



Intuitive Simplicity for Biopharma

Featuring MaxPeak
High Performance Surfaces
(HPS) Technology

MAXPEAK™
HIGH PERFORMANCE SURFACES

alliance™ **is** | bio

Waters™



More confident bioseparations start here.

Biopharmaceutical quality control (QC) labs face relentless demand to do more with less amid higher staff turnover and the need to reduce errors.

Coupled with growing levels of biological sample complexity, the need for simplicity has never been greater.

Waters understands the challenges you face, and with capabilities developed specifically for the QC laboratory, combined with MaxPeak™ High Performance Surfaces (HPS) Technology, the Alliance™ IS Bio HPLC System will quickly become your go-to ally, offering:

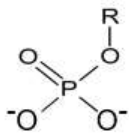
- Reduction in non-specific adsorption
- Corrosion-resistant materials
- Error reduction as standard
- Intuitively simple guidance at the point of need
- Faster, more reproducible results
- Improved data integrity

Your Lab Ally – Exceedingly inert for bioseparations

Non-specific adsorption (NSA) of metal-sensitive compounds, such as oligonucleotides and phosphopeptides, is an unpredictable challenge, leading to long column passivation times, chromatography with large relative standard deviations (RSDs), and broad peaks that can be a challenge to detect.

The Alliance iS Bio HPLC System is a step-change above traditional biocompatible systems. Not only is it constructed with corrosion-resistant materials to maximize system robustness under high salt extremes, it is also designed with MaxPeak HPS Technology, which minimizes non-specific adsorption of metal-sensitive analytes without complicated mobile phases or laborious methods, resulting in:

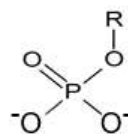
- Faster, more reproducible, and accurate data integration
- Shorter time from sample to result by eliminating the need for system conditioning
- Meeting compliance standards with higher quality data



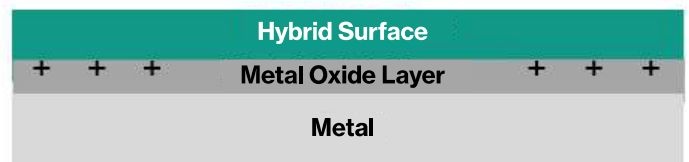
Adsorption onto metal hardware = loss of analyte recovery and poor peak shape



Electron-rich compounds, such as those containing phosphate or carboxylate groups, can be lost to non-specific adsorption on metal surfaces.



No adsorption



MaxPeak High Performance Surfaces are new and innovative technologies designed to increase analyte recovery, sensitivity, and reproducibility by minimizing analyte/surface interactions that can lead to sample losses.

Alliance iS Bio HPLC System: Intuitively Simple



System Status Lighting

Provides users a clear visual indication of the system status (in use, idle, etc.).



Made for Empower™ Software

Waters Empower Software Suite helps your entire laboratory operate better, with the industry's most advanced data acquisition, management, processing, analytics, and reporting capabilities. Empower Software provides you an environment where your records are traceable, so you always have full control of your most critical asset – your data.



Color-Coded Bottle Clips and Flags

Solvent tubing clips ensure the tubing remains organized to enable tracing from instrument to the solvent bottle flags, reducing the possibility of errors.



Intuitive Touchscreen

An easy-to-use, advanced touchscreen provides system health checks, sample status, guided set up, troubleshooting, and maintenance in easy-to-follow steps. Pre-run checks for common errors such as missing vials, an incorrect column, and qualification/preventative maintenance requirements enable users to catch these mistakes before they result in a sample analysis failure, preventing re-runs.



Corrosion-Resistant and Bio-Inert

Corrosion-resistant materials of construction help to maximize system robustness under high salt extremes. MaxPeak HPS Technology enhances separation and detection of metal-sensitive analytes, enabling you to minimize the risk of undetected analytes – for increased efficiency and confidence in your results.





Fittings built for you

- Tool-free, finger-tight
- Tested to 300 re-uses
- Virtually zero carryover
- Eliminate dispersion/
band-spread errors



Intuitive Innovation

Developed for QC labs, the Alliance iS Bio HPLC System includes a range of new and unique features, to deliver:

- Class-leading carryover and injection precision
- Robust performance when operating at extremes of the column heater cooler and sample manager temperature ranges
- Faster detector warm-up time and reduced drift
- Redesigned check valves and mixer for increased performance and robustness



Help at Your Fingertips

The Alliance iS Bio HPLC System's support journey delivers smart on-board technology that digitally brings you information you need at the new Waters Help Center. Train and troubleshoot with ease, knowing that Waters will support you at every stage.

Waters™ | [Help Center](#)



Intelligent Method Translator App (iMTA)

Working with Empower Software, the iMTA enables a user to create an Alliance iS Bio HPLC System method directly from a Waters or other third-party system. Basic chromatographic conditions will automatically be transferred. For compliance, the new instrument method will have a report providing traceability to the originator method.



Smart Column Capabilities

eConnect™-enabled HPLC Columns are Waters second-generation smart columns and a leap forward toward advancing today's QC laboratory to an entirely digital platform. Specifically developed to meet the unique needs of the compliant laboratory, the NFC-enabled eConnect Column tag is permanently secured onto the column body and carries all relevant identifying information to simplify LC run setup.

Advantage for Oligonucleotide Separations

Oligonucleotide Separations

The landscape for oligonucleotides is diverse. Modifications, conjugation, and novel formulations are also increasing the complexity of oligonucleotide therapeutics, necessitating analytical tools that deliver high-quality results, improve efficiency, and enable regulatory compliance.

With the Alliance iS Bio HPLC System, you can improve your recovery and robustness for your oligonucleotide separations, while reducing variability for increased confidence and accuracy in your results.

Whether your goal is to boost productivity, expand your operations, or improve performance, you can be confident that the Alliance iS Bio HPLC System will deliver. With error reduction as standard, intuitive operation, and performance you can trust, your lab ally is built to deliver for critical quality attributes (CQAs).

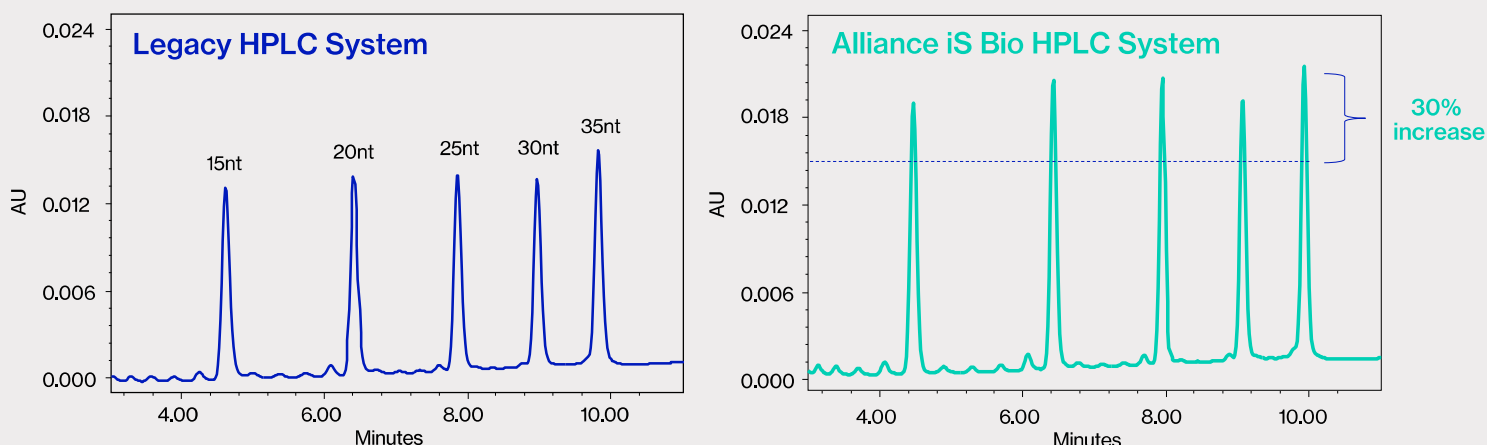


Figure 1. In this oligonucleotide separations example, the Alliance iS bio HPLC System and MaxPeak Premier BEH Column generated a 30% increase in peak height for improved sensitivity, and a 15% increase in peak area for improved recovery versus a legacy HPLC system and column.

Confidently Transfer Your mAb Methods

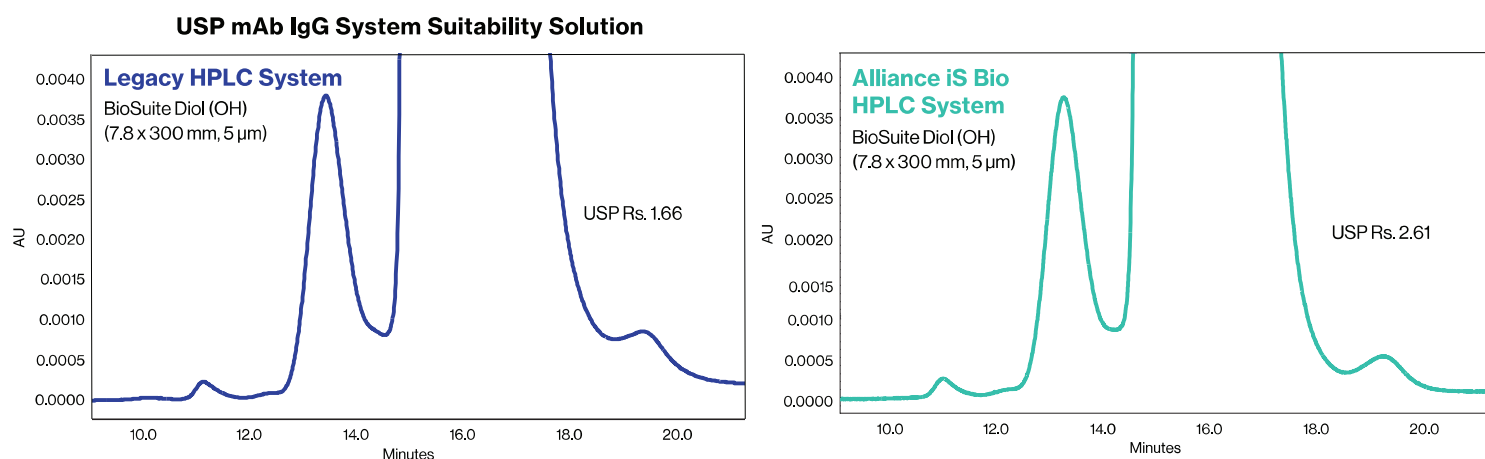
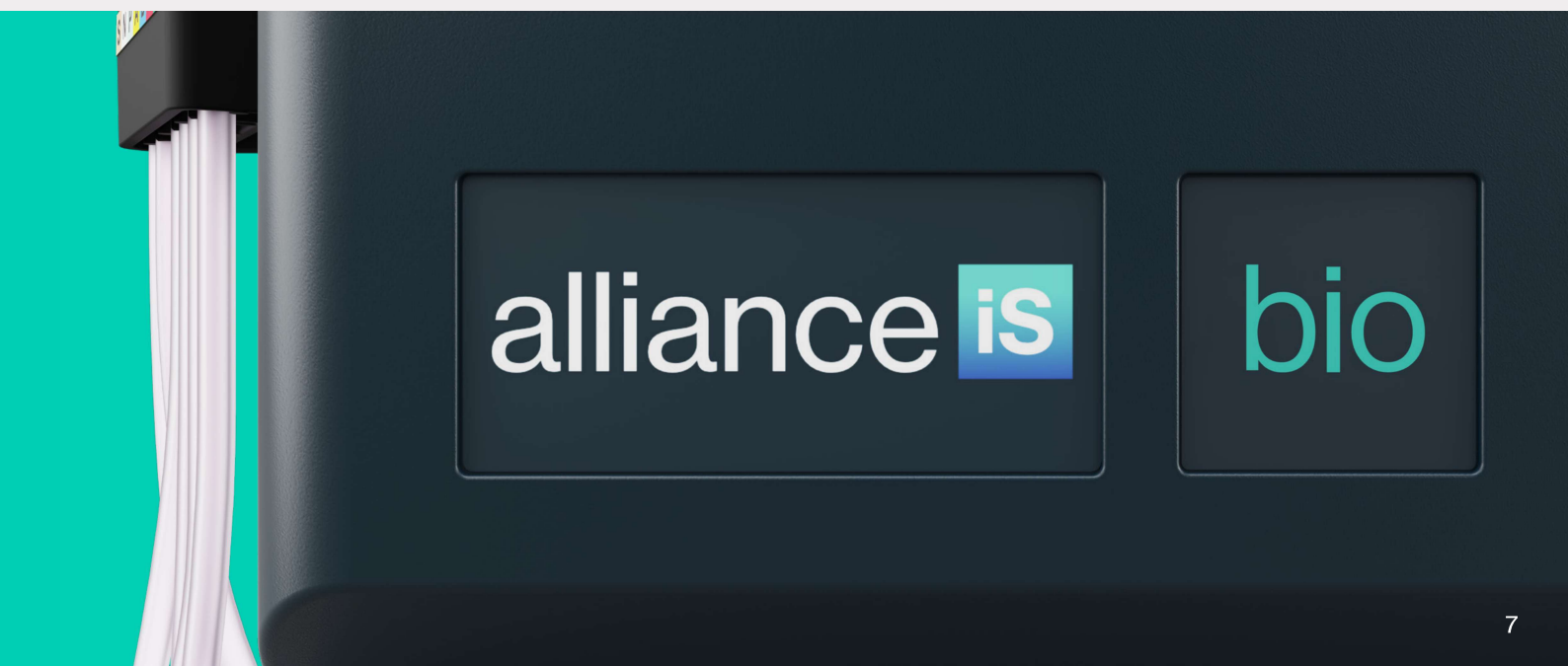


Figure 2. <129> SEC Method Migration from a legacy HPLC System to Alliance iS Bio HPLC System. All system suitability criteria were successfully passed.

Size-exclusion chromatography (SEC) is very useful for monoclonal antibody (mAb) characterization and quality control.

With the Alliance iS Bio HPLC System, you can confidently run your legacy mAb separations, while meeting system suitability criteria for compendial methods and improving resolution due to lower system dispersion.



Reliable Operation for the Most Demanding Peptide Separations

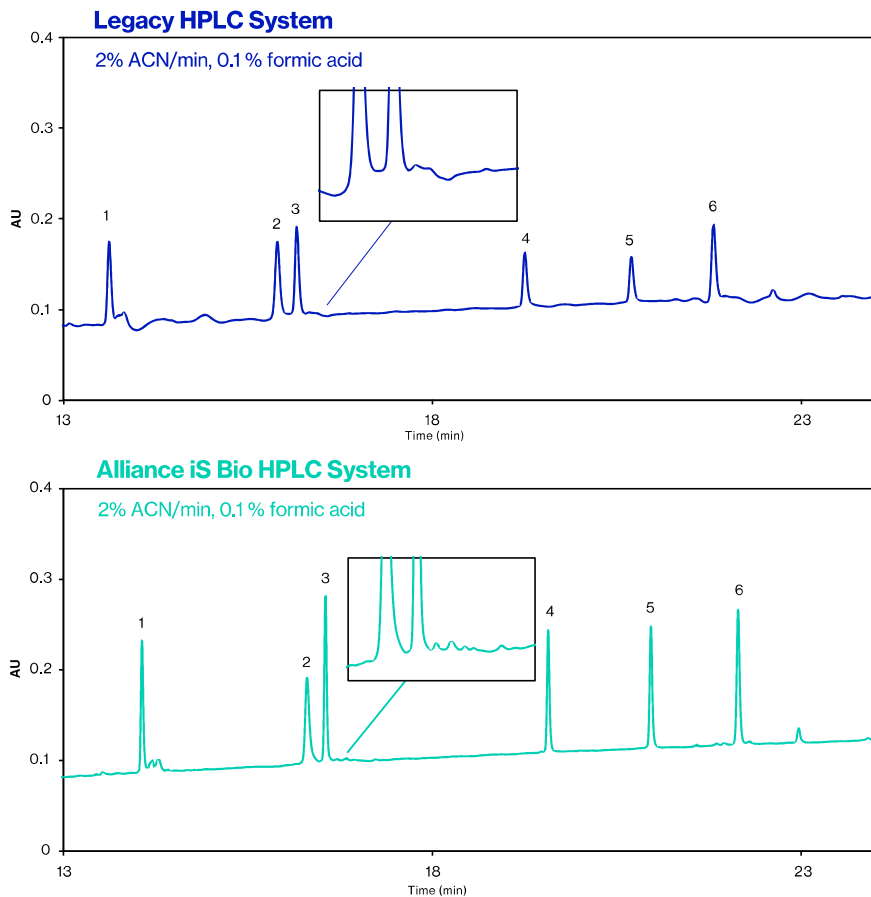


Figure 3. In this example a peptide assay was developed for glucagon and a panel of GLP-1 peptide drugs using conventional RPLC conditions with water and acetonitrile as mobile phases containing 0.1 % formic acid.

Acidic peptides and phosphopeptides can be very challenging to separate using legacy HPLC systems. The Alliance iS Bio HPLC System, featuring MaxPeak HPS Technology, is designed to minimize these unwanted interactions, while improving recovery, retention time consistency, and peak shapes.

With the Alliance iS Bio HPLC System, you can better control variability risks, enhance decision making, and improve lab productivity for even the most challenging peptide separations.



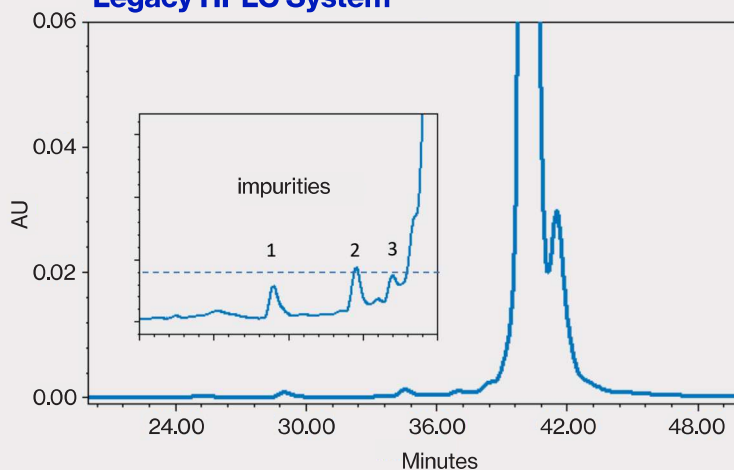
Advanced Tools for Future Bioseparations Needs

Your systems need to support both legacy and new methods that can be operated repeatably anywhere in the world while meeting regulatory requirements. These requirements can also place a large burden on your analysts, but failing to perform necessary tasks could put your organization at risk. One of the advanced tools available with the Alliance iS bio HPLC System is the Intelligent Method Translator App (iMTA), which will assist you with method migration from other systems, automatically and compliantly.

Legacy HPLC Method

| Time | Flow | %A | %B | %C | %D | Curve | |
|------|--------|------|------|------|-----|-------|---|
| 1 | 0.50 | 56.0 | 44.0 | 0.0 | 0.0 | 6 | |
| 2 | 4.00 | 0.50 | 56.0 | 44.0 | 0.0 | 6 | |
| 3 | 48.00 | 0.50 | 34.0 | 66.0 | 0.0 | 6 | |
| 4 | 60.00 | 0.50 | 34.0 | 66.0 | 0.0 | 6 | |
| 5 | 62.00 | 0.50 | 25.0 | 0.0 | 0.0 | 75.0 | 6 |
| 6 | 74.00 | 0.50 | 25.0 | 0.0 | 0.0 | 75.0 | 6 |
| 7 | 84.00 | 0.50 | 56.0 | 44.0 | 0.0 | 0.0 | 6 |
| 8 | 100.00 | 0.50 | 56.0 | 44.0 | 0.0 | 0.0 | 6 |

Legacy HPLC System



Alliance iS Bio HPLC System Method

| Time (min) | Flow (mL/min) | %A | %B | %C | %D | Curve |
|------------|---------------|------|------|-----|------|---------|
| Initial | 0.500 | 56.0 | 44.0 | 0.0 | 0.0 | Initial |
| 4.00 | 0.500 | 56.0 | 44.0 | 0.0 | 0.0 | 6 |
| 48.00 | 0.500 | 34.0 | 66.0 | 0.0 | 0.0 | 6 |
| 60.00 | 0.500 | 34.0 | 66.0 | 0.0 | 0.0 | 6 |
| 62.00 | 0.500 | 25.0 | 0.0 | 0.0 | 75.0 | 6 |
| 74.00 | 0.500 | 25.0 | 0.0 | 0.0 | 75.0 | 6 |
| 84.00 | 0.500 | 56.0 | 44.0 | 0.0 | 0.0 | 6 |
| 100.00 | 0.500 | 56.0 | 44.0 | 0.0 | 0.0 | 6 |

Alliance iS Bio HPLC System

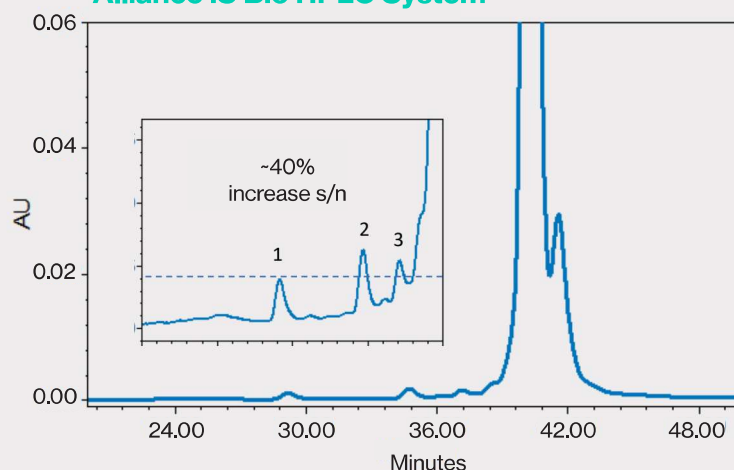


Figure 4. In this example, a legacy HPLC method was translated using the iMTA. The Alliance iS Bio HPLC System was used to analyze an oligonucleotide therapeutic candidate: GEM91. With its integrated MaxPeak HPS technology, the Alliance iS Bio HPLC System resulted in up to a 40% increase in signal-to-noise for the trace impurities.

Take Your Bioseparations to the Max



The Alliance iS Bio HPLC System is designed to operate with columns from multiple vendors for seamless transition of existing methods. For optimum performance at every sample touchpoint, Waters QuanRecovery™ Vials and Plates, and MaxPeak Premier Columns are designed with MaxPeak HPS Technology, ensuring you minimize the risk of undetected analytes – for increased efficiency and confidence in your results.

Critical Quality Attributes and Recommended Columns & Consumables for Proteins and mAbs

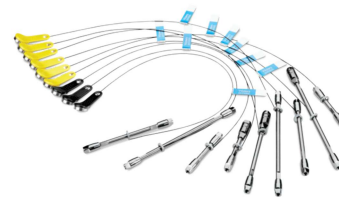
| CQA | LC Technique | Columns | | | Sample Prep Kits & Buffers | LC Vials |
|-----------------|-----------------------------------|--|--|---|--|---|
| Aggregation | SEC | XBridge™ Premier Protein SEC 250Å, 2.5 µm | | | Critical | LCGC Certified Vial, Max Recovery Polypropylene 300 µL vials |
| Identity | RP [Peptide Mapping] | XSelect™ Premier Peptide CSH™ C ₁₈ 130Å, 2.5 µm | XBridge Premier Peptide BEH™ C ₁₈ 130Å & 300Å, 2.5 µm | XSelect Premier Peptide HSS T3, 100Å 2.5 µm | PeptideWorks™ Tryptic Protein Digestion Kits IonHance DFA | QuanRecovery MaxPeak HPS Vials and Plates |
| Charge Variants | IEX | BioResolve™ SCX mAb, 3 µm | | | BioResolve CX pH Buffers IonHance™ CX-MS Buffers | LCGC Certified Vial, Max Recovery Polypropylene 300 µL vials |
| Glycosylation | HILIC and Mixed Mode | XBridge Premier Glycan BEH Amide 130Å, 2.5 µm [HILIC] | XBridge Premier Glycan BEH C ₁₈ AX 95Å, 2.5 µm [Mixed Mode] | | GlycoWorks™ RapiFluor-MS™ and GlycoWorks™ Eco N-Glycan Kits | LCGC Certified Vial, Max Recovery Polypropylene 300 µL vials |
| Identity | RP [Intact Mass/Subunit Analysis] | BioResolve RP mAb Polyphenyl, 2.7 µm | XBridge Premier Protein BEH C ₄ 300Å, 2.5 µm | | IonHance DFA | LCGC Certified Vial, Max Recovery Polypropylene 300 µL vials |



MaxPeak Premier Column (bio-inert)



Stainless steel column



QuanRecovery Vials and Plates with MaxPeak HPS Technology are designed to enable you to meet recovery, sensitivity and reproducibility challenges in peptide and protein quantification.

MaxPeak Premier Columns with MaxPeak HPS Technology effectively reduce non-specific adsorption losses due to metal interactions. These columns are also designed to reduce time wasted on column passivation and method optimization, while increasing reproducibility, sensitivity, and overall quality of results.

Critical Quality Attributes and Recommended Columns and Consumables for Oligonucleotides, mRNA, Adeno-Associated Viruses (AAVs), Lipid Nanoparticles (LNP)

| CQA | LC Technique | Columns | | Sample Prep Kits | LC Vials |
|--------------------------------------|----------------------|--|---|--|---|
| AAV Aggregation | SEC | XBridge Premier GTx BEH SEC 450Å, 2.5 µm | | | |
| AAV Purity: Intact Capsid Protein | RP | XBridge Premier Protein BEH C ₄ 300Å, 2.5 µm | | | LCGC Certified Vial, Max Recovery Polypropylene 300 µL vials |
| AAV Purity: Empty/Full Capsid | AEX | Protein-Pak Hi Res Q, 5 µm | | | |
| AAV Sequence Variants | RP [Peptide Mapping] | XSelect Premier Peptide CSH C ₁₈ 130Å, 2.5 µm | XBridge Premier Peptide BEH C ₁₈ 130Å & 300Å, 2.5 µm | | |
| OligoIdentity: Purity and Impurities | IPRP and HILIC | XBridge Premier Oligonucleotide BEH C ₁₈ 130Å & 300Å, 2.5 µm [IPRP] | XBridge Premier BEH Amide 130Å, 2.5 µm [HILIC] | OligoWorks™ SPE Kits [oligo bioanalysis] | QuanRecovery MaxPeak HPS Vials and Plates |
| mRNA Modifications: 5' Cap | IPRP | XBridge Premier Oligonucleotide BEH C ₁₈ 130Å, 2.5 µm | | | |
| mRNA: Identity Integrity | AEX | Protein-Pak Hi Res Q, 5 µm | | | LCGC Certified Vial, Max Recovery Polypropylene 300 µL vials |
| Plasmid/DNA Impurities & Identity | AEX | Protein-Pak Hi Res Q, 5 µm | | | |



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Waters™



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