



BioPharma

Chromatography columns and consumables
BioPharma workflow solutions

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Complete biopharma workflow solutions

For scientists pursuing robust and reproducible methods when working with biopharmaceuticals, selecting the correct workflow is imperative for success in quantitating and quality assuring APIs.

reproducible methods with great results despite working with complex samples. The workflows in this brochure offer a sampling from Thermo Fisher Scientific.

We strive to create a better understanding of how to compose an optimal workflow allowing scientists to create a robust and

Peptide mapping

- Thermo Scientific™ SMART Digest™ kits
- Thermo Scientific™ AccuCore™ (U)HPLC columns
- Thermo Scientific™ Hypersil GOLD™ (U)HPLC columns
- Thermo Scientific™ Acclaim™ (U)HPLC columns
- Thermo Scientific™ SureSTART™ vials and caps

Charge variants

- Thermo Scientific™ MAbPac™ (U)HPLC columns
- Thermo Scientific™ ProPac™ (U)HPLC column
- Thermo Scientific™ CX-1 pH gradient buffers
- SureSTART vials and caps

Intact mass and aggregates

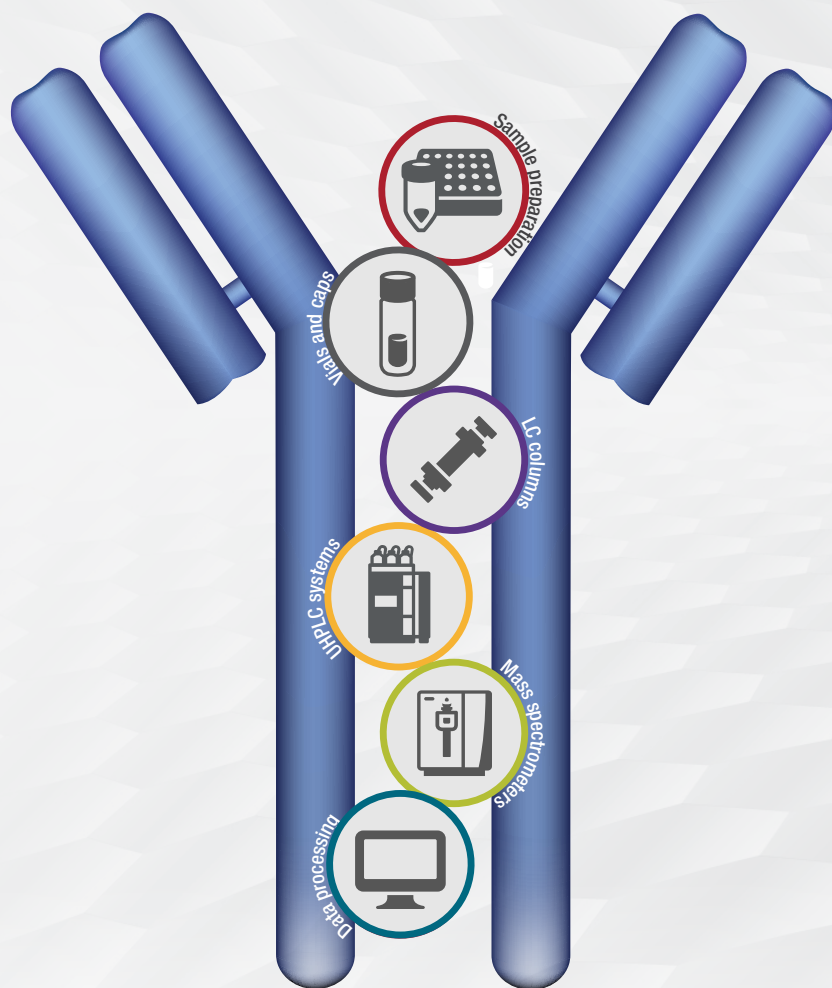
- MAbPac (U)HPLC columns
- ProPac (U)HPLC columns
- SureSTART vials and caps

Glycan analysis

- Thermo Scientific™ GlycanPac™ (U)HPLC columns
- AccuCore (U)HPLC columns
- SureSTART vials and caps

DNA and RNA analysis

- Thermo Scientific™ Smart Digest™ RNase kits
- Thermo Scientific™ DNAPac™ (U)HPLC columns
- SureSTART vials and caps



Contents

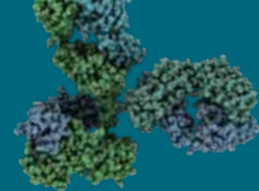
BioPharma workflow solutions

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Charge variant analysis workflow



QC antibody charge variant analysis on ProPac Elite WCX columns

Monoclonal antibodies (mAbs) are a preferred class of protein therapeutics used for the treatment of various diseases because of their ability to target specific tissues. The structure of monoclonal antibodies is often heterogeneous due to post-translational modifications and degradation during cellular production and downstream processing. Modifications can impart additional cationic and anionic charges, increasing the charge heterogeneity of the mAb. To analyze variants based on their charge, ion exchange chromatography (IEX) is a commonly used technique to separate analytes including proteins based on differences in charge. Thermo Scientific™ ProPac™ Elite WCX columns (5 μm) possess weak cation exchange functionality designed for the analysis of proteins. Thermo Scientific CX-1 pH gradient buffers generate a linear pH gradient that simplifies method optimization for high resolution separation of the main product and impurities.

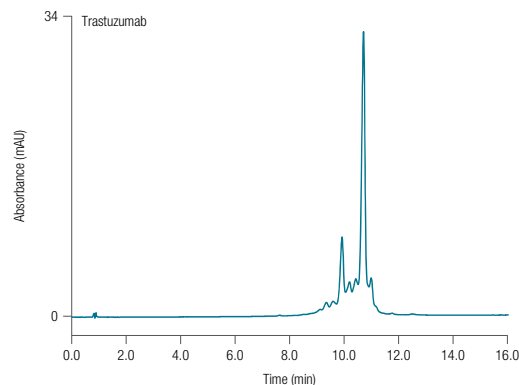


Figure 1. Separation of IgG1 therapeutic mAbs using a 20 to 70% B pH gradient on the 4 x 150 mm column



Workflow solution

Thermo Scientific instrument	Cat. no.
Thermo Scientific™ Vanquish™ Flex UHPLC system with a DAD detector	—
Thermo Scientific columns and guard columns	Cat. no.
ProPac Elite WCX column	—
Thermo Scientific™ ProPac™ WCX-10 guard column	11311743
Thermo Scientific gradient buffers	Cat. no.
Thermo Scientific™ CX-1 pH gradient buffer A	15870452
Thermo Scientific™ CX-1 pH gradient buffer B	15880452
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 2 mL GOLD-Grade clear glass vial	17374073
Thermo Scientific™ SureSTART™ 9 mm screw cap	17334063
This workflow includes the newest recommended products	

mRNA sequencing workflow

QC mRNA high throughput and high robustness sequencing

Large RNA including mRNA (messenger RNA) has emerged as an important new class of therapeutics. Recently, this has been demonstrated by two highly efficacious vaccines based on mRNA sequences encoding for a modified version of the SARS-CoV-2 spike protein. There is currently significant demand for the development of new and improved analytical methods for the characterization of large RNA including mRNA therapeutics. This workflow is an automated, high throughput workflow for the rapid characterization and direct sequence mapping of large RNA and mRNA therapeutics. Partial RNase digestions using RNase T1.

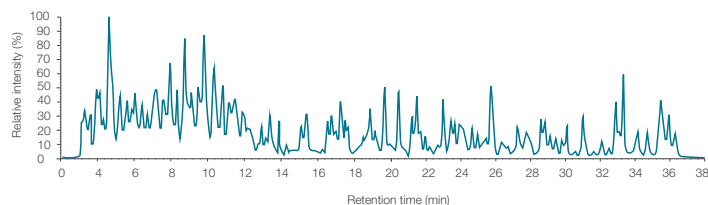
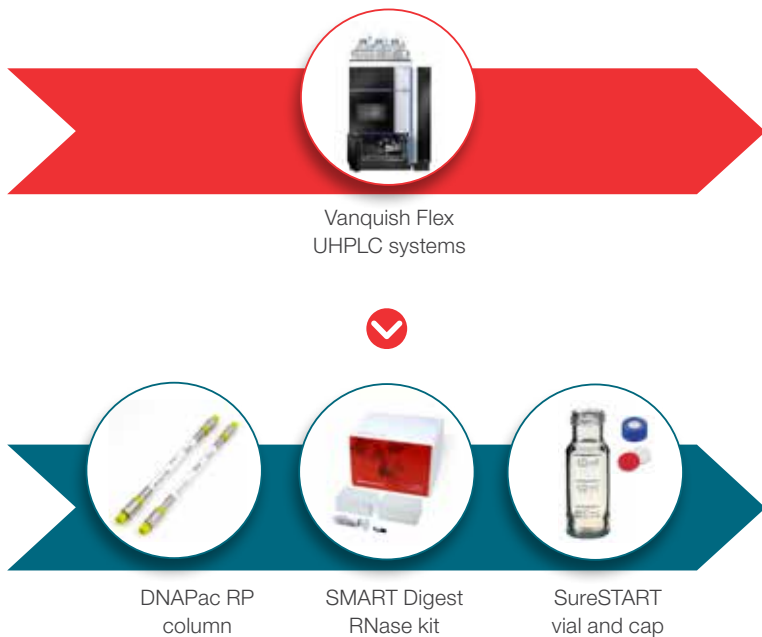


Figure 2. RNA sequence mapping of mRNA therapeutics and long RNA

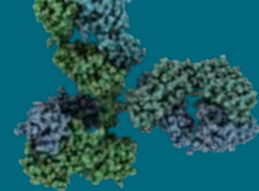
[Article:](#) Characterization and sequence mapping of large RNA and mRNA therapeutics using mass spectrometry



Workflow solution

Thermo Scientific instrument	Cat. no.
Vanquish Flex UHPLC system	—
Thermo Scientific columns and guard columns	Cat. no.
Thermo Scientific™ DNAPac™ RP HPLC column	15531693
DNAPac RP guard column	15551693
Thermo Scientific™ Acclaim™ guard holder and coupler	11321933
Thermo Scientific digest solutions	Cat. no.
Thermo Scientific™ SMART Digest™ RNase T1 mag bulk kit	17716789
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 2 mL polypropylene vial	17303923
Thermo Scientific™ SureSTART™ 9 mm screw cap	17334043
This workflow includes the newest recommended products	

Lipidomics workflow



Understanding the lipids

Natural lipidomes are characterized by extremely high complexity and dynamic range of lipid concentrations, and are increasingly important for our evolving vaccine development. High diversity of lipid physicochemical properties requires high resolving powers for both chromatographic and mass spectrometric analytical platforms. Thermo Scientific™ Accucore™ C30 columns proved to be one of the most resolving columns for this workflow capable of resolving complex mixtures of lipids in 32 min of analysis in human blood plasma.

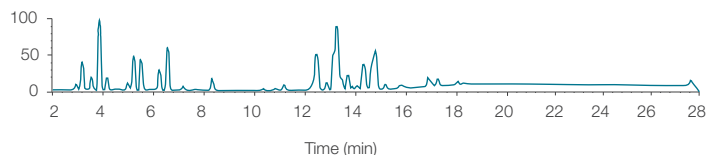


Figure 3. Lipids characterization on Accucore C30 columns

[Article:](#) Rational selection of reverse phase columns for high throughput LC-MS lipidomics



Workflow solution

Thermo Scientific instrument	Cat. no.
Vanquish Flex UHPLC system with a DAD detector	—
Thermo Scientific columns and guard columns	Cat. no.
Accucore C30 LC column	13485679
Accucore C30 LC guard colum	13582950
Thermo Scientific™ Uniguard™ direct-connection guard cartridge holder	10776714
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 1.7 mL snap vial	17354033
Thermo Scientific™ SureSTART™ 11 mm snap cap	17354003
This workflow includes the newest recommended products	

Monoclonal antibody workflow

Monoclonal antibody titer analysis by affinity chromatography

The Thermo Scientific™ MAbPac™ Protein A column is specifically designed to provide fast mAb titer analysis of harvest cell cultures (HCC). The HPLC compatibility of this column in combination with low back pressure and high efficiency allows automation, providing higher throughput and more accurate analysis. The column format allows rapid automation of loading, binding, elution and collection using Thermo Scientific biocompatible systems. The Thermo Scientific™ MAbPac™ Affinity column is fast and reproducible and determines the IgG titers using pH gradient mobile phases.

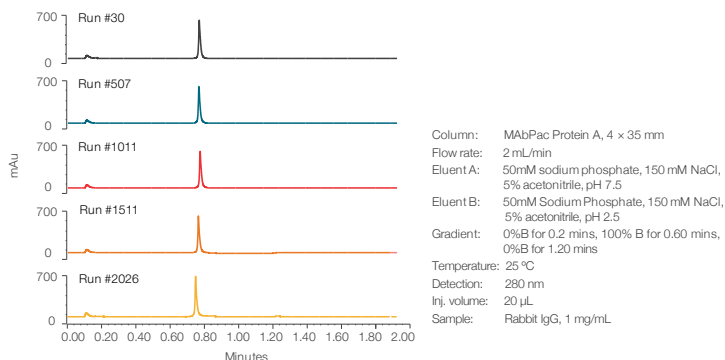


Figure 4. 20 µg Rabbit IgG loaded onto MAbPac Protein A column for 2,000 injections at 2 mL/min



Workflow solution

Thermo Scientific instrument	Cat. no.
Vanquish Flex UHPLC system with a DAD detector	—
Thermo Scientific columns and guard columns	Cat. no.
MAbPac Protein A LC column	15156844
Thermo Scientific gradient buffers	Cat. no.
CX-1 pH gradient buffer A	15870452
CX-1 pH gradient buffer B	15880452
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 1.5 mL snap vial	17364033
SureSTART 9 mm screw cap	17334063
This workflow includes the newest recommended products	

Columns and guard columns



ProPac Elite WCX liquid chromatography columns

Discover the unique ProPac Elite WCX weak cation exchange (WCX) liquid chromatography column. Designed for protein characterization including therapeutic proteins, mAb, antibody drug conjugates (ADCs) and biosimilar proteins, this column offers high resolution, high efficiency separation of proteins and their charge variants. The unique column chemistry provides excellent performance under a broad range of pH, temperature and mobile phase compositions with excellent recovery and low carryover.

ProPac WCX-10 HPLC columns

Use ProPac WCX-10 LC columns to provide exceptionally high resolution for separations of proteins and their variants. Based on stationary phases composed of 10 µm nonporous polymeric beads, ProPac columns resolve isoforms that differ by a single charged residue. A thin, hydrophilic layer grafted to the particle core eliminates unwanted secondary interactions. The cation-exchange surface provides pH-based selectivity control and fast mass transfer for high-efficiency separation and moderate capacity.



MABPac Protein A LC columns

Run fast, accurate titer analysis of mAb in harvest cell cultures with the MABPac Protein A LC columns. This column provides high throughput and accurate analyses through a combination of low backpressure and high efficiency. Its unique format makes automation of loading, binding, elution and collection using biocompatible systems quick and easy. A nonporous, polymeric resin with a hydrophobic divinylbenzene core and a hydrophilic surface optimized for affinity separation makes this column rugged and reproducible.



ProPac Elite WCX columns

Format	Length (metric)	Particle size	Cat. no.
Analytical column	150 mm	5 µm	15993932

ProPac WCX-10 guard columns

Format	Length (metric)	Particle size	Cat. no.
Guard column	50 mm	10 µm	11311743

MABPac Protein A LC columns

Format	Length (metric)	Particle size	Cat. no.
LC column	35 mm	12 µm	15156844

Columns and guard columns continued



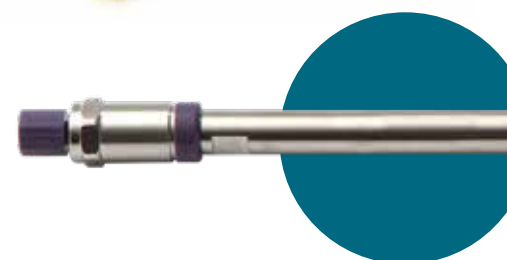
DNAPac RP HPLC columns

Achieve superior reversed phase oligonucleotide separations using the DNAPac RP HPLC columns. The unique chemistry is designed for analysis of oligonucleotides and double-stranded (ds) DNA/RNA fragments using LC-UV or LC-MS. The column chemistry provides excellent performance under a broad range of pH, temperature, and mobile phase compositions. In addition, the wide pore size of the resin provides excellent separation of large double-stranded nucleic acids up to 10k base pairs.



Accucore C30 HPLC columns

Achieve fast, high-resolution separations of hydrophobic, long-chain compounds using Accucore C30 LC columns. Rugged 2.6 μm solid-core particles enable fast, high-resolution separations at low backpressures. The C30 stationary phase offers unique shape selectivity for structurally related isomers and is compatible with highly aqueous mobile phases. Robust bonding technology and automated packing procedures ensure excellent reproducibility and long column lifetimes.



Uniguard direct-connection guard cartridge holders

Eliminate the requirement for extra fittings using Uniguard direct-connection guard cartridge holders. They are reusable, stainless-steel guard cartridge holders that attach directly to the analytical column inlet.



DNAPac RP columns

Format	Length (metric)	Particle size	Cat. no.
HPLC column	100 mm	4 μm	15531693
Guard cartridge	10 mm	4 μm	15551693

Accucore C30 columns

Format	Length (metric)	Particle size	Cat. no.
HPLC column	150 mm	2.6 μm	13485679
Guard cartridge (4/pk)	10 mm	2.6 μm	13582950

Uniguard direct-connection guard cartridge holders

Uniguard direct-connection guard cartridge holders			10776714
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SMART Digest RNase kits

Obtain high-quality analytical results from mRNA digestions using SMART Digest RNase kits (Thermo Scientific™ SMART Digest™ RNase T1 kit and Thermo Scientific™ SMART Digest™ RNase A kit). A significant advance in sample preparation for oligonucleotide mapping, the kits provide fast and simple digestion with high reproducibility, high sensitivity, and high levels of data quality in a format that is compatible with automation. RNase kits use optimized heat-stable enzymes on magnetic beads allowing control of partial digestion to produce required fragments of ideal length for sequencing by HRAM MS.

RNase kits are available with with two enzyme specificities:

- **SMART Digest RNase T1 kit** is an endoribonuclease that specifically degrades single-stranded RNA at G residues
- **SMART Digest RNase A kit** is an endoribonuclease that specifically degrades single-stranded RNA at C and U residues

Easy and simple

- Sample process and control of digestion time ensures required fragment length
- Easily automate entire protocol for high-throughput processing
- Single nuclease digestion

Reliable results

- Increased reproducibility over existing protocols
- Higher data confidence
- No nuclease contamination of the analytical column



SMART Digest RNase kits

Description	Cat. no.
SMART Digest RNase T1 mag bulk kit (using magnetic beads)	17716789
SMART Digest RNase A mag bulk kit	17726789

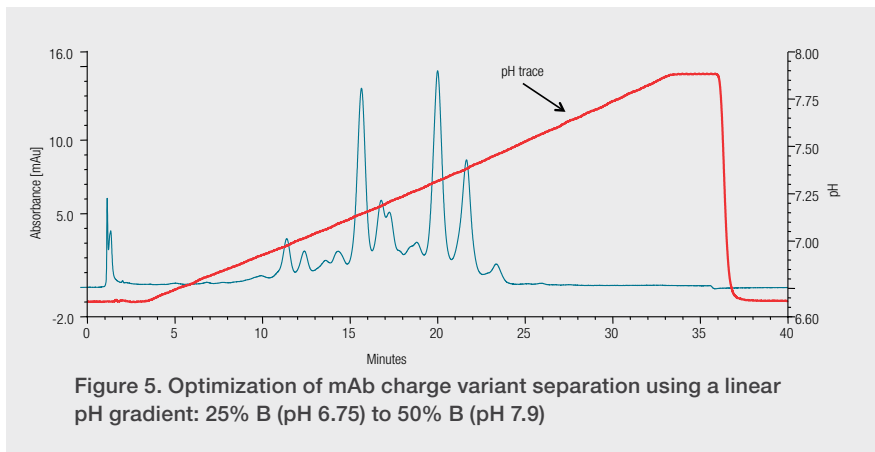
pH gradient buffers

Ready-to-use buffers for simple method development during charge variant characterization

The Thermo Scientific pH gradient platform accelerates method development and facilitates method transfer to QA/QC for a wide range of protein and mAb charge variants through a generic LC-based approach to charge variant characterization.

Thermo Scientific pH buffer concentrates can be purchased individually or as a pair, in quantities of 125 mL or 250 mL. For added convenience, the 125 mL buffers can also be bundled with columns in a number of specifically preconfigured kits.

- Patented buffer formulations enable fast, robust and reproducible pH gradients that are simple to optimize and easily automated
- Ready to use with existing LC columns and systems, without the need for time consuming mobile phase adjustments
- Applicable to the majority of mAbs



pH gradient buffers

Description	Cat. no.
CX-1 pH gradient buffer A (pH 5.6)	15870452
CX-1 pH gradient buffer B (pH 10.2)	15135624

Vials and caps



SureSTART 1.5 mL snap vials

Choose SureSTART 1.5 mL total recovery glass screw top microvials, performance level 3, when you need to maximize the injection volume for <2 mL samples.



SureSTART 2 mL snap vials

Choose SureSTART high recovery glass snap top microvials, performance level 3, to maximize injection volume when analyzing <2 mL samples.



SureSTART 11 mm snap caps

Use SureSTART 11 mm snap caps with snap vials that have an 11 mm opening.



SureSTART 2 mL GOLD-Grade glass screw and crimp vials

Choose SureSTART 2 mL GOLD-Grade clear glass screw and crimp top vials, performance level 3, when analyzing analytes such as polar compounds that strongly adsorb on the glass surface or are sensitive to sample pH changes.



SureSTART 2 mL polypropylene screw vials

Use performance level 1 SureSTART 2 mL polypropylene screw top microvials for everyday chromatography analysis of <2 mL samples. They provide an affordable choice and can be used with all HPLC/UHPLC instrument types.



SureSTART 9 mm screw caps

Use SureSTART 9 mm screw caps with screw vials that have a 9 mm opening.



SureSTART snap vials and caps

Material	Diameter	Total volume	Usable volume	Cat. no.
Clear glass	11 mm x 32 mm	1.5 mL	1.1 mL	17364033
		1.7 mL	1.5 mL	17354033
Septum	Closure material	Thickness	Closure size	Cat. no.
White silicone/red PTFE	Blue polyethylene	1.3 mm	11 mm	17354003

SureSTART screw vials and caps

Material	Diameter	Total volume	Usable volume	Cat. no.
Clear glass	9 mm x 32 mm	2.0 mL	1.5 mL	17374073
Clear polypropylene		1.5 mL	1.0 mL	17303923
Septum	Closure material	Thickness	Closure size	Cat. no.
White silicone/red PTFE	Blue polypropylene	1 mm	9 mm	17334043
Red PTFE/white silicone/red PTFE		1 mm	9 mm	17334063

Chromatography columns and consumables

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- **Educational resources** available online with training courses and webinars for your applications

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