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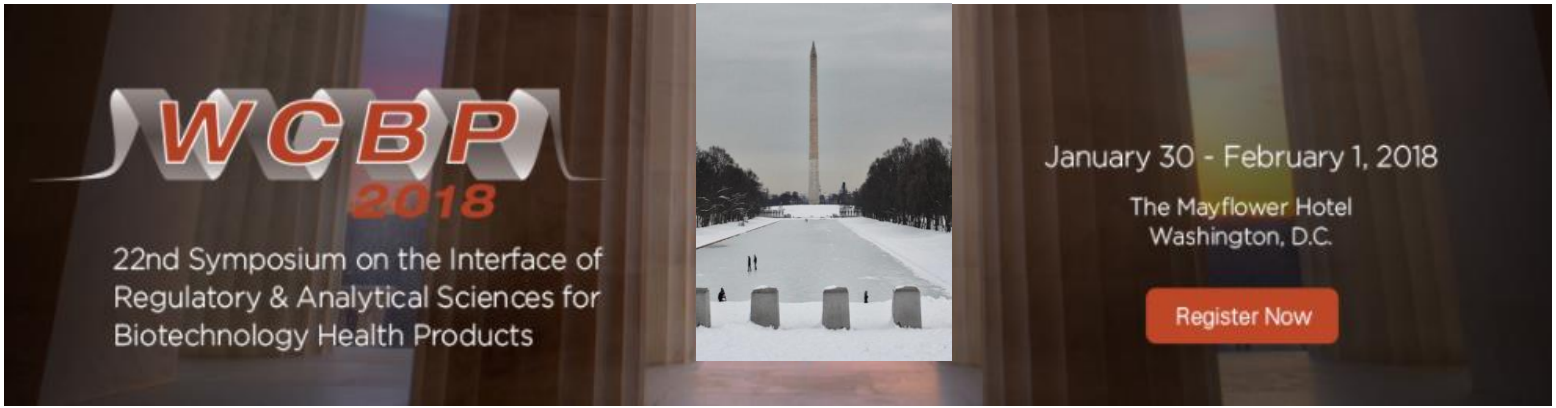
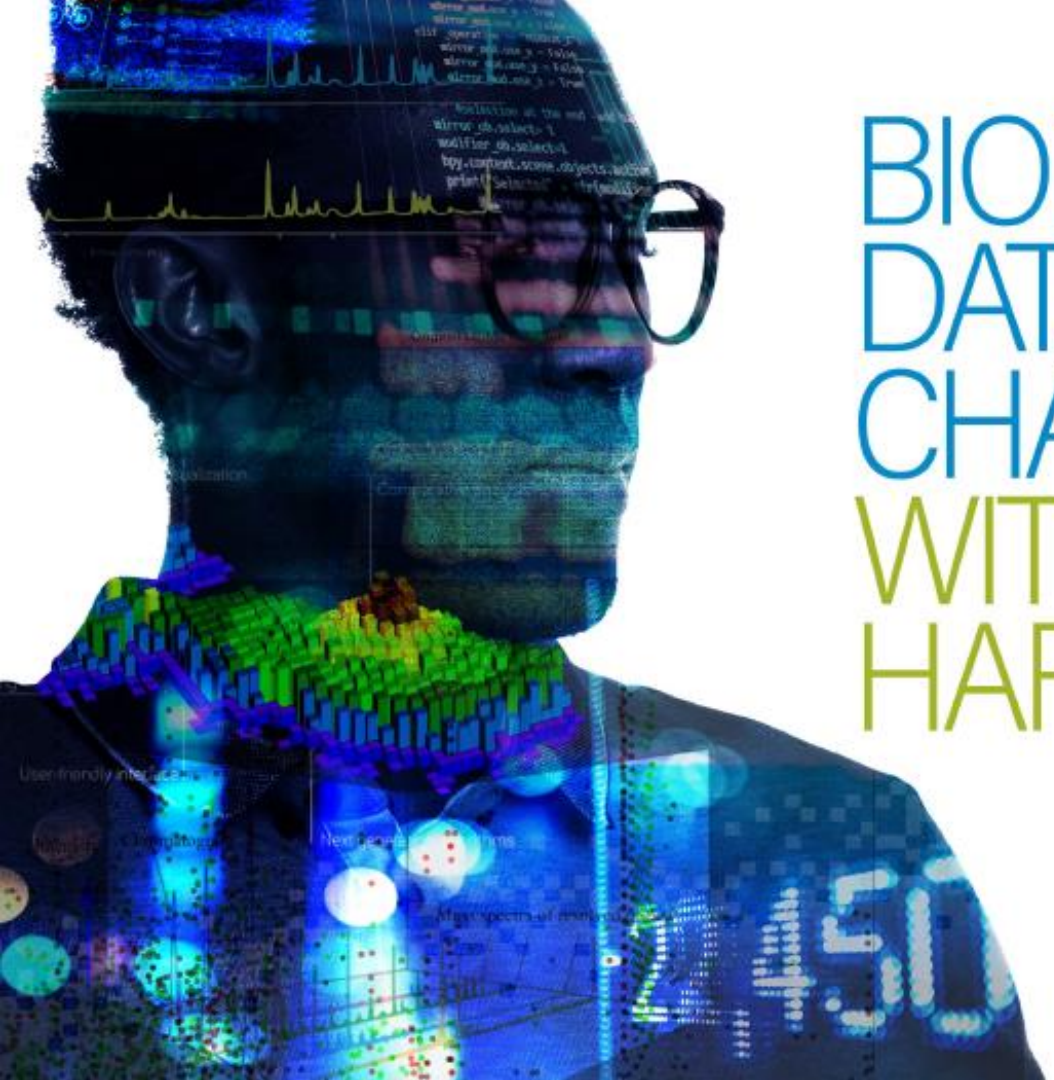
Data is the common currency: What does it take to harmonize technologies and workflows across biopharmaceutical organizations?

WCBP 2018 Wed Lunch Session



With our compliments……

……a perfect fit for those chilly labs, offices and most Jan WCBP meetings



BIOPHARMA DATA IS JUST CHAOS WITHOUT HARMONIZATION.

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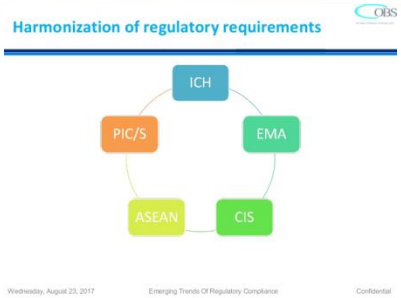

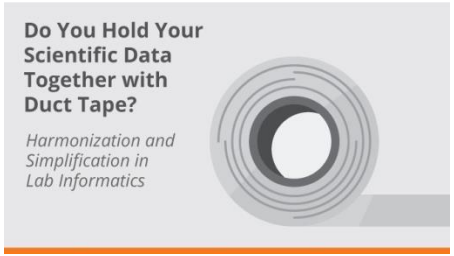

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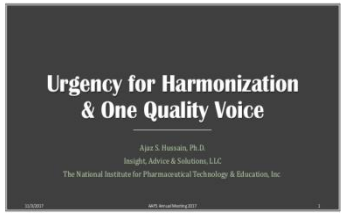
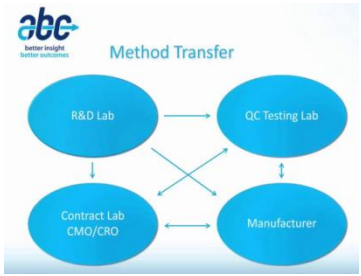
Harmonization:

As a corporate strategy, harmonization is the effort to minimize organizational chaos, and institute an integrated strategy for deploying and maintaining analytical and informatics resources.





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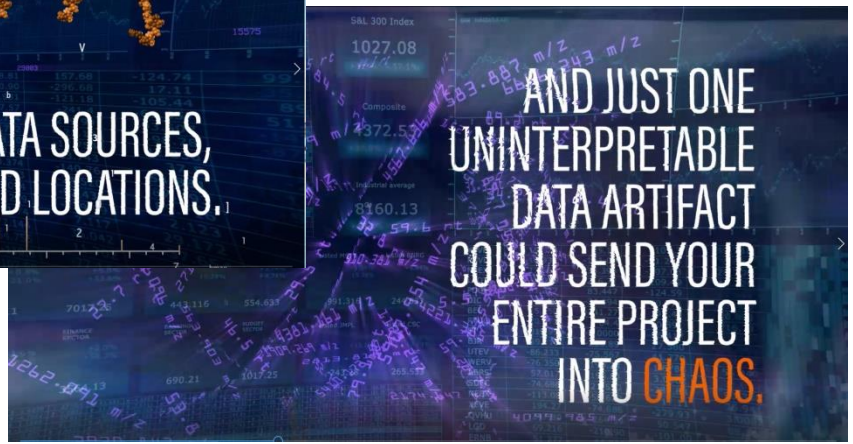

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WHAT IF YOUR DATA COULD BE HARMONIZED?

FROM DEVELOPMENT TO MANUFACTURING AND QC

FROM CENTRAL LABS TO DISTRIBUTED LABS

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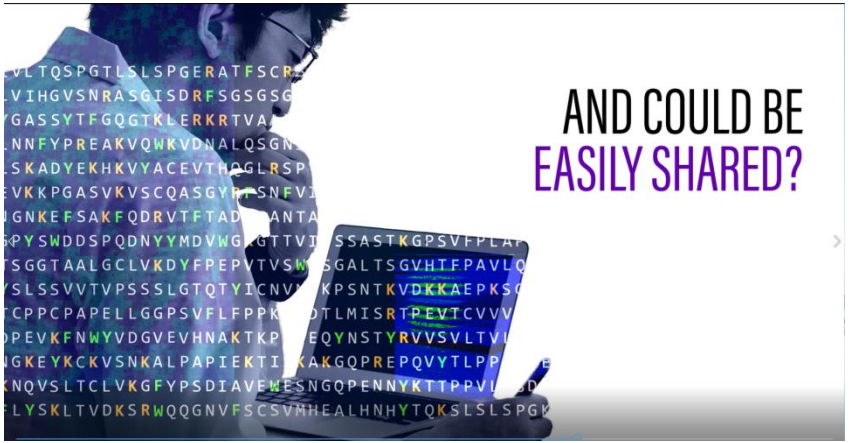

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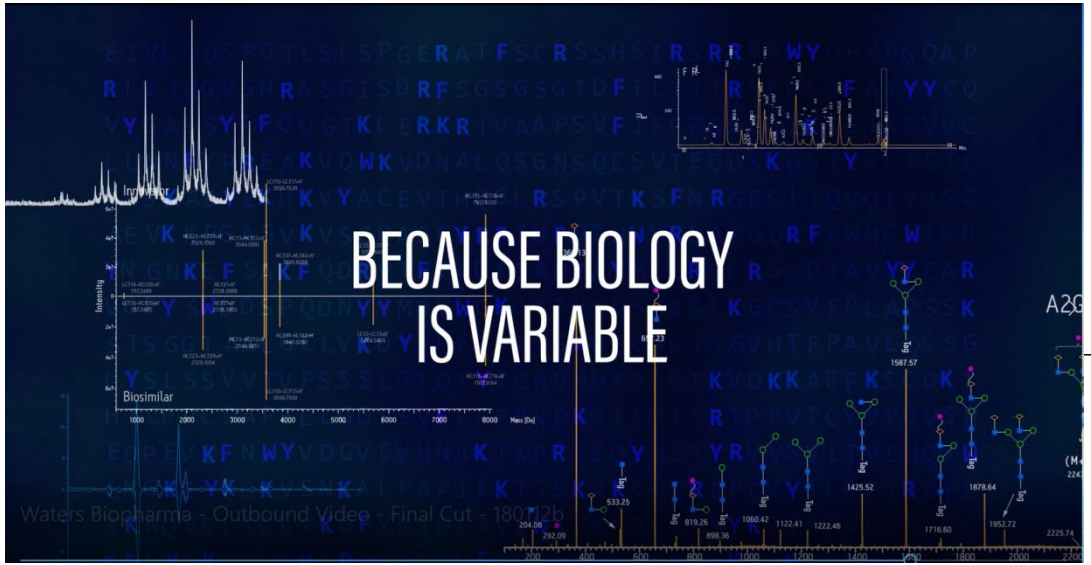

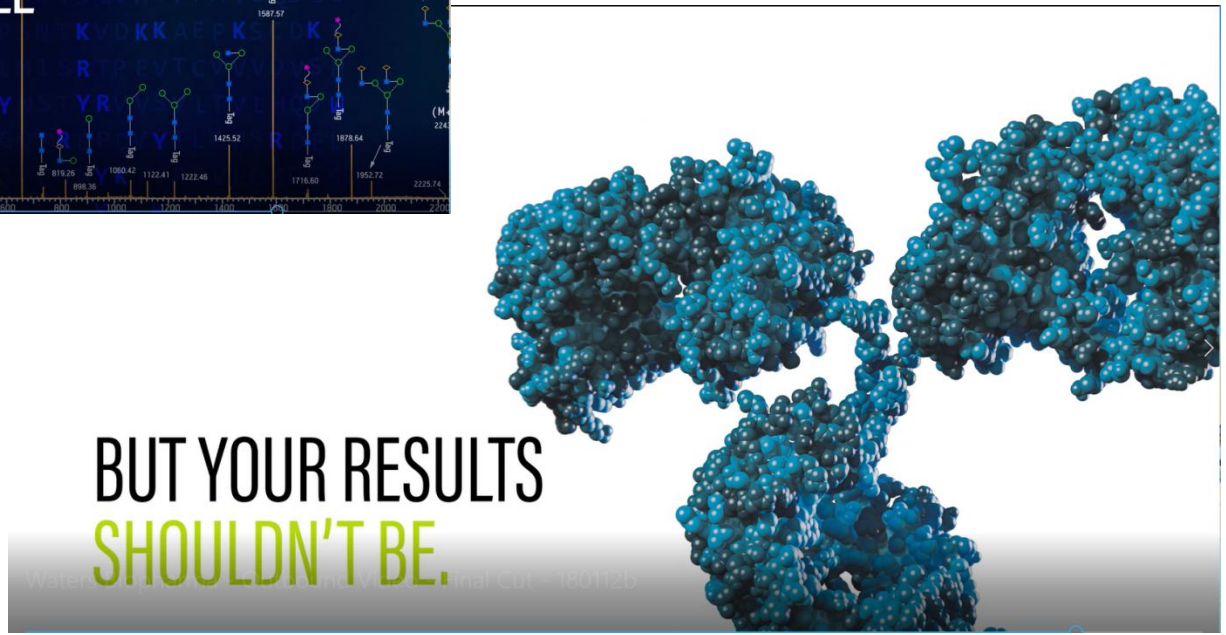

Innovation at the Center of Corporate Strategy

*Growth through **focus, innovation, and quality** of the total customer experience*

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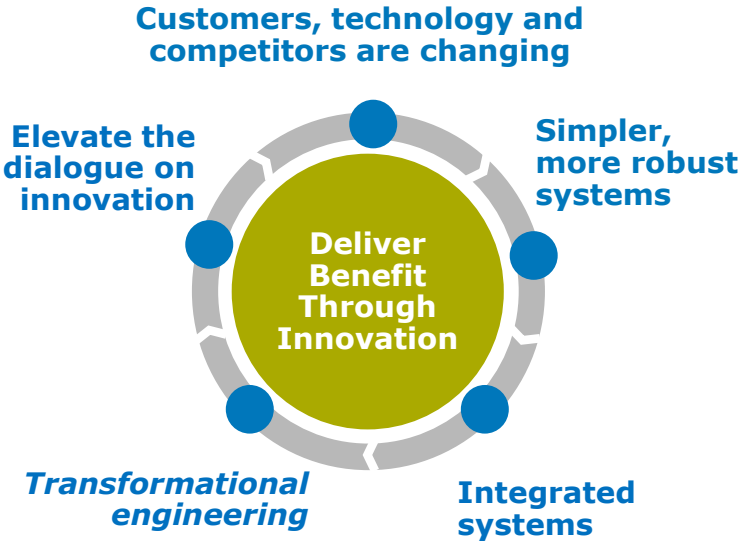

Innovation Leadership

- Advance **best-of-breed technologies** for the most demanding analytical measurement needs
- Redefine innovation as **simpler, smarter, more robust and deployable** solutions that will change the basis of competition
- **Breakthrough innovation** harnessing the potential of technology to one day change the world

R&D growing to **8.5%** of sales, from 7.5% just **5** years ago

Harmonization: The need to transfer methods and molecules

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Harmonization: The need for methods to move across platforms

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ACQUITY Arc **Bio** System

A Solution For your Daily Bioseparations Challenges

Which systems are the best for your challenges?

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	Alliance HPLC	ACQUITY Arc / Arc Bio (UHPLC)	ACQUITY UPLC H-Class H-Class Bio/ I-Class
Chemistry Compatibility	≥ **4.6 mm** ID Columns ≥ **3.5 µm** Porous Particles	≥ **3.0 mm** ID Columns ≥ **2.5 µm** Porous Particles	≥ **2.1 mm** ID Columns ≥ **1.7 µm** Porous Particles
Detection	Optical (UV, PDA, FLR) and ACQUITY QDa Mass Detection		
MS Compatibility	SQD2		SQD2, QQQ, TOF, QTof
Software Compatibility	Empower, MassLynx		Empower, MassLynx, UNIFI
Common Role(s)	Routine analysis (QA/QC) Monitoring (Late Development)	Monitoring (Late Development) Routine analysis (QA/QC) Method Development & Transfer Characterization (Development)	Characterization (Development) Monitoring (Late Development) Routine analysis (QA/QC)

ACQUITY Arc Bio: A Biocompatible UHPLC

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Bio-inert Flow Paths
Minimize undesirable protein interactions and maximize system robustness under salt and pH extremes to maximize system uptime

Auto•Blend Plus Technology
Program gradients directly in terms of pH and ionic strength to minimize manual mobile phase preparation, reduce human error and accelerate method robustness testing for Reversed-Phase or Ion-Exchange chromatographic methods.

ACQUITY QDa Mass Detector
Increase the analytical value of every analysis by adding mass information for improved sample characterization

Arc™ Multi-Flow Path Technology
Delivers HPLC and UHPLC method compatibility through selectable dwell volume, simplifying method transfer

bioQuaternary Solvent Management
Precise and accurate blending of up to four solvents accommodating the range of aqueous, high ionic strength mobile phases and organic solvents used in Bioseparations.

Address your Workflow
With a comprehensive portfolio of column chemistries and standards specifically developed and QC tested for Bioseparations.

Supported by industry-leading informatics software, including Empower and MassLynx.

Peptide Standards: Common 10 min gradient method

XBridge® BEH™ Peptide C18 130 Å, 2.5 µm, 4.6 x 100 mm

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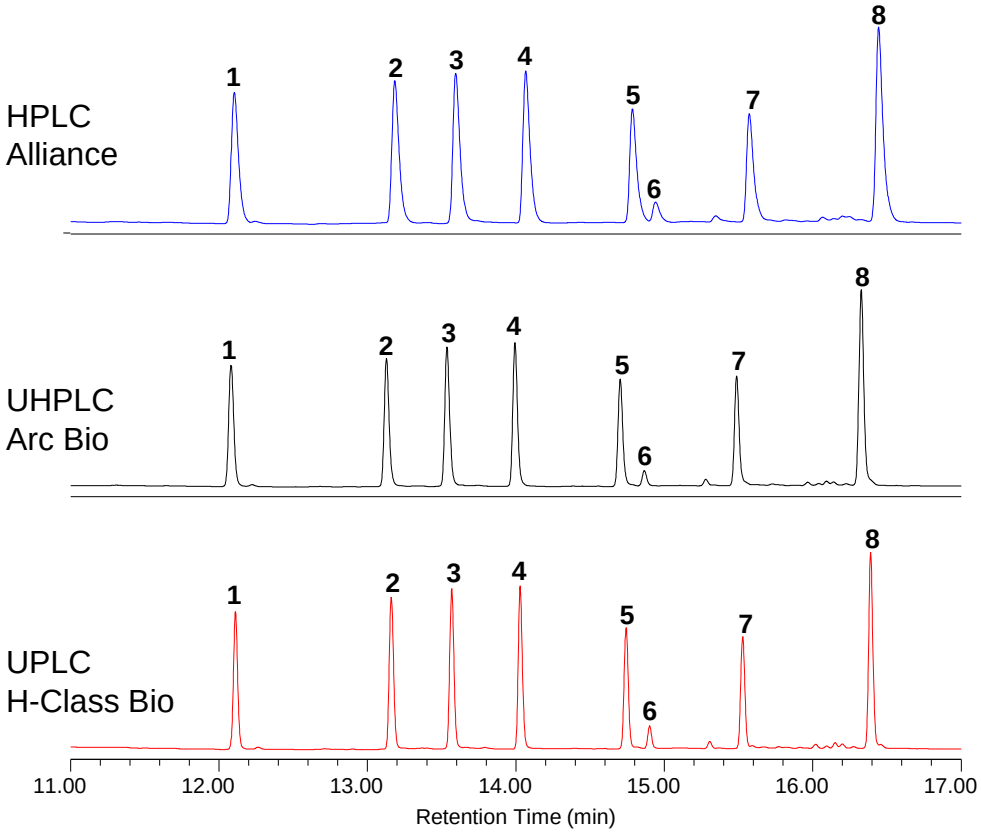

$$P_{c,4\sigma} = 1 + \left[\left(\frac{2.35}{4}\right)\left(\frac{t_{gradient}}{w_{h,avg}}\right)\right]$$

	Alliance	Arc	H-Class
Resolution P5-P6	1.7	2.7	3.1
Pc,4σ (Ave P1-P8)	118	170	196

Poster P116T Assessing Performance and Method Transfer of Monoclonal Antibody and Peptide Bioseparation Methods Using a Novel Biocompatible UHPLC System

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A Next Generation Reversed-Phase Column for Monoclonal Antibody, Antibody Subunit and ADC Separations

More Than Just a Column.™

BioResolve RP mAb, Polyphenyl:
Novel Phenyl Bonding on a new 450 Å, Solid Core Particle Technology

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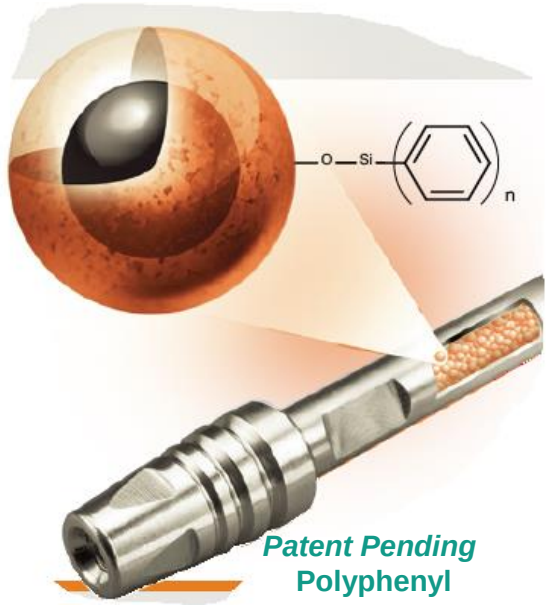
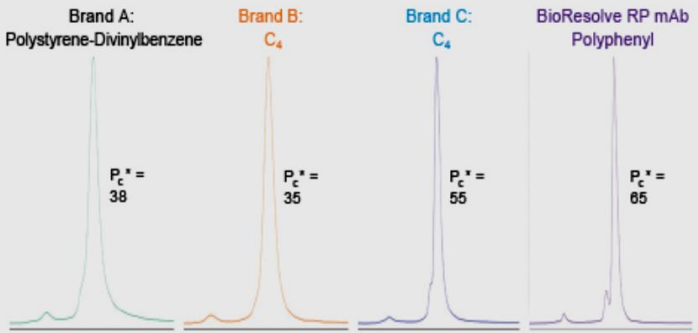


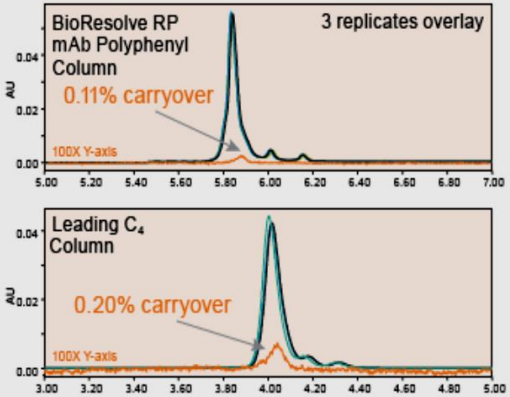
- Silica-based, solid core particles with defined 450Å pore coating delivers outstanding resolution, recovery, and low injection to injection carryover.
- Use of innovative polyphenyl ligand composition and bonding technology (patent pending) delivers superior intact mAb and subunits separations in LC (0.1% TFA) or LC/MS (0.02% TFA or 0.1% FA) applications.
- The above two attributes synergistically translate into…
  - Low pH stability leading to improved column lifetime
  - Better recoveries at lower temperatures
- 2.7 µm particles deliver near equivalent performance on HPLC, UHPLC, and UPLC instrumentation.

INCREASED COMPONENT RESOLUTION

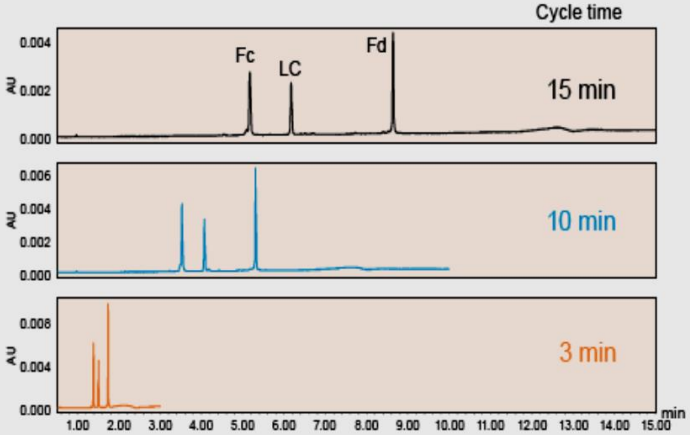


P_c* denotes effective peak capacity, which determines separation space according to the first and last eluting peak.

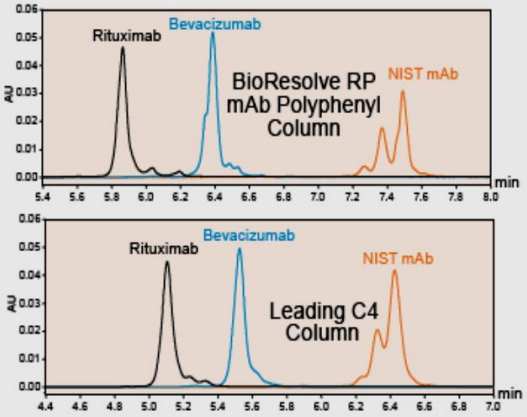
MINIMAL CARRYOVER



TECHNOLOGY FOR HIGH THROUGHPUT



IMPROVED SELECTIVITY



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- ✓ High Resolution
- ✓ Low Carryover
- ✓ Scalable Throughput
- ✓ Unique Selectivity

NEW !!! - mAb Subunit Standard (P/N 186008927)

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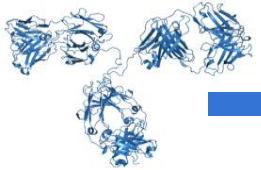
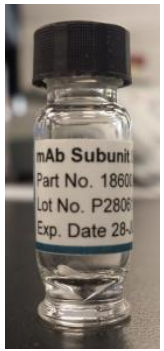
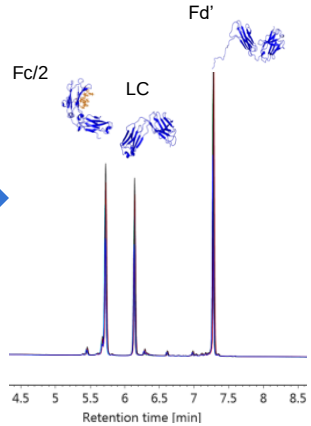
- 25 µg of Reduced, IdeS-digested NIST Reference Material 8671
- Desalted, stabilized with excipients, and lyophilized
- Excellent stability
- For proficiency testing and benchmarking of protein RPLC
- Used internally to QC Prototype batches and columns



NIST mAb 8671

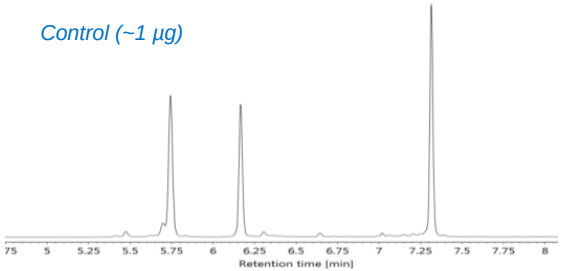


P/N 186008927

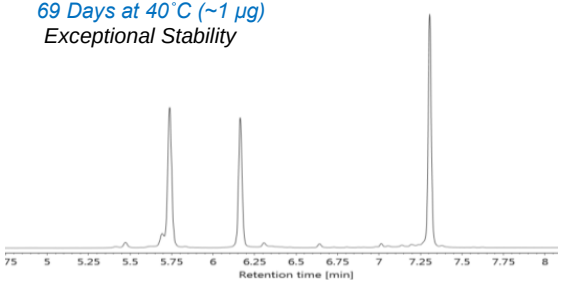


Good Reproducibility

Control (~1 µg)



69 Days at 40˚C (~1 µg)
Exceptional Stability



Characterization of mAb IdeS Subunits

Reversed Phase Workflow

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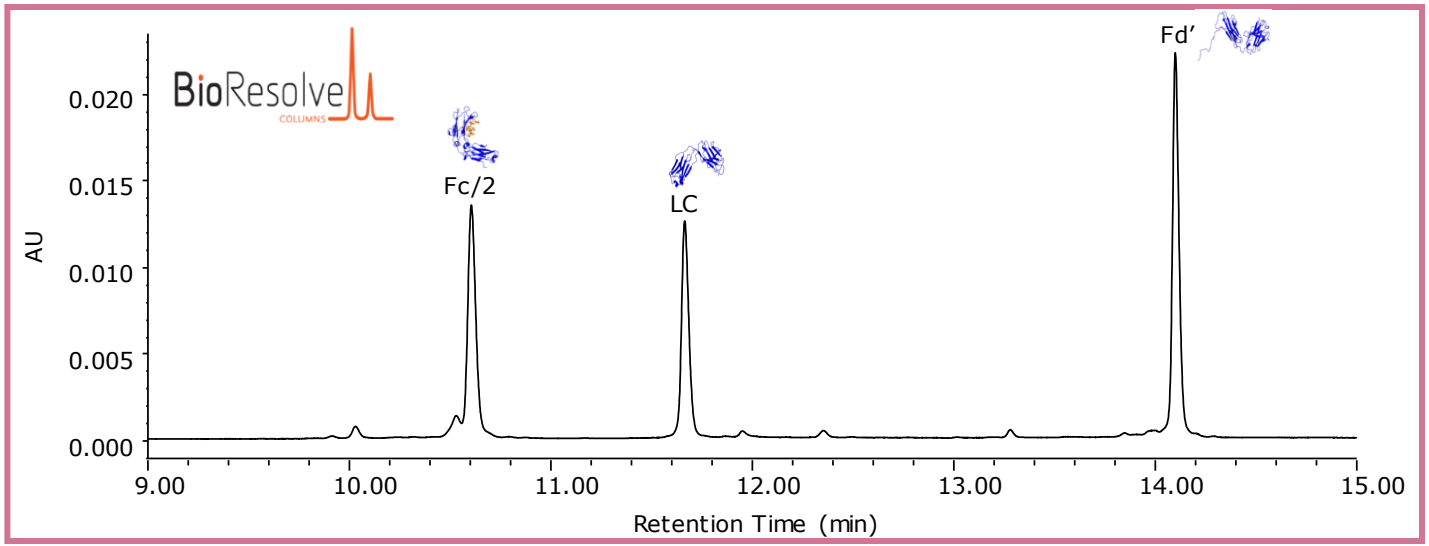
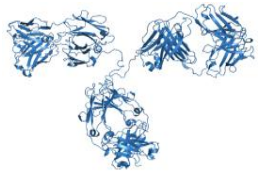
Sample Preparation	LC Separation	Column Chemistry	Detection	Analyze	Services
mAb Subunit Std	ACQUITY Arc Bio	BioResolve® RP-mAb 2.7 µm, 4.6 x 50mm	ACQUITY Arc 2489 UV/Vis	Empower 3 Software **Pre-configured Methods**	Method Development





- Enhanced mAb resolution and selectivity
- Excellent reproducibility with minimal carryover
- Individually tested with mAb subunit standard

Transferability: Alliance → Arc Bio → H-Class (60° C)

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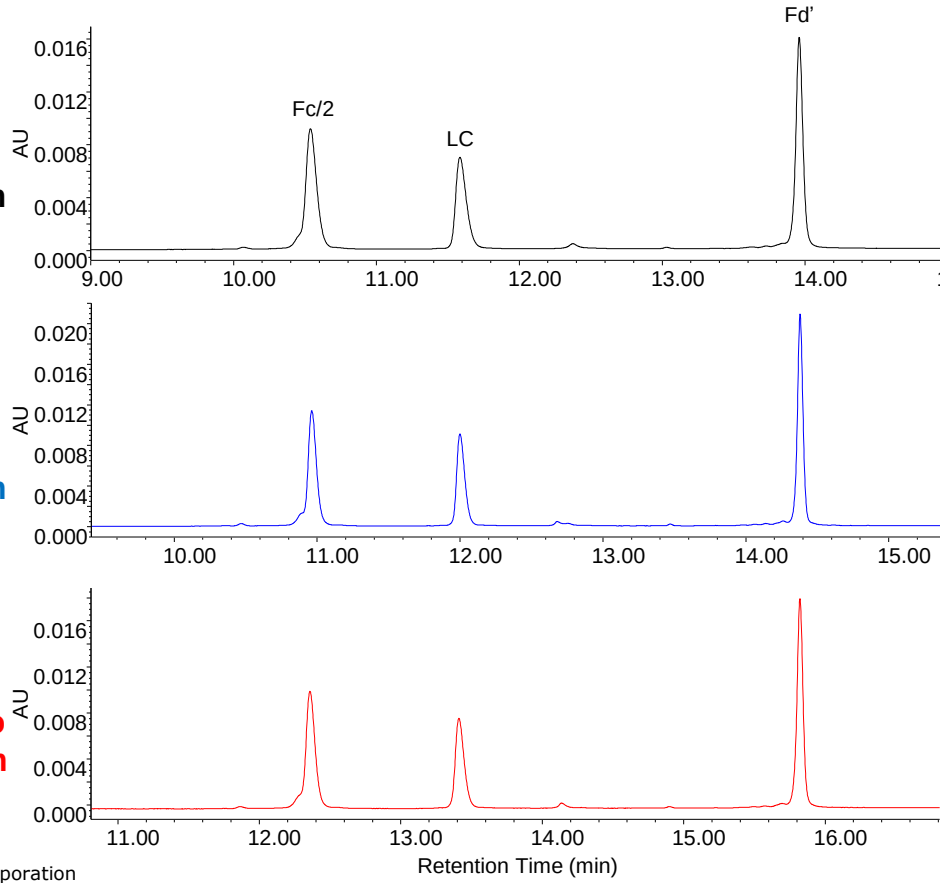
HPLC
Alliance
4.6 x 50 mm

UHPLC
Arc Bio
4.6 x 50 mm

UPLC
H-Class Bio
2.1 x 50 mm



Peak Area (%):

	Fc/2 (%)	LC (%)	Fd' (%)
Alliance	34.52	24.43	41.05
Arc Bio	34.23	24.47	41.30
H-Class Bio	34.50	24.31	41.19

Poster P106T A Novel Phenyl-Based RPLC Stationary Phase for High Throughput, High Resolution Characterization of Protein Therapeutics

Sample Preparation is no longer one dimensional
for Released N-Glycan Analysis with GlycoWorks RapiFluor-MS

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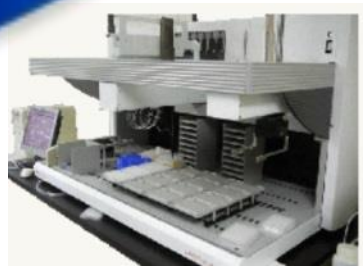
Manual Prep
8-96 samples

Low throughput
Semi-Automation
8-24 samples



Higher throughput
Automation
48-96 samples

- Platform scalability for **8 to 96 samples** at a time
- **Purposefully designed kits** for manual use and automated liquid handling platforms
- Available **base scripts** and **layouts** for simplified deployment on larger bed liquid handling platforms.

Sample Preparation is no longer one dimensional

for Released N-Glycan Analysis with GlycoWorks RapiFluor-MS

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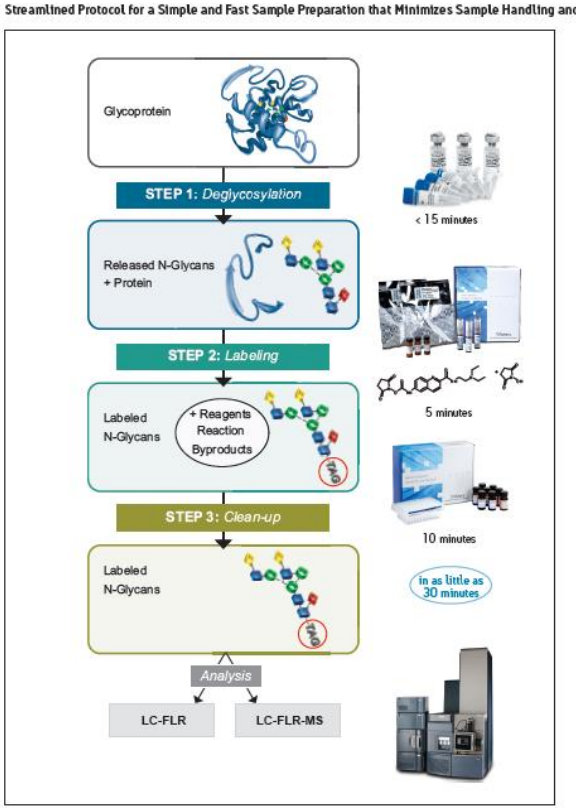
Manual

Two kit options:
24-sample (3 sets x 8 samples)
96-sample (4 sets x 24 samples)



Semi-Automated

Andrew Alliance

Low throughput
(8-24 samples)

Glycan Sample Prep Automation with Andrew Alliance

Waters
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- Single-channel - Lower throughput (8 - 24 samples)
- Direct transfer of current pipette based methods
- Flexible modular footprint – Only 20 lbs.
- Industry leading software provided with system
- 1/10th the cost of large bed automation platforms
- Uses standard GlycoWork *Rapi*Fluor-MS kit

Andrew Alliance

CHECK THIS OUT!

At the Waters Booth

Sample Preparation is no longer one dimensional

for Released N-Glycan Analysis with GlycoWorks RapiFluor-MS

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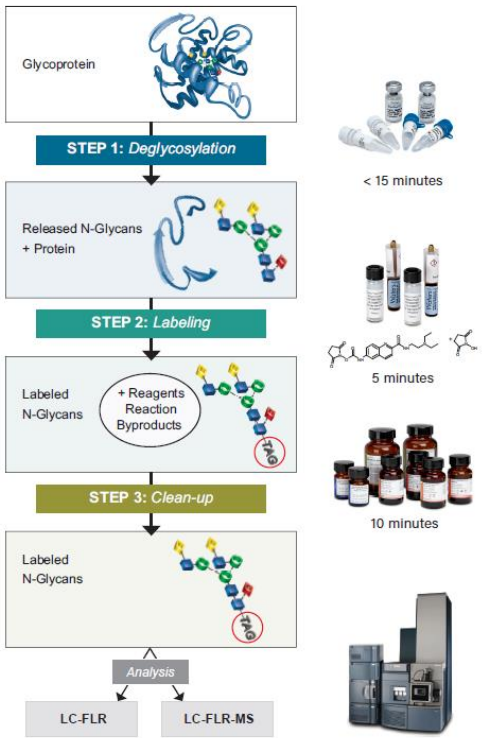
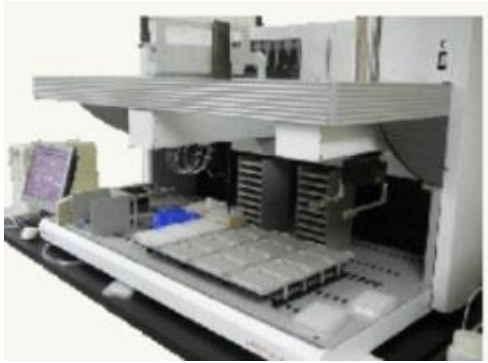
Streamlined protocol for a simple and fast sample preparation that minimizes sample handling and loss



Full Automation



TECAN.

HAMILTON®

- Kit Volumes adjusted for 2 x 48 or 1 x 96
- Automation Script for Tecan
- Sample Parameters Script for other platforms
- Less than 3h (96 samples with normalization)

Released N-Glycan UPLC Analysis Workflows

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SAMPLE PREP

GlycoWorks *Rapi*Fluor-MS N-Glycan Kit

Deglycosylation, Labeling and Clean-up in as little as 30 min

Options for Automation

Unmatched sensitivity for FLR and MS detection

SEPARATION

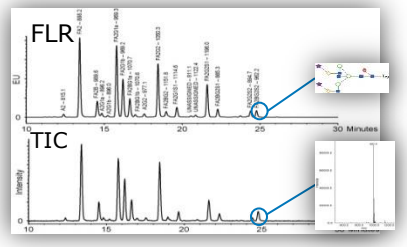
ACQUITY UPLC Glycan BEH Amide Column

DETECTION & INFORMATICS

Glycan Monitoring

Empower 3 SOFTWARE

ACQUITY FLR/QDa and Empower 3 Software

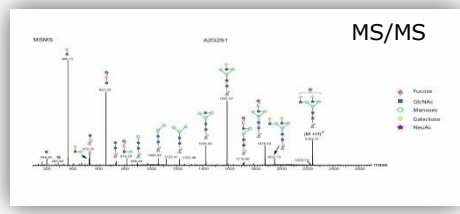


FLR Quantification
GU Retention
MS Confirmation

Glycan Characterization

UNIFI

FLR/Xevo G2-XS QTof MS and UNIFI Scientific Information System



FLR Quantification
GU Retention
Accurate Mass Confirmation
MS/MS Fragmentation

Using LCMS to Assess and Control the Influence of Fab Glycosylation on the Pharmacological Properties of a Monoclonal Antibody

Bryan J. Harmon, PhD.

Research Fellow, Bioproduct Research and Development

Eli Lilly and Company