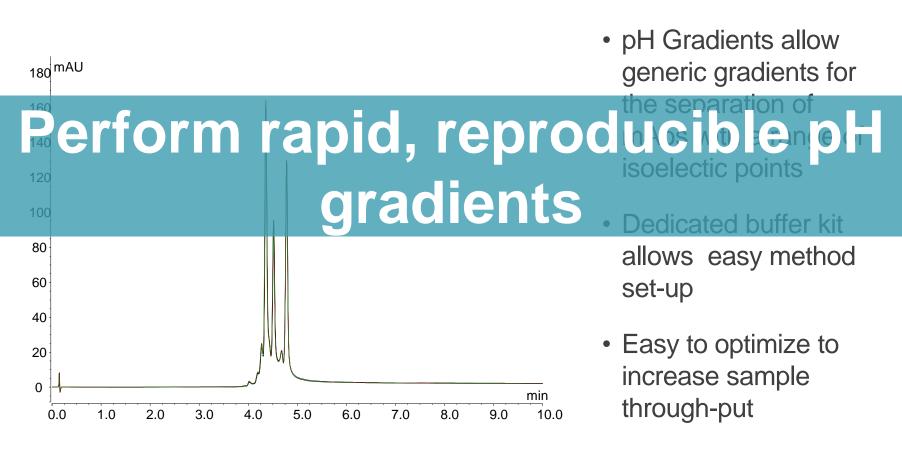


- pH Gradients allow generic gradients for the separation of mAbs with a range of isoelectic points
- Dedicated buffer kit allows easy method set-up
- Easy to optimize to increase sample through-put

3. Charge Variant Analysis



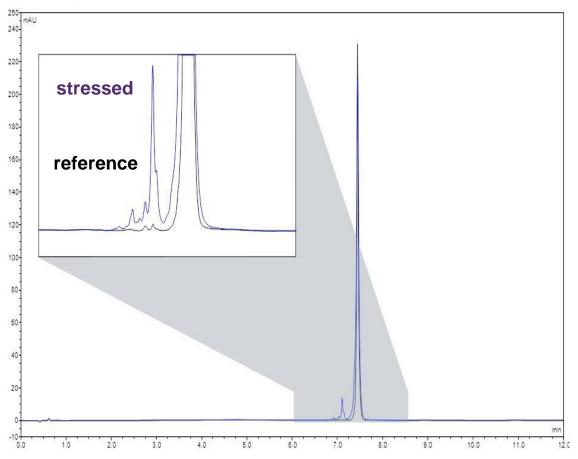
Charge variant analysis of a mAb by pH gradient on the Thermo Scientiifc™ MAbPac™ SCX column (overlay of six runs)



4. Intact Protein Analysis



Separation of reference and stressed intact mAb on the Thermo Scientific™ MAbPac™ RP column



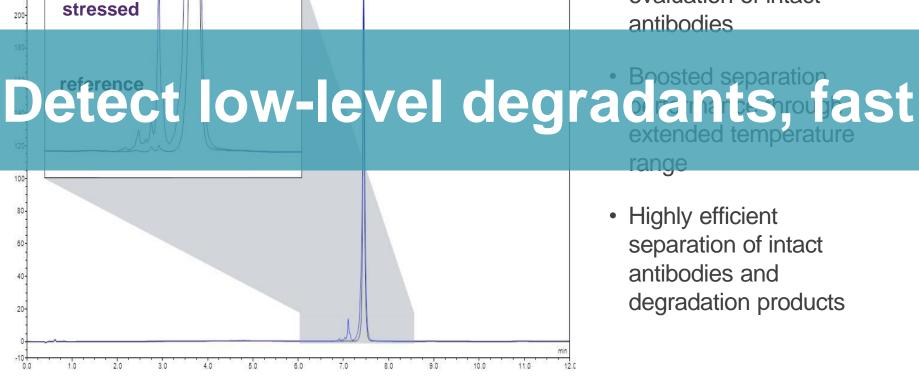
- Fast method for stability evaluation of intact antibodies
- Boosted separation performance through extended temperature range
- Highly efficient separation of intact antibodies and degradation products

4. Intact Protein Analysis



220-

Separation of reference and stressed intact mAb on the Thermo Scientific™ MAbPac™ RP column



 Fast method for stability evaluation of intact antibodies

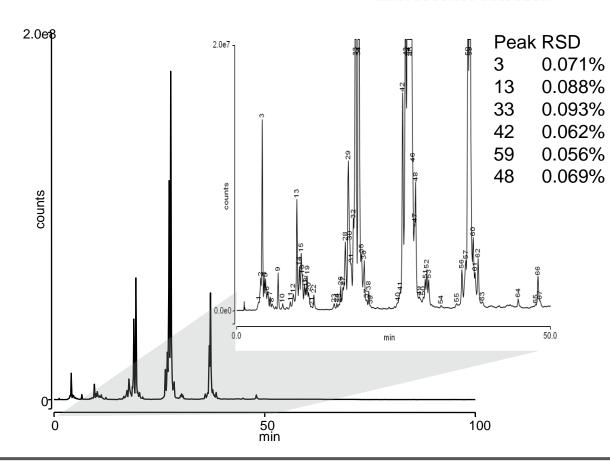
 Highly efficient separation of intact antibodies and degradation products

range

5. Glycan Analysis



2 AB-labeled glycans separated on the Thermo Scientific™ GlycanPac™ AXR-1 column, Vanquish Flex with fluorescence detection

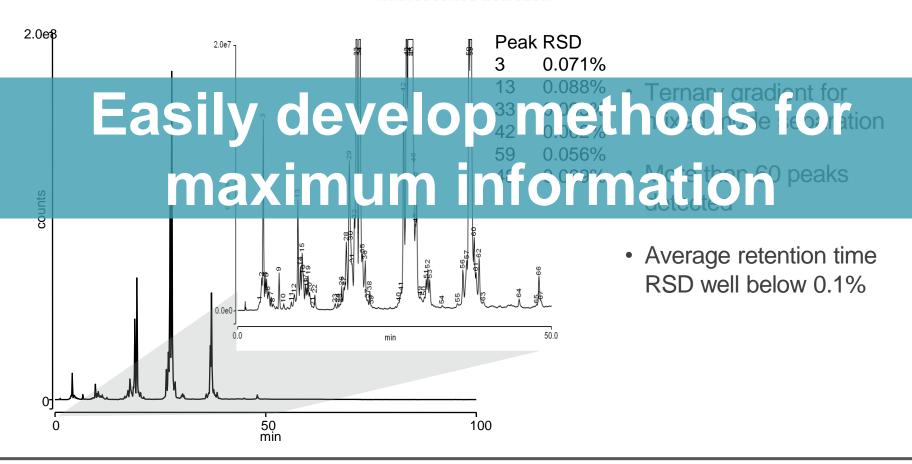


- Ternary gradient for mixed mode separation
- More than 60 peaks detected
- Average retention time RSD well below 0.1%

5. Glycan Analysis



2 AB-labeled glycans separated on the Thermo Scientific™ GlycanPac™ AXR-1 column, Vanquish Flex with fluorescence detection



Summary

Built to exacting standards, specifically for biopharma

Simply, you can have the most versatile, high performance UHPLC that gives you more confidence in your results

Unlock total workflow solutions for peptide mapping, glycans, intact protein analysis, charge variant profiling and aggregate analysis



Thank you



