



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

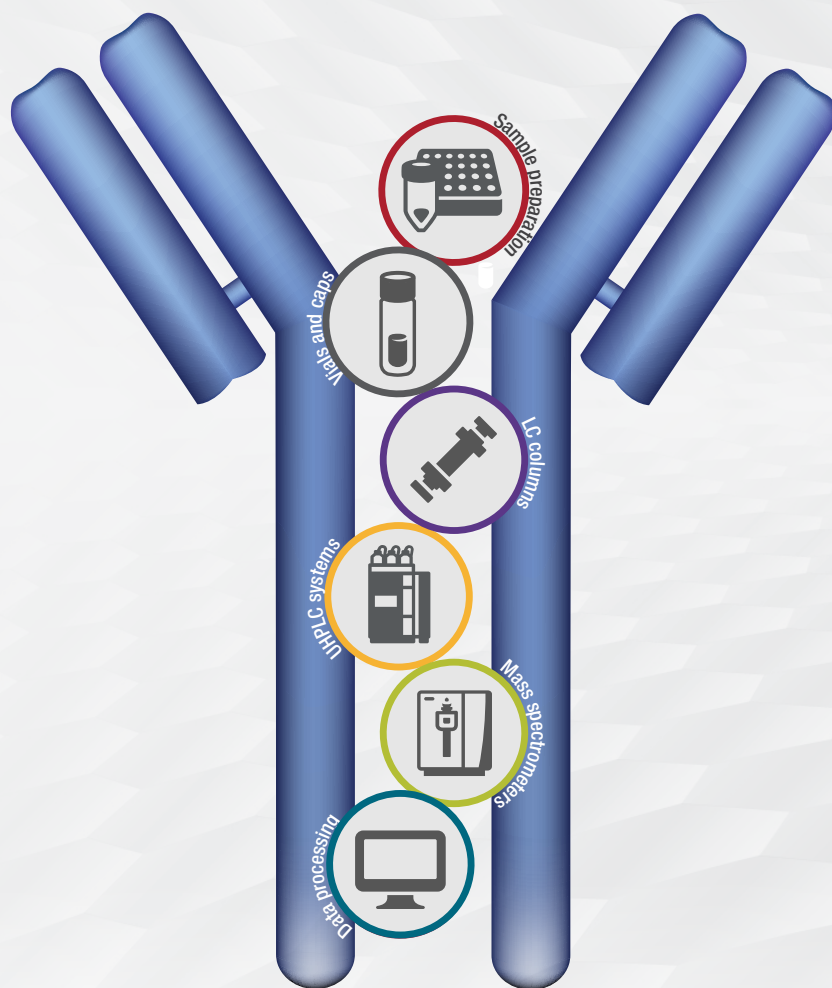
- MAbPac (U)HPLC columns
- ProPac (U)HPLC columns
- SureSTART vials and caps

## 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



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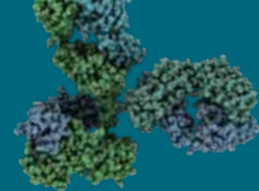
## Featured products

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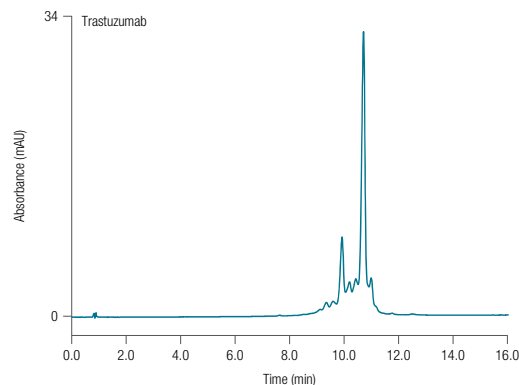
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# Charge variant analysis workflow



## 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**



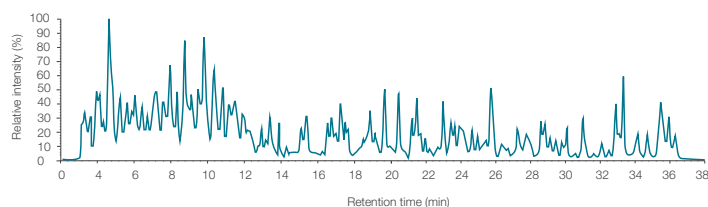
### Workflow solution

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	DX054994
Thermo Scientific gradient buffers	Cat. no.
Thermo Scientific™ CX-1 pH gradient buffer A	NC1952925
Thermo Scientific™ CX-1 pH gradient buffer B	03254083
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 2 mL GOLD-Grade clear glass vial	03452241
Thermo Scientific™ SureSTART™ 9 mm screw cap	03452267
This workflow includes the newest recommended products	

# mRNA sequencing workflow

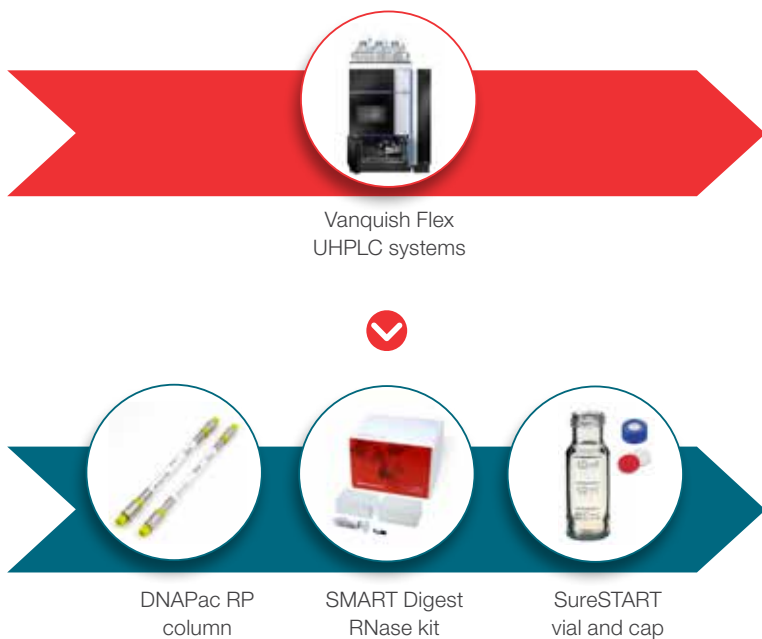
## QC mRNA high throughput and high robustness sequencing

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**

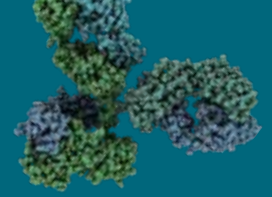
[Article:](#) Characterization and sequence mapping of large RNA and mRNA therapeutics using mass spectrometry



### Workflow solution

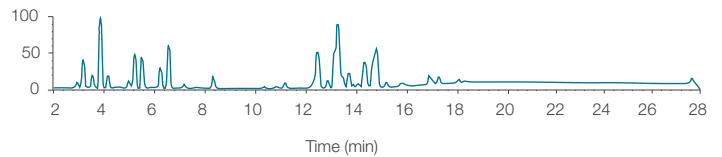
Thermo Scientific instrument	Cat. no.
Vanquish Flex UHPLC system	—
Thermo Scientific columns and guard columns	Cat. no.
Thermo Scientific™ DNAPac™ RP HPLC column	DX088923
DNAPac RP guard column	DX088925
Thermo Scientific™ Acclaim™ guard holder and coupler	DX069707
Thermo Scientific digest solutions	Cat. no.
Thermo Scientific™ SMART Digest™ RNase T1 mag bulk kit	01257521
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 2 mL polypropylene vial	03452260
Thermo Scientific™ SureSTART™ 9 mm screw cap	03452269
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# 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	03452139
Accucore C30 LC guard colum	03452143
Thermo Scientific™ Uniguard™ direct-connection guard cartridge holder	85200
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 1.7 mL snap vial	03452371
Thermo Scientific™ SureSTART™ 11 mm snap cap	03452373
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.

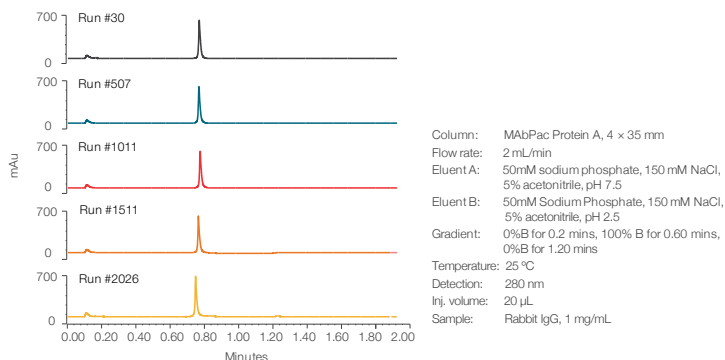


Figure 4. 20 µg Rabbit IgG loaded onto MAbPac Protein A column for 2,000 injections at 2 mL/min



### 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	DX082539
Thermo Scientific gradient buffers	Cat. no.
CX-1 pH gradient buffer A	NC1952925
CX-1 pH gradient buffer B	03254083
Thermo Scientific vials and caps	Cat. no.
Thermo Scientific™ SureSTART™ 1.5 mL snap vial	03452549
SureSTART 9 mm screw cap	03452267
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	03251449

### ProPac WCX-10 guard columns

Format	Length (metric)	Particle size	Cat. no.
Guard column	50 mm	10 µm	DX054994

### MABPac Protein A LC columns

Format	Length (metric)	Particle size	Cat. no.
LC column	35 mm	12 µm	DX082539



# Columns and guard columns continued



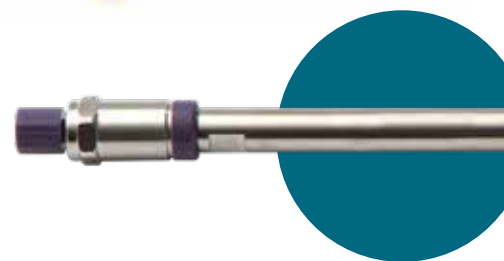
## DNAPac RP HPLC columns

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  $\mu\text{m}$  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 $\mu\text{m}$	DX088923
Guard cartridge	10 mm	4 $\mu\text{m}$	DX088925

### Accucore C30 columns

Format	Length (metric)	Particle size	Cat. no.
HPLC column	150 mm	2.6 $\mu\text{m}$	03452139
Guard cartridge (4/pk)	10 mm	2.6 $\mu\text{m}$	03452143

### Uniguard direct-connection guard cartridge holders

Uniguard direct-connection guard cartridge holders	85200
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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)	01257521
SMART Digest RNase A mag bulk kit	01257522

# pH gradient buffers



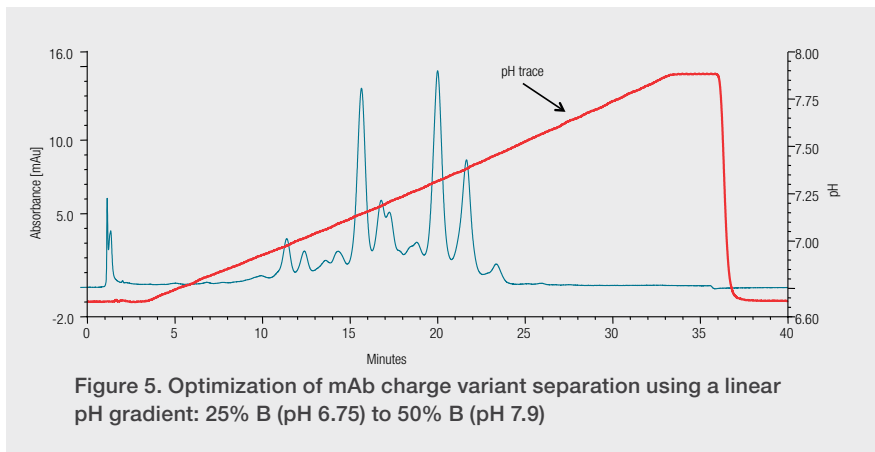
## pH gradient buffers

### 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)	NC1952925
CX-1 pH gradient buffer B (pH 10.2)	DX083275

# 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	03452549
		1.7 mL	1.5 mL	03452371
Septum	Closure material	Thickness	Closure size	Cat. no.
White silicone/red PTFE	Blue polyethylene	1.3 mm	11 mm	03452373

### 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	03452241
Clear polypropylene		1.5 mL	1.0 mL	03452260
Septum	Closure material	Thickness	Closure size	Cat. no.
White silicone/red PTFE	Blue polypropylene	1 mm	9 mm	03452269
Red PTFE/white silicone/red PTFE		1 mm	9 mm	03452267

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