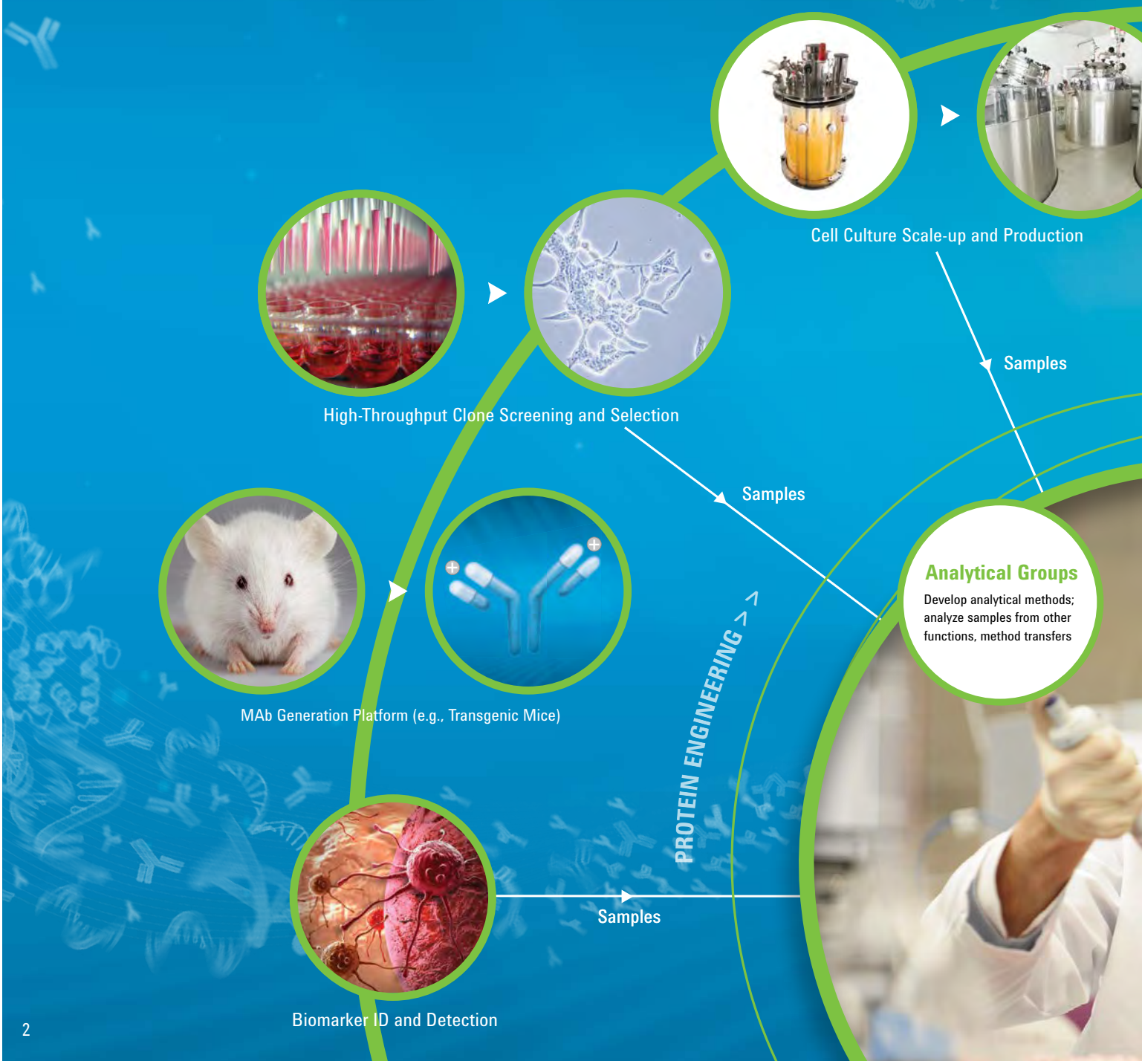
Решения для рабочего процесса BioPharma

Технические характеристики

COMPLEX CHALLENGES

The work you do is extraordinarily complicated and labor-intensive; we can help

We know you have a lot of samples to analyze, and we know what an understatement that is. The samples come to you from a wide range of sources involved in a wide range of projects—and everyone wants results right away. We understand, and we can help you get the results you need.



The throughput and productivity challenge

- Increasing number of mAb candidates in the pipeline
- Increasing number of samples to analyze with limited resources
- Driving adoption of high-throughput and high-productivity methods

Downstream Processing and Purification

Formulation and Stability

DEVELOPMENT >>

Samples

Samples

PROCESS SCALE-UP >>

Preclinical

Clinical

Manufacturing

Methods

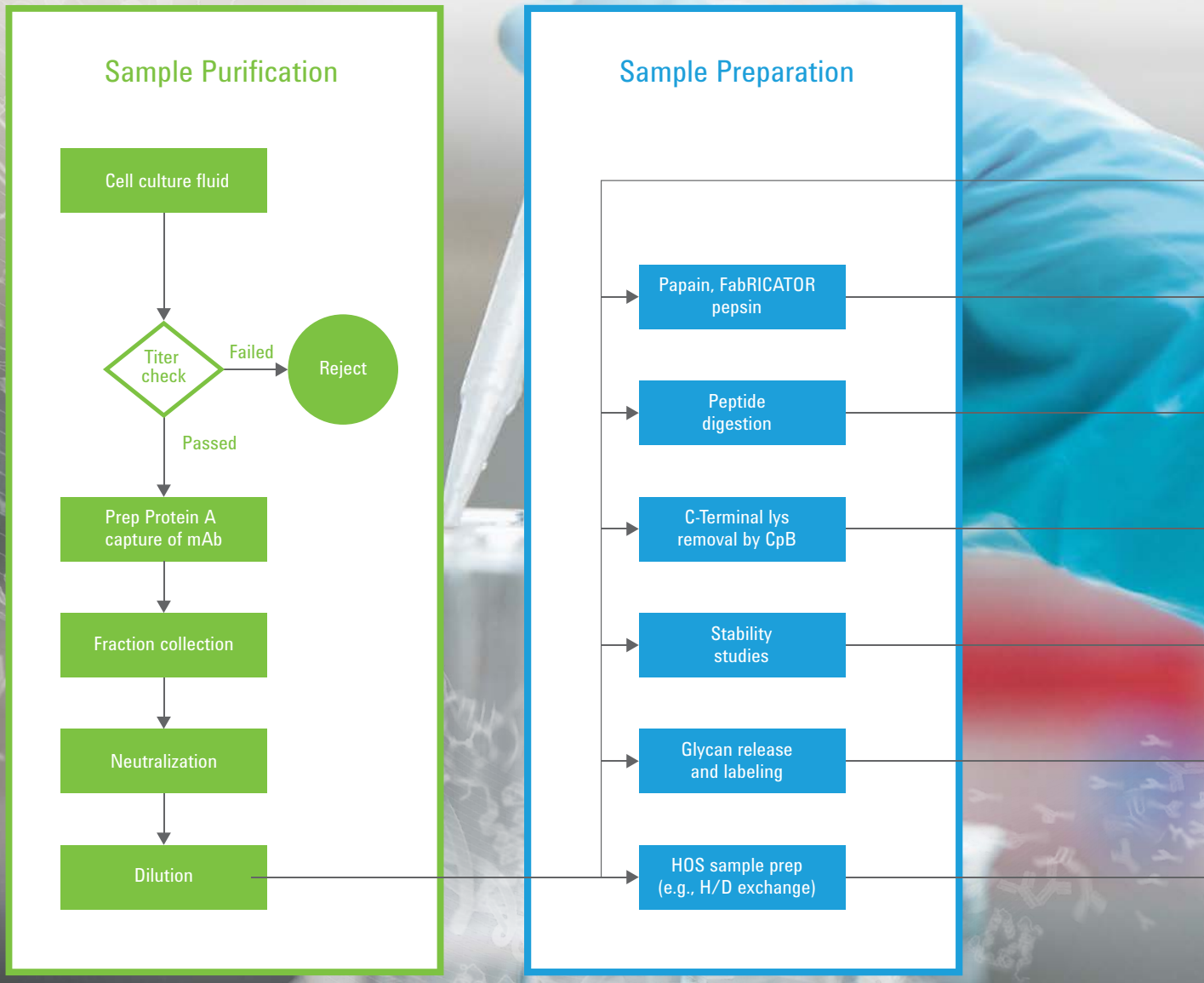
QA/QC

Market

INTEGRATED SOLUTIONS

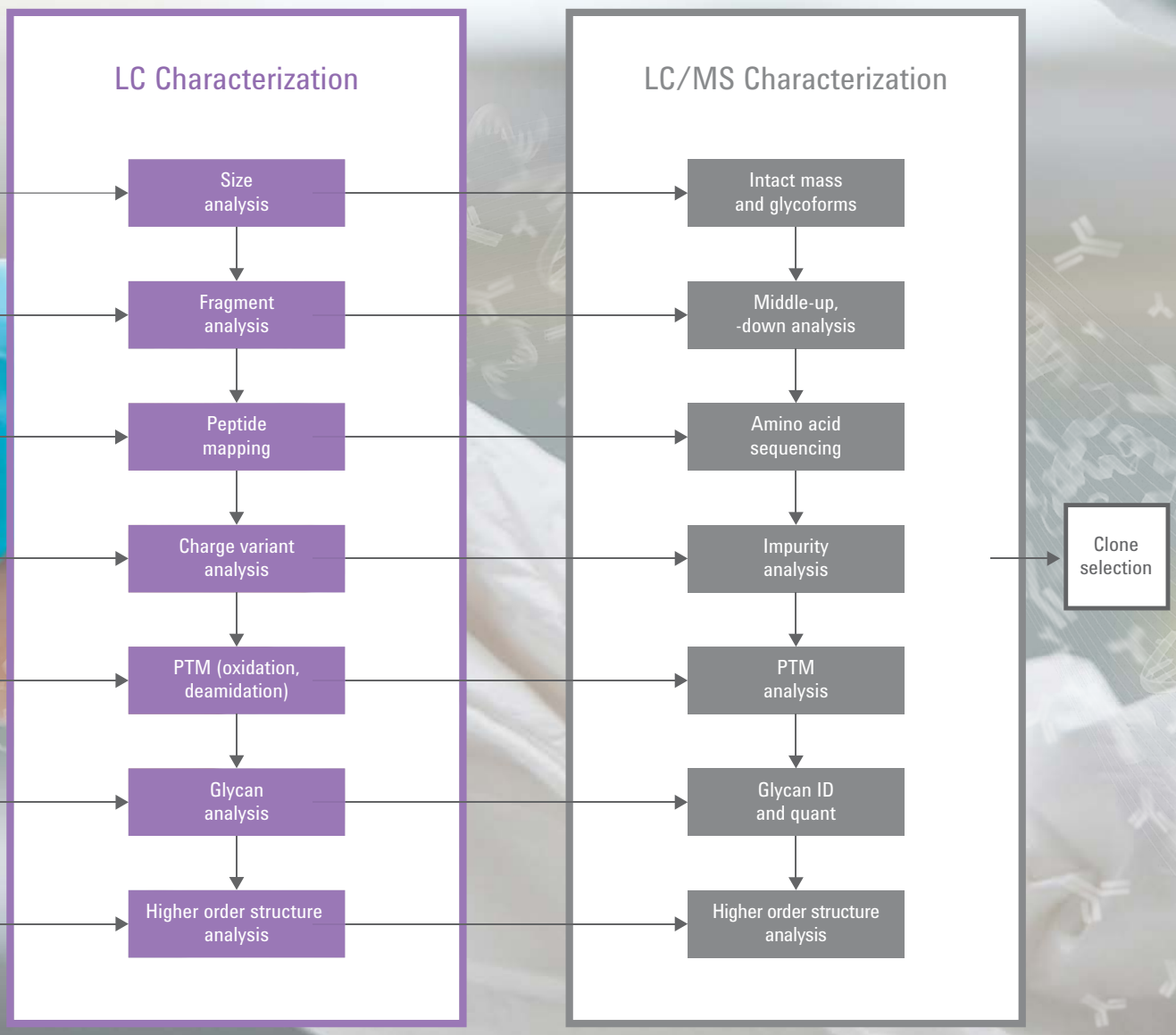
Life is easier when everything works together

Biopharma workflows have become increasingly complex, labor intensive, and time consuming. So how can you speed things up and be more productive, without sacrificing accuracy? We'll work with you to address your most complex workflows with fully integrated solutions that span from sample prep to final analysis.



Agilent biopharma analytical solutions

- Best-in-class HPLC and UHPLC solutions for higher throughput and productivity
- Walkup sample prep automation
- Best-in-class biocolumns
- High-resolution accurate mass TOF and Q-TOF for routine and walkup LC/MS applications
- High-resolution 2D-LC solutions for glycan analysis
- CE and simple plug-and-spray CE/ME solution
- Sample QC by automated microfluidic chip and next-generation sequencing electrophoresis



TRULY BIO-INERT, FAST METHOD DEVELOPMENT

System and software combine for better analysis, faster method development

When you're analyzing biomolecules, you don't want extraneous materials showing up in your results, so our Bio-inert LC system ensures that you're analyzing just the sample and no trace elements from the system itself.

Increase the quality of characterization

The Agilent 1260 Infinity II Bio-inert LC system is designed to work under even the harshest bioseparation conditions such as ADC analysis by HIC (hydrophobic interaction chromatography) using 2M ammonium sulfate. The system is truly metal-free, starting from the point of sample entry. Only bio-inert titanium is used in the pump head—no other questionable alloys.

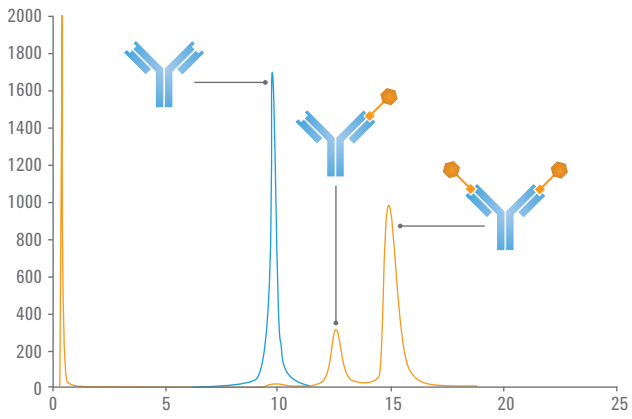
NEW detectors (improved specifications)

NEW column compartment (easier to install bio-inert heat-exchanger, QuickChange bio-inert fittings)

NEW bio-inert multisampler (ideal for microtiter plate based workflows, high capacity, faster, lowest carry over)

NEW bio-inert pump (improved usability, full backwards method compatibility)

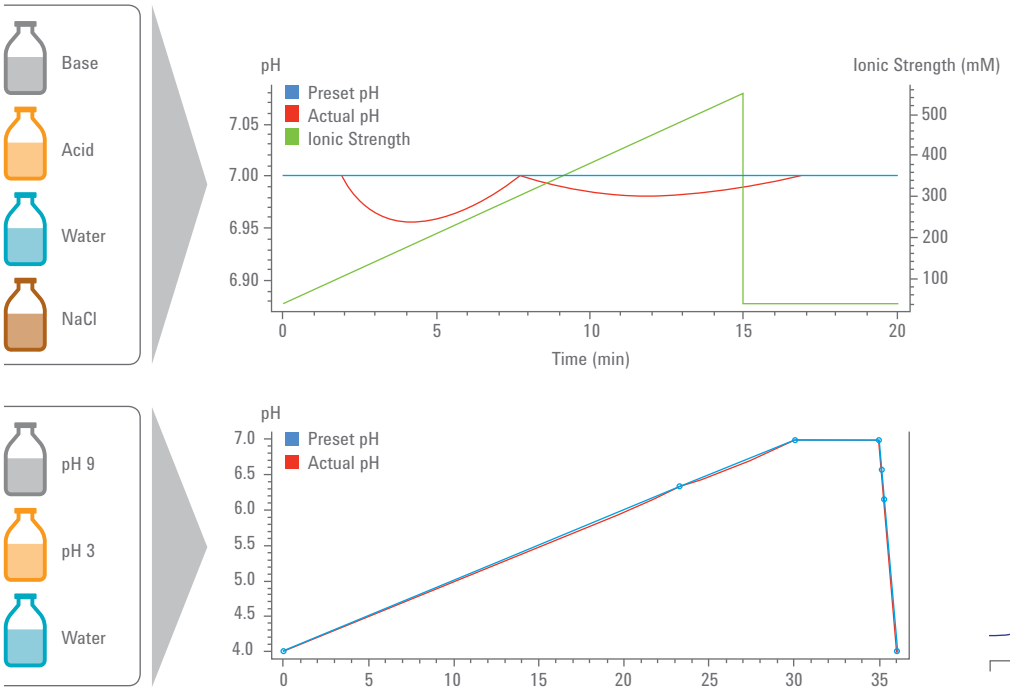
Leverage techniques that improve your characterization without compromise



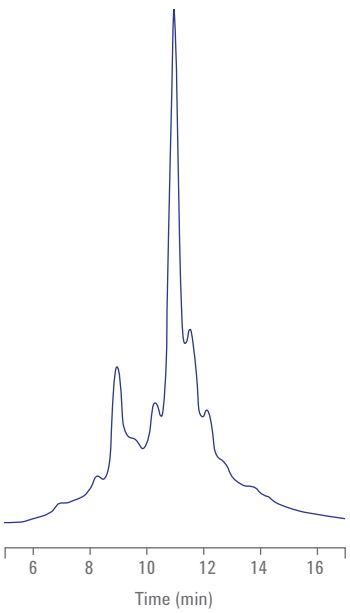
HIC is routinely used to determine the ADC drug-to-antibody ratio. It is a gentle method that retains mAb structure lacking normal disulfide bonds as found in some conjugates. Harsh HIC 2.0 M (NH4)2 SO4 conditions necessitate the use of a fully bio-inert LC system.

Reduce analysis time and increase accuracy with Agilent Buffer Advisor

The example below shows monoclonal antibody charge variant analysis by means of pH gradient ion-exchange chromatography using Agilent Bio-MAb 5 µm, 4.6 x 50 mm column.



Salt and pH gradients are easily created from stock solutions.

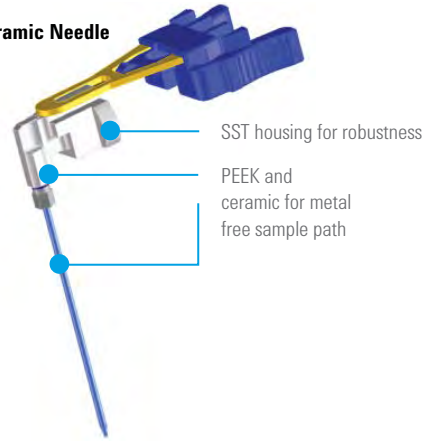


mAb charge heterogeneity analysis by pH gradient using Agilent Buffer Advisor.

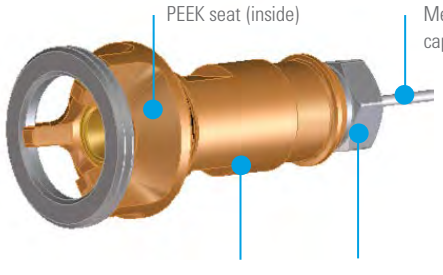
What makes the 1260 Infinity II Bio-Inert LC truly bio-inert?

New capillary and fitting technology for robust and secure operation—day in, day out.

Inert Ceramic Needle



PEEK Needle Seat



SUPERFAST SEPARATIONS

The Agilent 1290 Infinity II LC offers unique advantages for protein separations

If long separation times are keeping you from getting through an extensive list of samples, we have an ultra-high-performance LC for you. With our 1290 Infinity II system, you can achieve exceptional throughput and resolution. Our shorter separation methods will give you an advantage you can't get anywhere else.

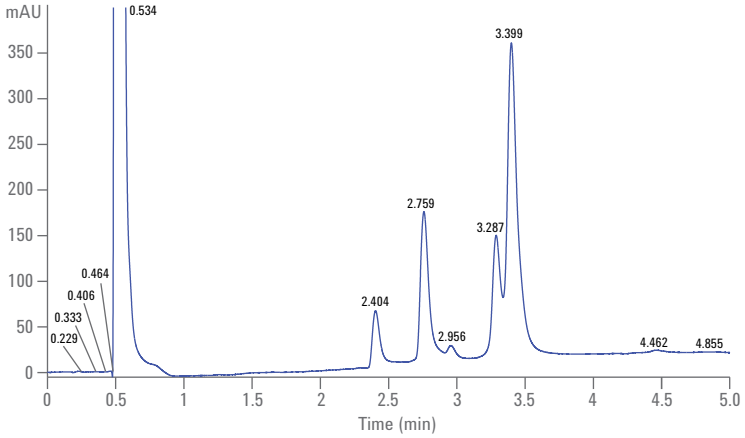
1290 Infinity II LC and 1290 Infinity II Flexible Pump

This system offers performance combined with flexibility. The 1290 Infinity II Flexible Pump is the only low-pressure mixing quaternary UHPLC pump with binary-like accuracy and precision. Other advantages include:

- UHPLC power range with up to 1300 bar and 5 mL/min for super-fast run times
- BlendAssist, the easiest tool for accurate buffer and additive blending—a big time saver!
- UHPLC productivity with HPLC ownership costs

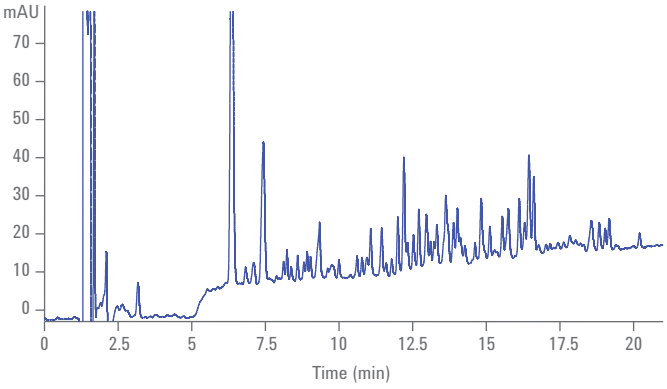
Use for method development or walkup systems with accurate buffer blending

Rapid monoclonal antibody fragment analysis

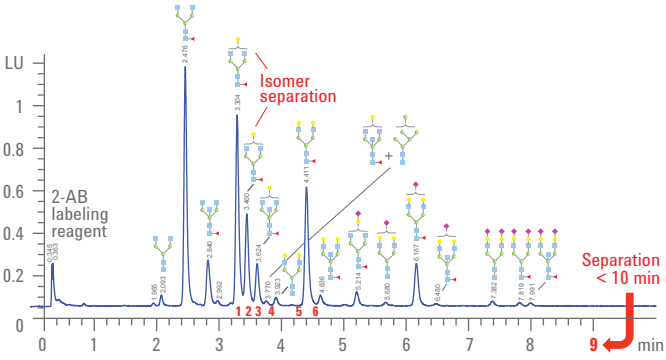


Reversed-phase separation of a reduced monoclonal antibody using Agilent ZORBAX Rapid Resolution High Definition (RRHD) 300SB-C8, 2.1 x 50 mm column on Agilent 1290 Infinity UHPLC. The separation was achieved in under 5 minutes.

Faster, better separations using the Agilent 1200 Infinity Series LC system



Fast and efficient high-resolution peptide mapping for 100% sequence coverage using Agilent AdvanceBio peptide mapping column.



Column	Rs 2,1	Rs 3,2	Rs 4,3	Rs 6,5	avg. PW (min)	Peak capacity
AdvancedBio Glycan Mapping Column, 1.8 µm	1.63	1.70	3.05	2.09	0.059	135

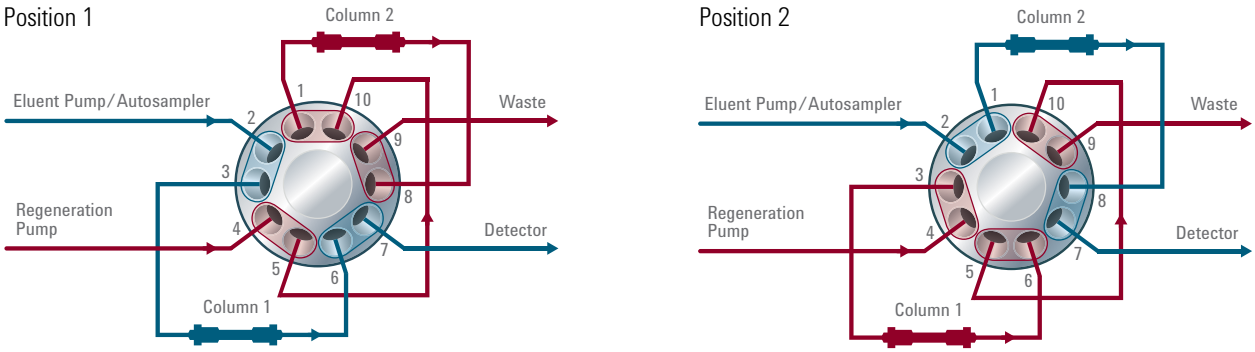
Fast-sub-10-minute separation of N-linked glycans of human IgG using Agilent AdvanceBio glycan mapping column, 1.8 µm on an Agilent 1290 Infinity Quaternary LC system.

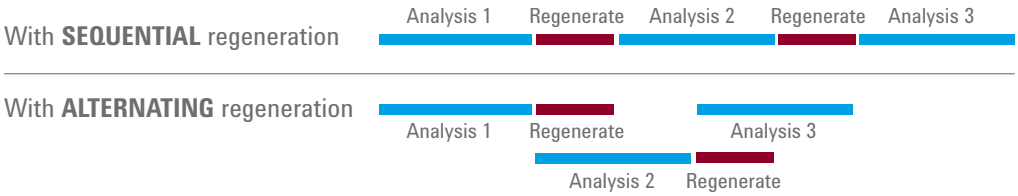
MULTIPLY YOUR ANALYTICAL ABILITIES

Imagine how much more you could do if run times were cut in half

At Agilent, we're fully focused on making your lab more productive. We do it with ultra-high-pressure instruments and with applications that address your most pressing needs: From offline column regeneration (which can shorten run times by as much as 50 percent) to method scouting and application switching.

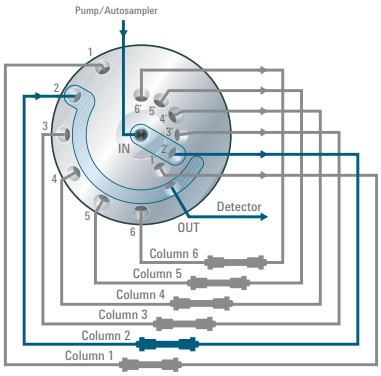
Shorten run times by 20-50% with automated offline column regeneration





Automated method scouting and application switching

The process of using alternate bioseparation techniques (e.g., IEX, SEC, HIC, or RP) can be accelerated significantly using novel valve technology. The same setups can be used for automated application switching for multiple attribute analysis from the same sample plate, saving time and resources.



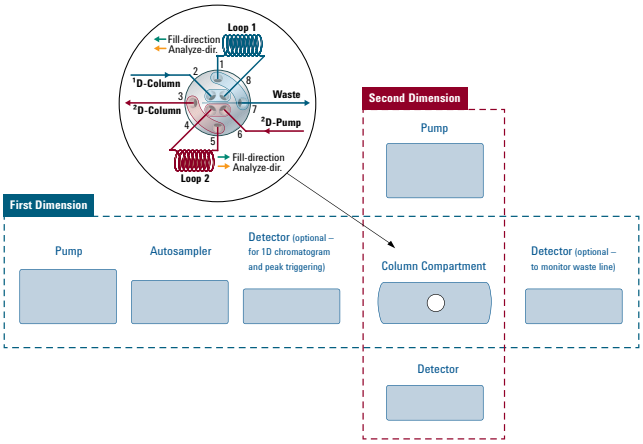
COMPLEXITY SIMPLIFIED

Add a new dimension to your analysis, with unexpected ease

Two-dimensional liquid chromatography is proving to be an effective tool in biopharma, but it is often considered too complex, which has kept many labs from implementing the technology. Agilent's ready-to-go 2D-LC is the first commercial product of its kind on the market—and it provides an intuitive interface that makes it easy to set up.

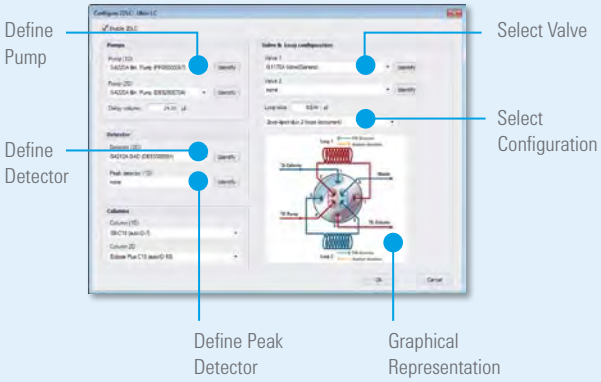
Perform automated online impurity analysis

Agilent's innovative and exceptionally easy to use Agilent 1290 Infinity II 2D-LC solution allows product and impurity analysis from harsh bioseparation methods like IEX, HIC, SEC, and Protein A to be fully automated.

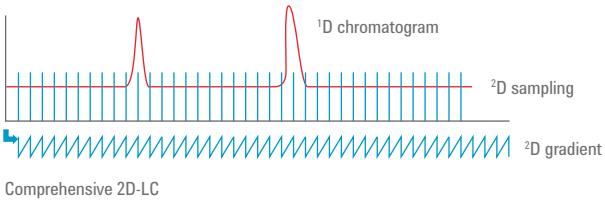


Setup is simple with one screen

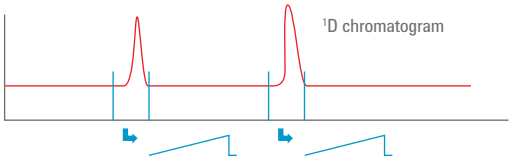
One simplified user screen for the entire system setup makes the Agilent 2D-LC system truly easy to use.



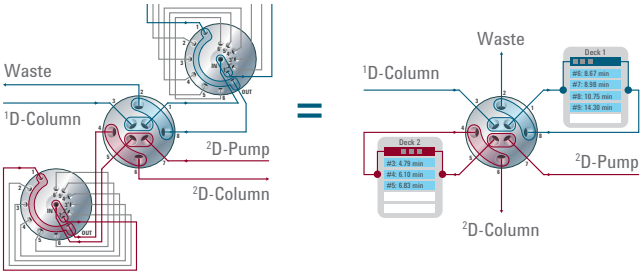
Flexibility with both comprehensive and heart-cutting 2D-LC



Comprehensive 2D-LC



Heart-cutting 2D-LC



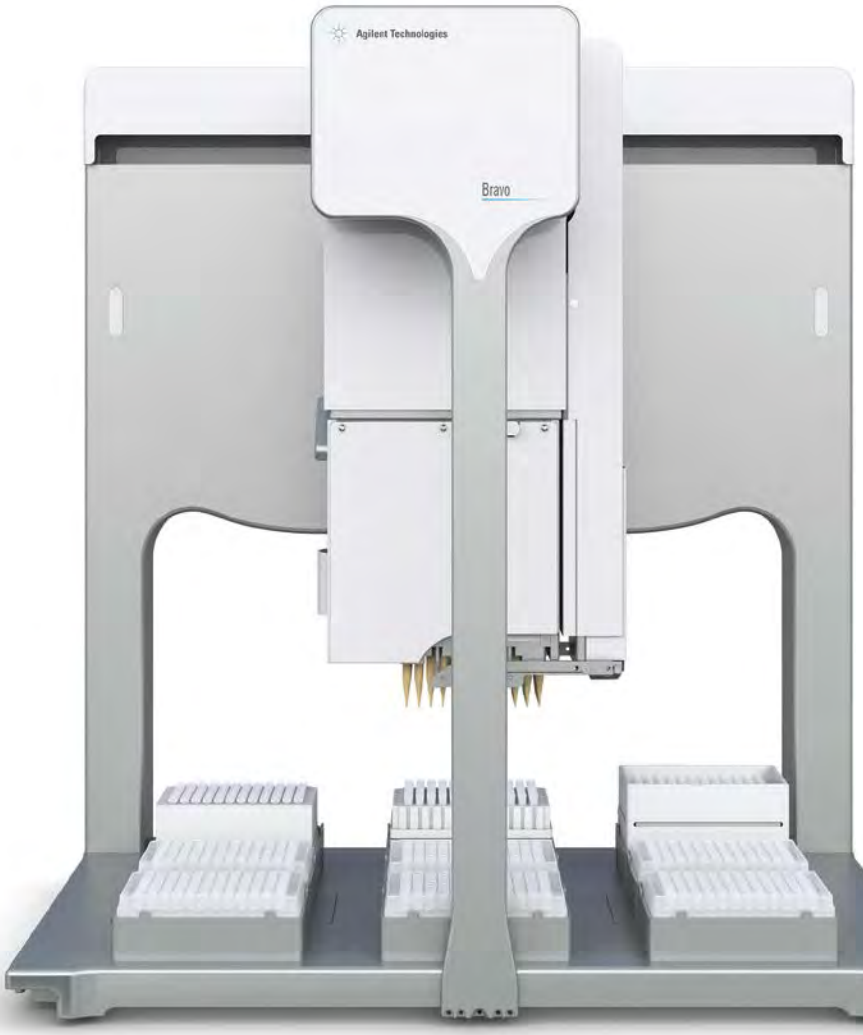
Multiple heart-cutting configuration with novel parking deck cluster (PDC) allows parking of up to twelve peaks for subsequent analysis in the second dimension.

AUTOMATE YOUR SUCCESS

Do it fast and do it right, every time

Biopharma sample prep is highly complex, requiring numerous timed steps—and the reproducibility of the method often depends on the analyst. Unless you automate. Agilent offers state-of-the-art sample prep automation, with kits and simplified interfaces for a far better user experience.

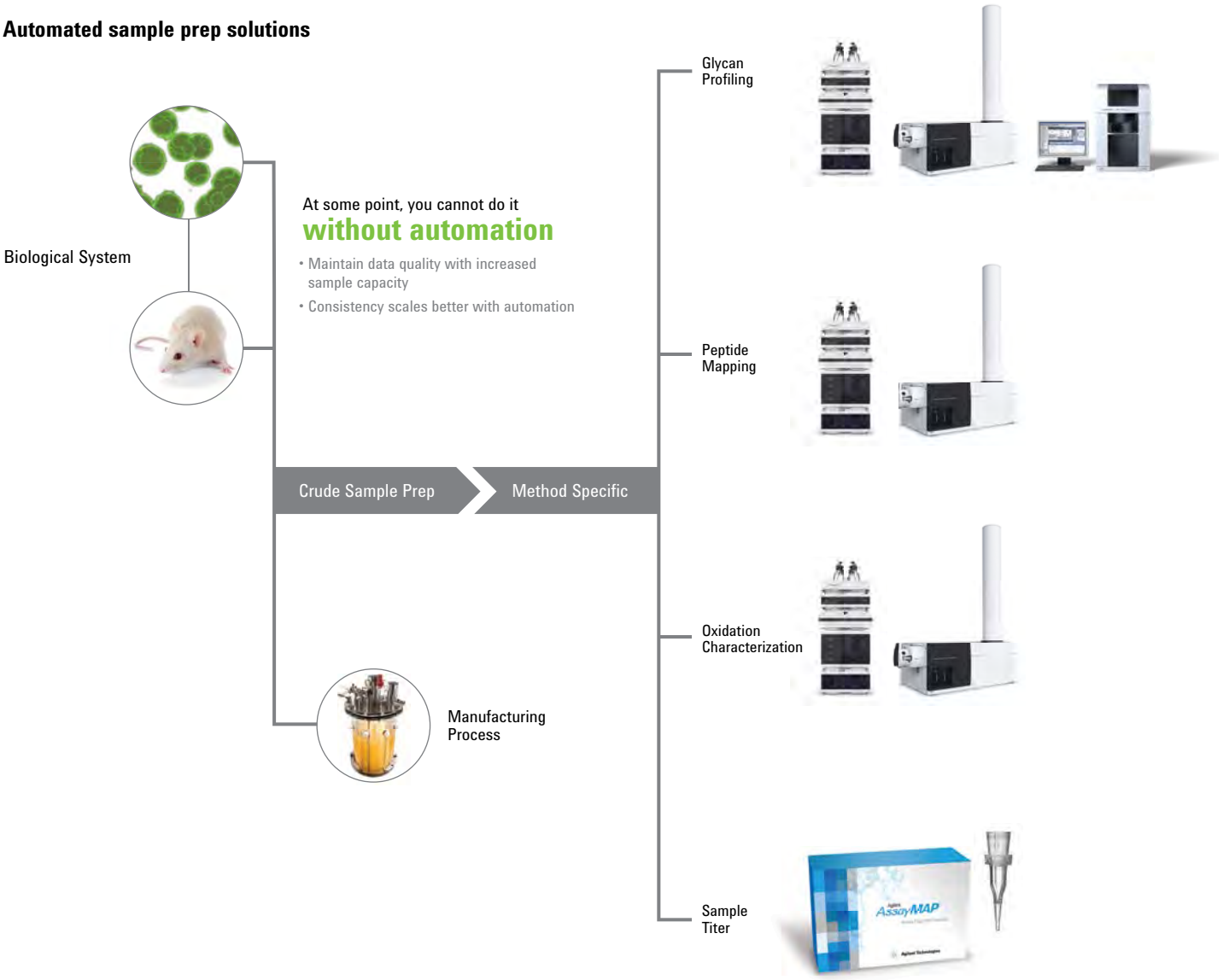
Only Agilent AssayMAP Automated Protein Sample Prep technology successfully integrates multiple labor-intensive operations such as affinity purification, digestion, and desalting into high-precision workflows designed to enhance analysis by mass spectrometry.

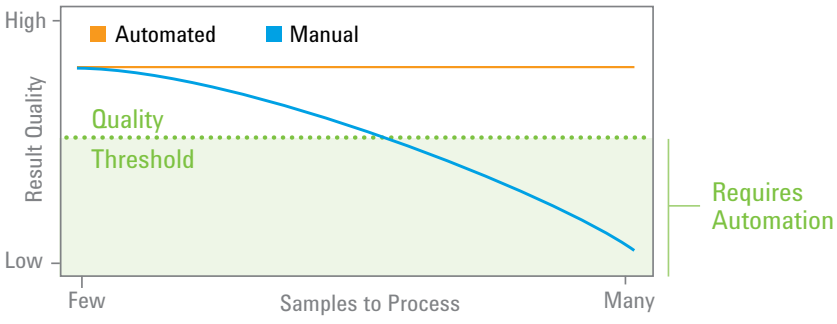


Automate:

- Antibody and peptide enrichment
- Digestion
- Glycan mapping
- Fractionation

Automated sample prep solutions



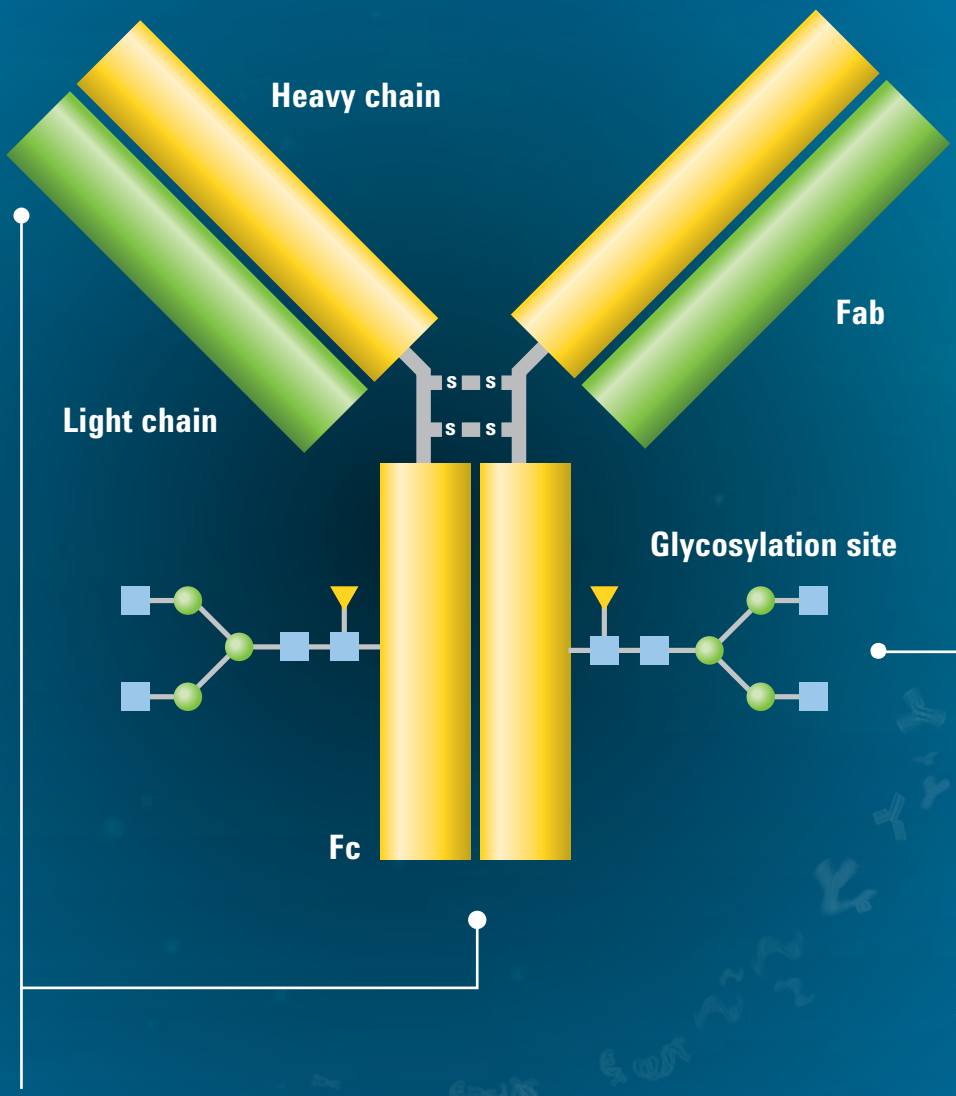


As sample capacity increases, only automation scales to maintain consistency and data quality.

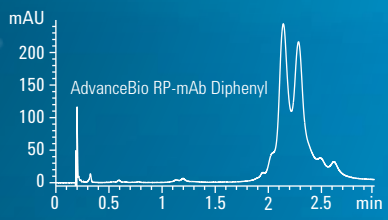
A COMPLETE TOOLSET TO CHARACTERIZE YOUR PROTEIN

Improve productivity for reversed-phase, peptide mapping, size exclusion, ion-exchange, and affinity techniques

Agilent offers the industry's widest range of biocolumns, providing leading-edge technology for every major technique. Agilent AdvanceBio columns are designed to advance accuracy and productivity for biomolecule separations.



IgG2 Lambda Intact



AdvanceBio RP-mAb diphenyl provides an optimal level of detail for this IgG2 separation.

Intact protein analysis: heavy chains, light chains, Fc region and absolute mass

New AdvanceBio RP-mAb features a 450Å pore size and Poroshell technology to deliver high resolution, high efficiency mAb characterization. Agilent has the largest selection of reversed-phase biocolumns available.

MAb titers from cell culture broth

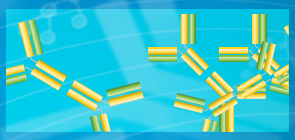
BioMonolith Protein A column, an AdvanceBio column

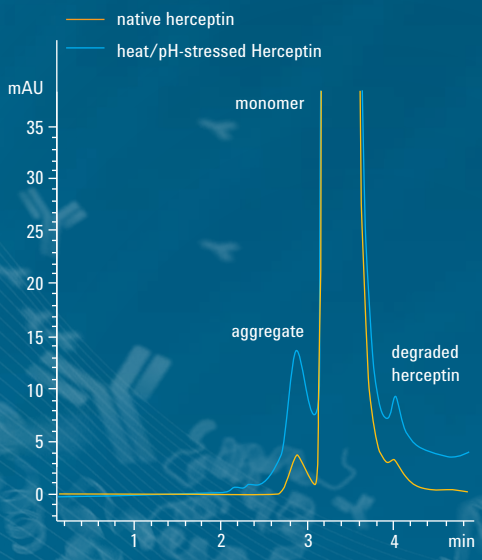
- Captures mAbs fast
- Long column life: minimal clogging

Dimers and higher aggregates

Size exclusion chromatography, using Agilent AdvanceBio SEC

- Reliable performance: hydrophilic layer assures minimal secondary interactions



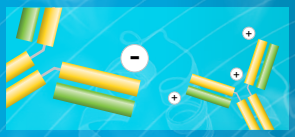


Chromatogram of native (control; red trace) innovator mAb, herceptin and ADC overlaid with heat/pH stressed (blue trace) using an Agilent AdvanceBio SEC 300Å, 4.6 × 150mm, 2.7 µm column.

Charge variant analysis

Ion-exchange chromatography, using Agilent Bio MAb and Agilent Bio SCX

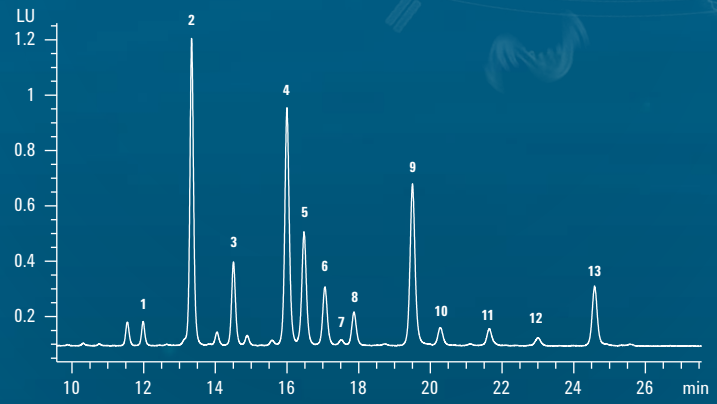
- Hydrophilic coating eliminates most nonspecific interactions



Glycosylation

AdvanceBio glycan mapping columns

- Fast, high resolution, reproducible glycan mapping
- Available in two UHPLC configurations: 2.7 µm superficially porous for high resolution, lower backpressure and 1.8 µm for highest resolutions
- Each media lot is tested with a glycan reference mix to ensure performance

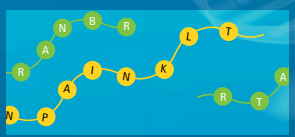


2.7 µm AdvanceBio glycan mapping column enables fast, high resolution glycan mapping with lower backpressure.

Peptide mapping

AdvanceBio peptide mapping columns

- Fast, high resolution, reproducible peptide mapping
- Each media lot is tested with a challenging peptide mix to ensure performance



END-TO-END SOLUTIONS

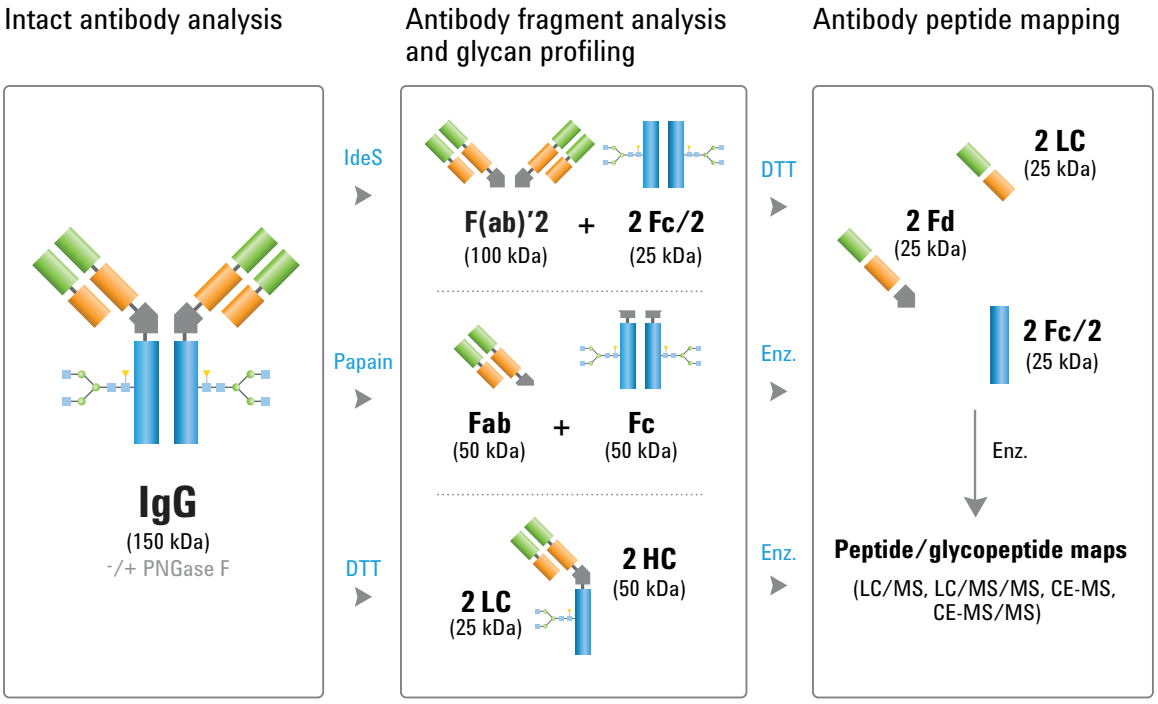
From preparing samples to analyzing results, Agilent has you covered

Confirmation of intact protein mass, major glycoforms, and other post-translational modifications (PTMs) are all critical measurements for characterizing proteins and understanding their efficacy and stability. Mass spectrometry is the primary tool that enables all of these measurements on a single platform with high mass accuracy, analytical specificity and sensitivity.

Agilent offers highly accurate solutions developed for routine measurements of intact protein mass and common PTMs using accurate-mass time-of-flight LC/MS and accurate-mass quadrupole time-of-flight LC/MS platforms.

MS strategies for the characterization of antibodies

Top-down, middle-down and -up, bottom-up.

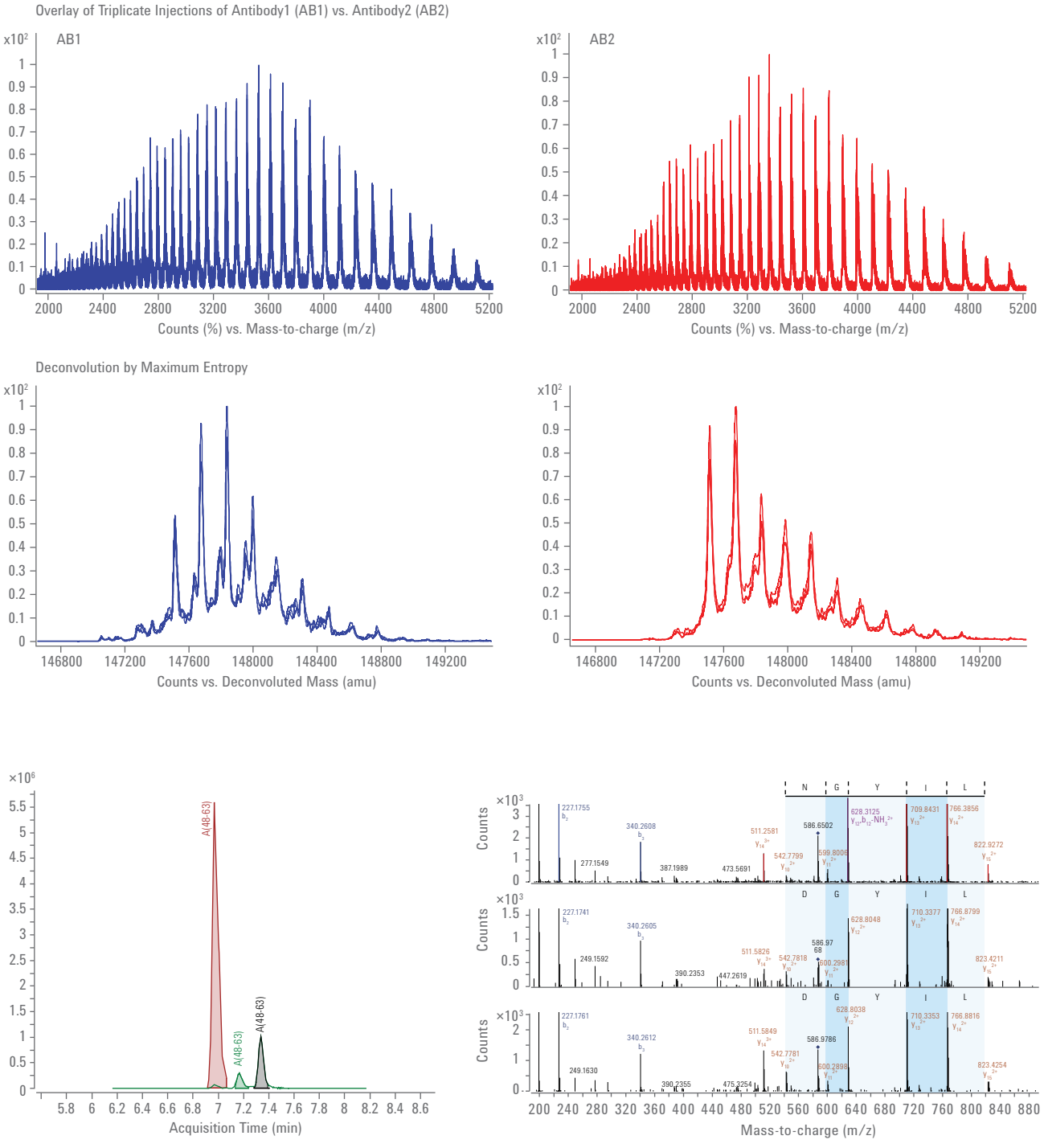


Agilent can deliver the highest analytical sensitivity available using 2.1 mm ID columns (replacing capillary LC) with no loss of sensitivity!

IgG are characterized as whole antibodies, fragments (including light chains, heavy chains, glycans, Fc regions) and by peptide/glycopeptide mapping (LC/MS and LC/MS/MS)

ACCURATE MASS YOU CAN COUNT ON

Agilent's mass accuracy is exceptional, as demonstrated by the consistency in these triplicate-run spectra.

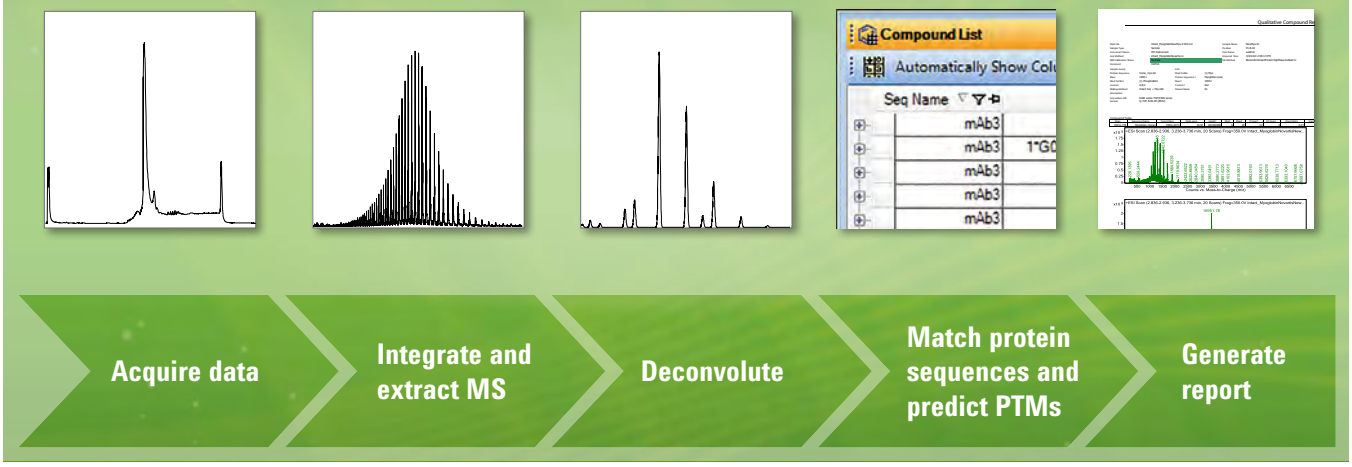


Deamidation is an important post-translational modification to monitor in peptide mapping. Deamidation can occur during storage, purification, and sample manipulation. Deamidation can be identified by an LC/MS/MS peptide mapping experiment.

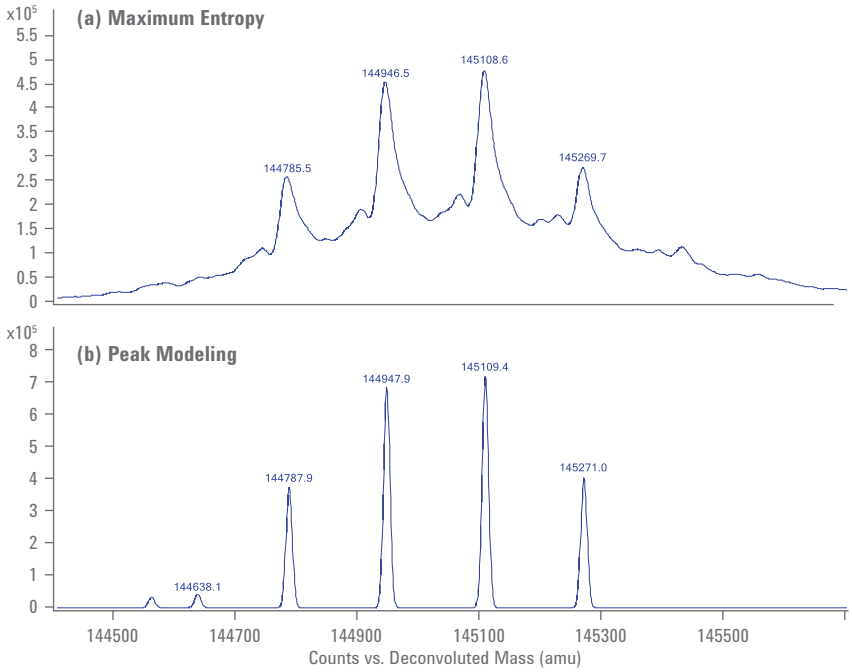
ENVISION PRECISE PROTEIN CONFIRMATION

BioConfirm provides both classical maximum entropy deconvolution and enhanced peak modeling (pMod) deconvolution to determine the molecular weight of intact proteins. ADC DAR calculator automatically calculates drug-to-antibody ratio and streamlines the data analysis process.

Intact Protein Workflow



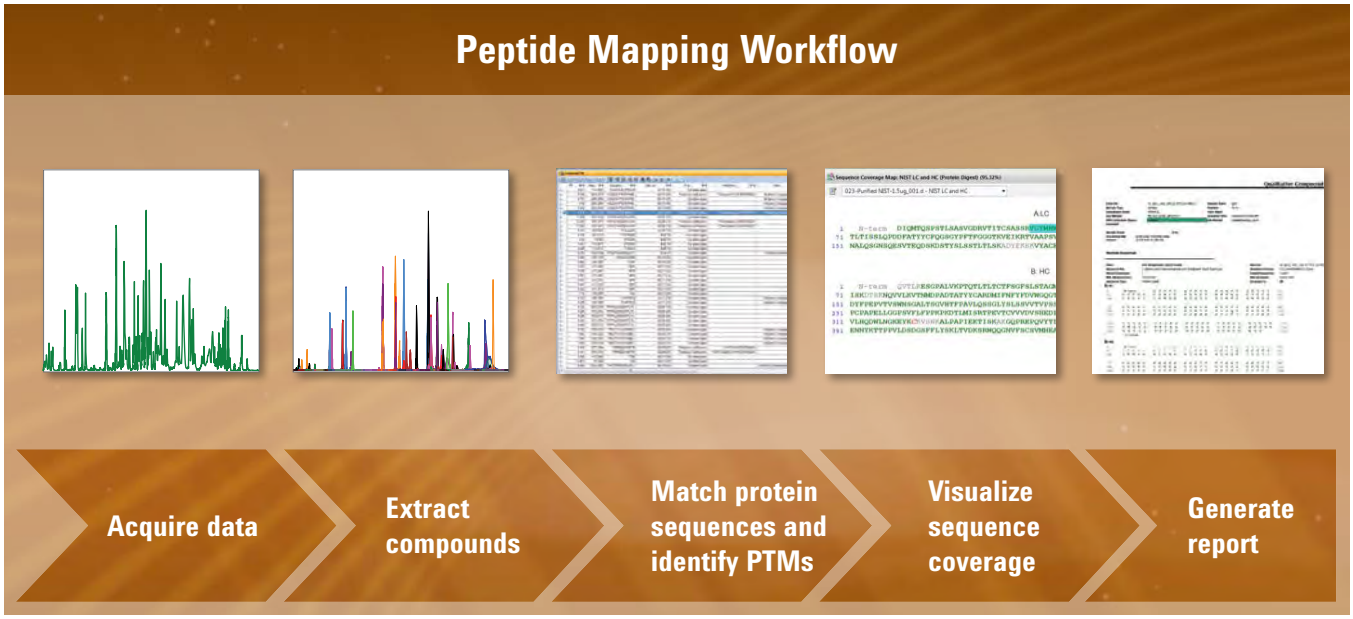
Maximum entropy deconvolution provides rapid transformation of multiple charged mass spec data into accurate protein mass. The peak modeling (pMod) algorithm employs additional steps to reduce artifacts and enhance resolution, which helps to resolve overlapping peaks and provide cleaner data, so you can be more confident in your answer.



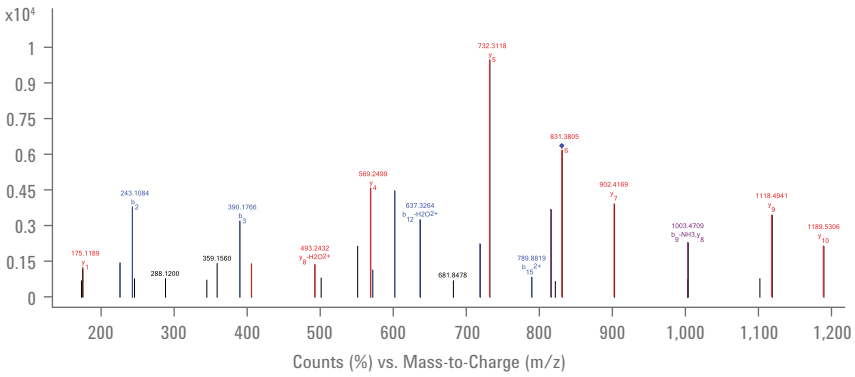
Deconvoluted spectra via maximum entropy and pMod algorithms.

ENVISION POWERFUL PEPTIDE MAPPING CAPABILITIES

BioConfirm provides enhanced processing of MS/MS data for streamlined mapping and data interpretation.



BioConfirm identifies peptides and PTMs based on peptide masses and product ions (b, y, and immonium ions) in the MS/MS spectra. This allows for faster and more streamlined processing of MS/MS data for peptide mapping.



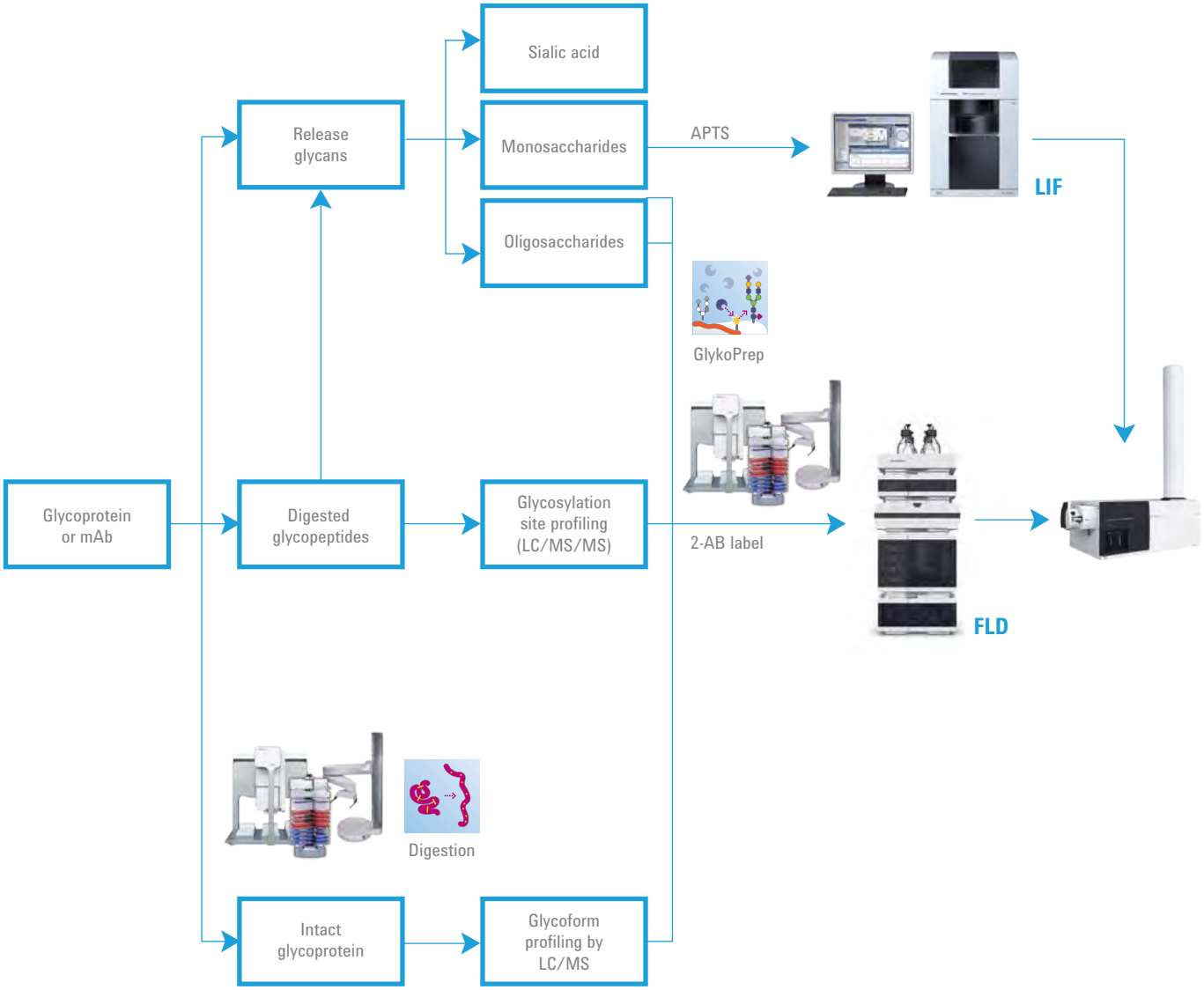
Peptide MS/MS spectrum product ion assignment.

WE PUT THE *CAN* IN GLY*CAN* CHARACTERIZATION

Take your pick of fast, fully automated analysis strategies

Glycan analysis is so complex it can be difficult to determine which analytical strategy will work best. Rest assured that Agilent has proven solutions to address every facet of your glycan analysis.

Strategies for intact glycoform profiling, glycopeptide and glycosylation site identification, and release glycan analysis

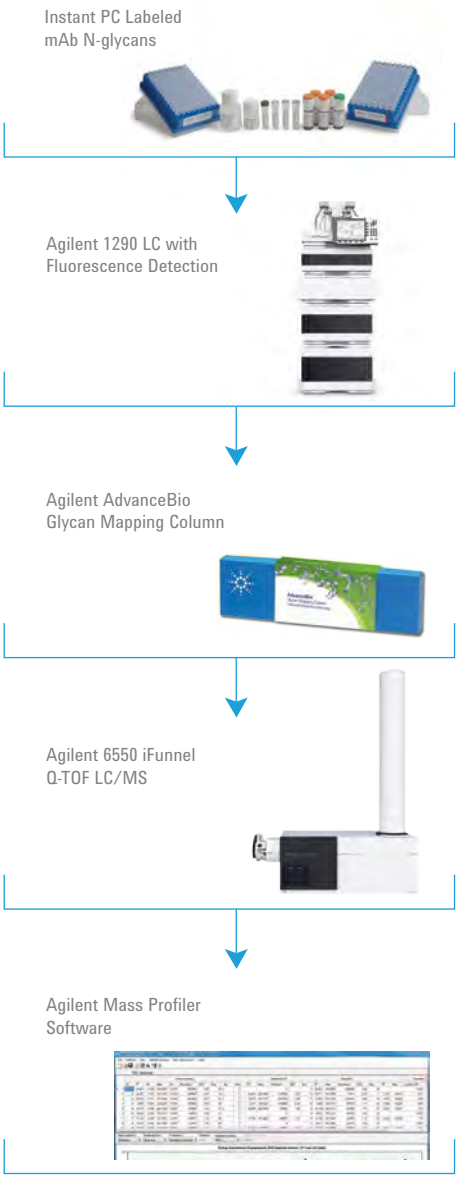


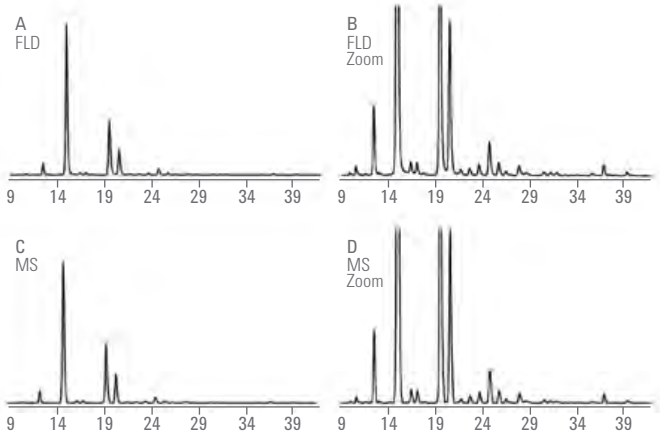
Released glycans with no labeling are also run with MS.

GETTING GLYCAN IDENTIFICATION AND QUANTITATION AT THE SAME TIME

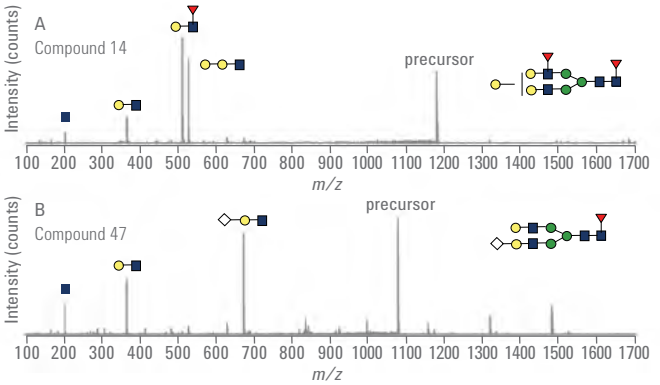
Agilent LC/FLD system offers accurate quantitation for glycan profiles, while LC/MS system provides the researcher with the capability to perform both identification and MS-based quantification of glycans. High quality Q-TOF MS data greatly facilitate peak assignment by offering accurate mass and tandem mass information for each of the glycans detected using FLD.

N-glycan identification and quantitation workflow





Comparison of FLD and MS chromatograms for mAb 1. A) FLD chromatogram of mAb 1 glycans. B) Zoom of FLD chromatogram of mAb 1 glycans. C) MS chromatogram of mAb 1 glycans. D) Zoom of MS chromatogram of mAb 1 glycans.



Tandem MS data were acquired for all glycans. MS/MS aided in compound identifi cation when accurate mass was insuffi cient. The two examples above are consistent with gal-gal and outer arm fucose (A) and NeuGC (B) modifi cations.

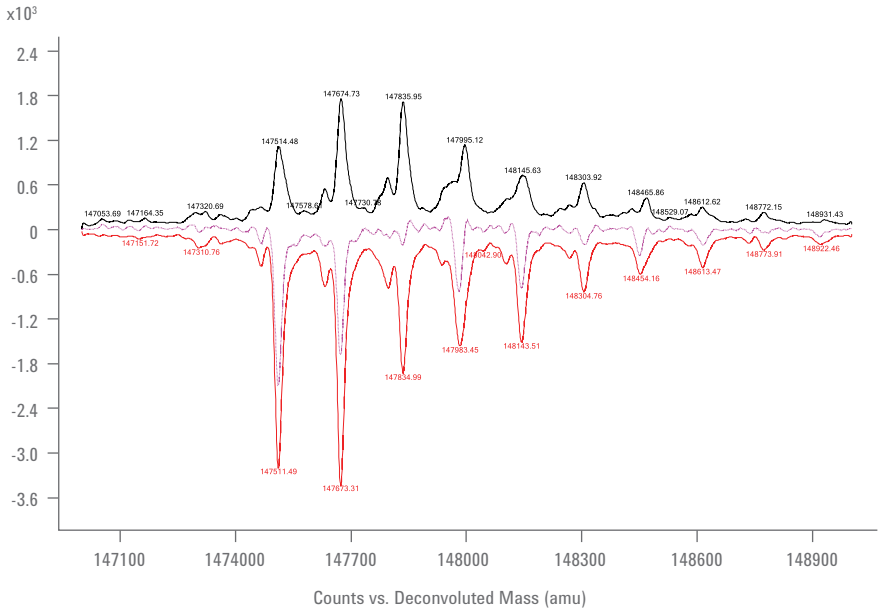
ENVISION EASY BATCH-TO-BATCH COMPARISON

MassHunter BioConfirm provides easy visual comparisons among samples, allowing for fast batch-to-batch analysis on both protein and peptide levels.

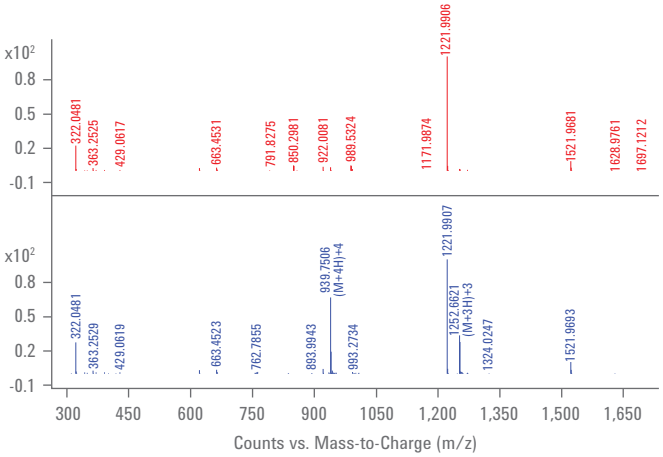
Mirror plot functionality enables rapid and reliable comparison of two samples, such as two batches of an engineered protein or biosimilars. Samples in the mirror plot can be switched quickly without reprocessing the data.

Monitor biosimilars and batch-to-batch variation by quickly comparing samples and reference

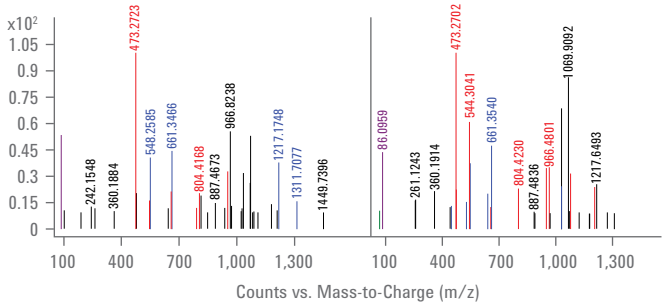
The comparative analysis module facilitates the identification and visualization of the differences between two batches of data for easy inspection. Samples can be compared to a reference using chromatograms, MS, and MS/MS spectra.



Mirror plot of two engineered proteins.



MS spectrum comparison results.



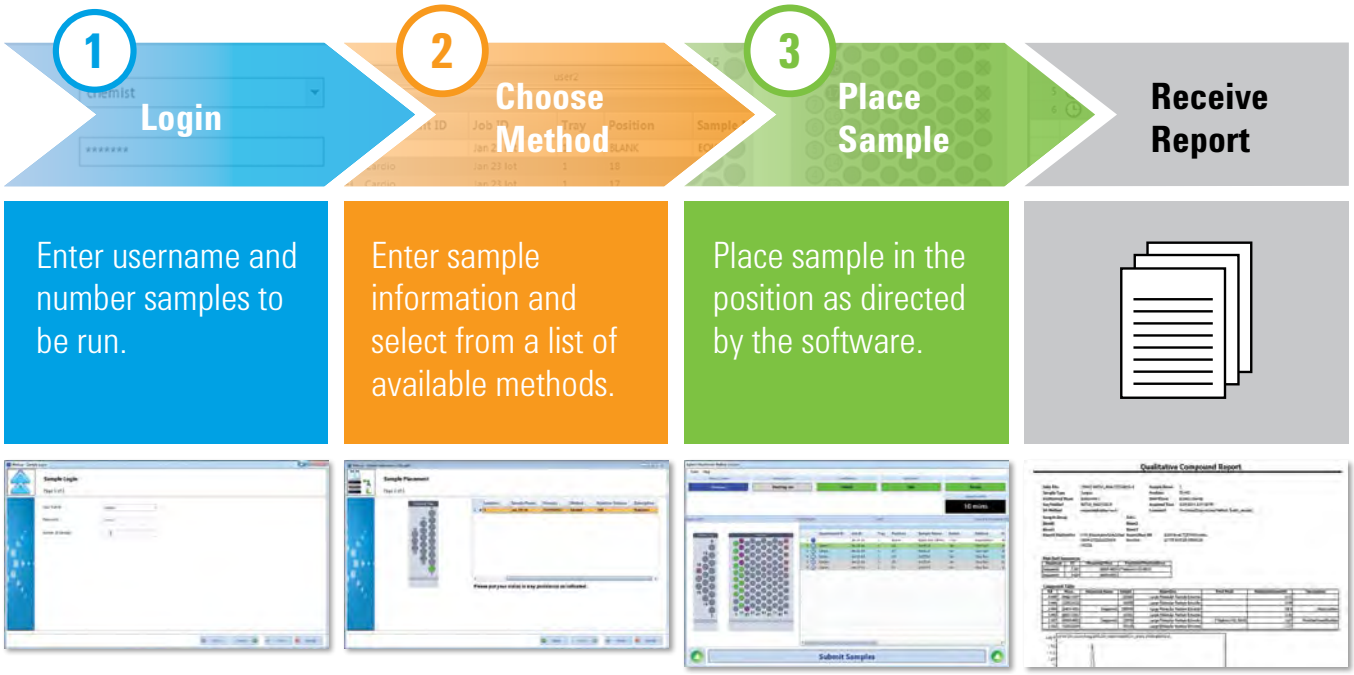
MS/MS spectrum comparison results.

WALKUP ACCESS FOR ALL

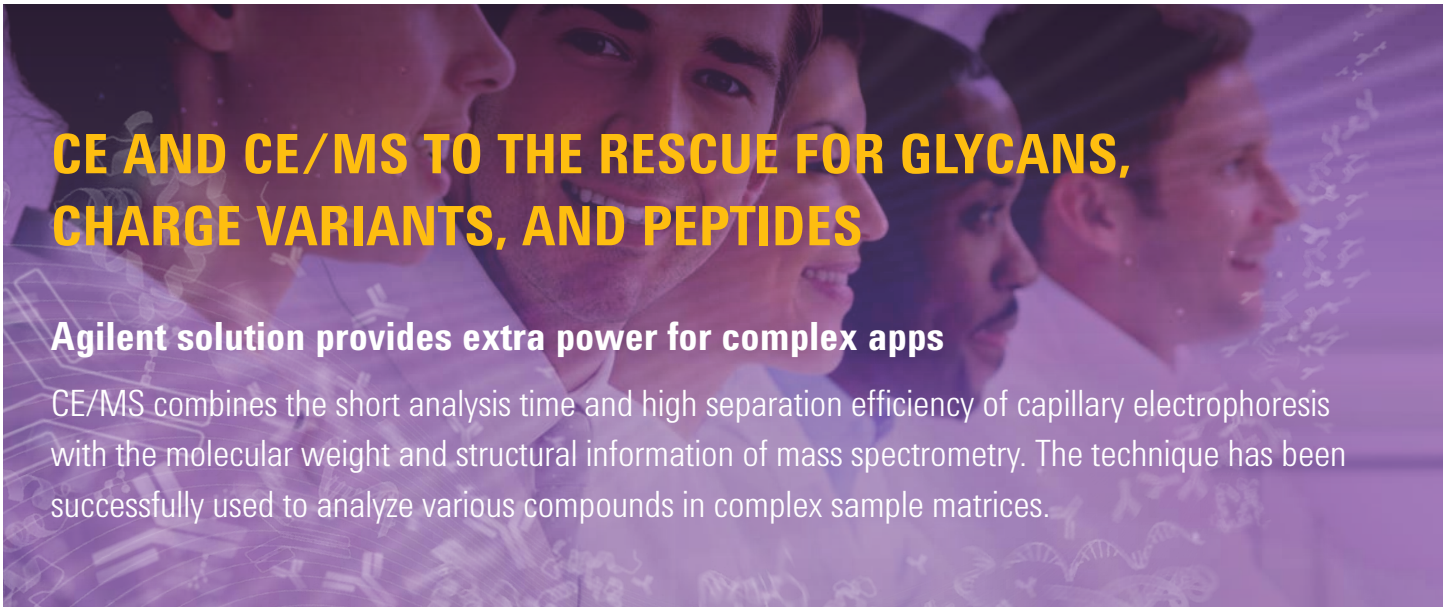
Let each of your biologists unleash the power of LC/MS characterization

The value of any resource is directly tied to the ease with which people can access and benefit from it. That's why we created Agilent MassHunter Walkup software: So more people can access your lab's LC/MS instrument, with ease. Now even untrained users can benefit, without assistance from your busy staff. This user-friendly software allows people of different skill levels to perform their own automated LC and LC/MS analyses. All they have to do is input some basic information, choose a method, and insert samples as directed. Results show up in the submitter's in-box automatically.

Simplified MassHunter Walkup user interface. Three steps to results.



Support virtually any analysis that can be automated.



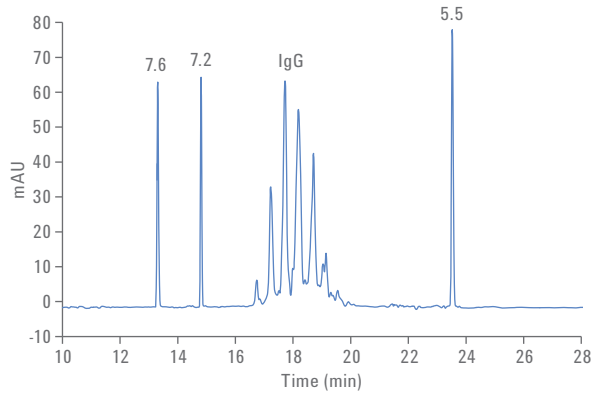
CE AND CE/MS TO THE RESCUE FOR GLYCANS, CHARGE VARIANTS, AND PEPTIDES

Agilent solution provides extra power for complex apps

CE/MS combines the short analysis time and high separation efficiency of capillary electrophoresis with the molecular weight and structural information of mass spectrometry. The technique has been successfully used to analyze various compounds in complex sample matrices.

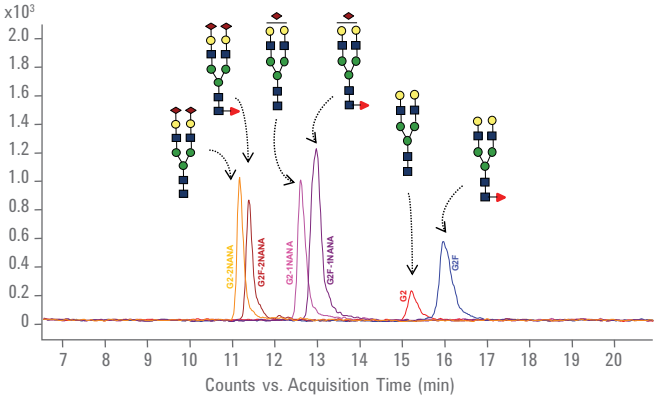
Examples of applications of capillary and microfluidic electrophoresis

Charge heterogeneity analysis by cIEF



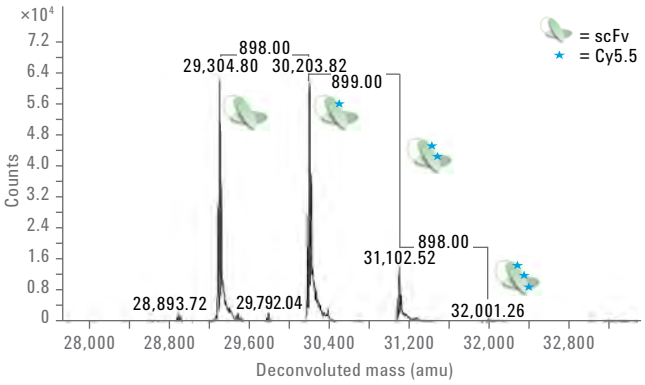
Truly pi-based, high resolution monoclonal antibody charge heterogeneity analysis by capillary isoelectric focusing

Glycan analysis by CZE-MS Q-TOF



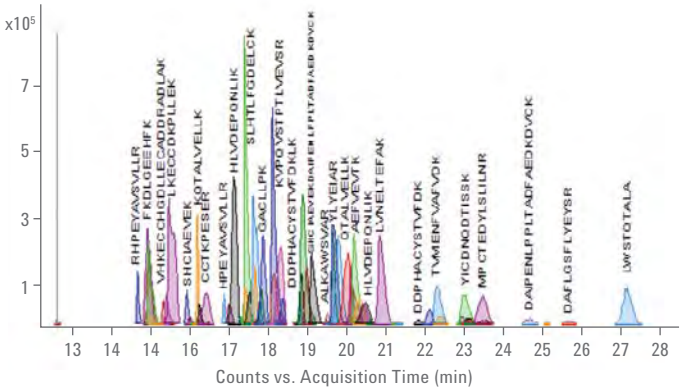
Mixture of neutral glycan and sialylated glycan separation based on mass-to-charge ratio using the Agilent 7100 CE system.

Antibody drug conjugate analysis by CE/MS



Deconvoluted mass spectrum of scFv-A conjugate. The assigned structures are based on deconvoluted mass.

Peptide mapping analysis



Peptide mapping by CE/MS routinely provides 100 percent sequence coverage and is regularly employed as an orthogonal method of LC/MS peptide mapping.

The technology behind Agilent CE/MS

Sample

Complex mixtures of charged molecules, ranging from inorganic ions to native proteins. CE offers the smallest injection volumes (nL range) with little sample preparation.

CE capillary

Separation based on mobility in an electrical field takes place in 50-100 cm (usually fused silica) capillaries filled with aqueous buffers.

Agilent iFunnel MS

Combines Agilent Jet Stream (precision sprayer to desolvate and concentrate ions), hexabore capillary (array of capillaries for sampling more ions) and dual-stage ion funnel (to efficiently remove gas while focusing ions).

TOF-MS analysis

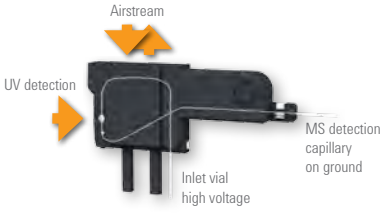
Flight tube with vacuum-insulated shell eliminates thermal mass drift due to temperature changes, for excellent mass accuracy. Reflectron and long flight tube improve mass resolution.

Agilent 7100 CE System

Agilent 6550 *Accurate-Mass Q-TOF*

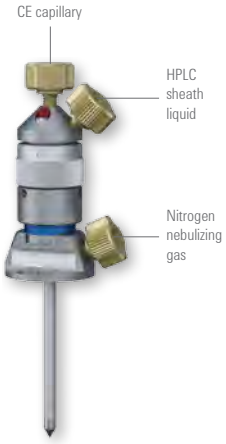
CE/MS cassette

First part of the CE/MS interface; houses separation capillary and controls temperature, providing a UV-detection window and an exit to external detectors.



CE-ESI/MS-sprayer

Triple-tube interface combines CE capillary with sheath liquid for stable flow rates and electrical contact, and isolates separation chemistry from MS ionization. Nebulization gas facilitates ESI.



Data analysis

Integrated software packages control the CE/MS system and interpret and filter the massive amount of data created during analysis.

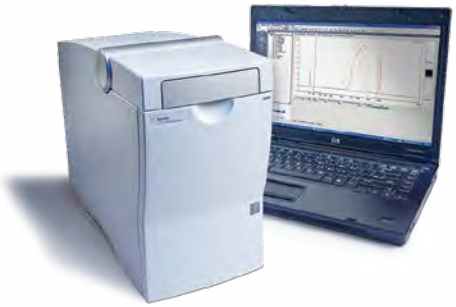
AUTOMATED ELECTROPHORESIS

Quality control of samples has never been so easy

The Agilent 2100 Bioanalyzer system with Protein 80, Protein 230, and High Sensitivity Protein 250 kits offers an easy to use, benchtop platform to reliably assess protein concentration, identity, and purity. The DNA ScreenTape assays with the Agilent 4200 TapeStation and Agilent 2200 TapeStation system were developed for the separation and analysis of DNA fragments and libraries up to 5000 base pairs. The Agilent RNA ScreenTape assay provides efficient and reliable analysis of total RNA samples from eukaryotic or prokaryotic origin, providing quality, quantity, and sizing information. DNA or RNA samples are automatically loaded, separated, imaged, and analyzed at the press of a button.

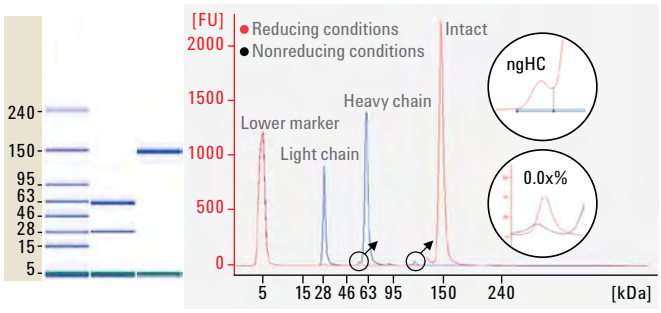
Applications

- Antibody QA/QC
- Protein purification analysis
- Protein expression analysis

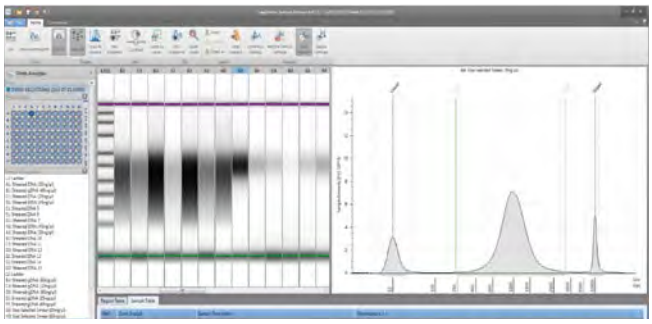


Agilent 2100 Bioanalyzer system

Agilent 4200 Tapestation system



The High Sensitivity Protein 250 kit on the 2100 Bioanalyzer system provides antibody analysis at the highest sensitivity, equivalent or better than SDS-PAGE silver stains. The dynamic range facilitates impurity detection down to the pg/uL range. Reduced (blue) and nonreduced (red) conditions can be analyzed in parallel on the same chip.

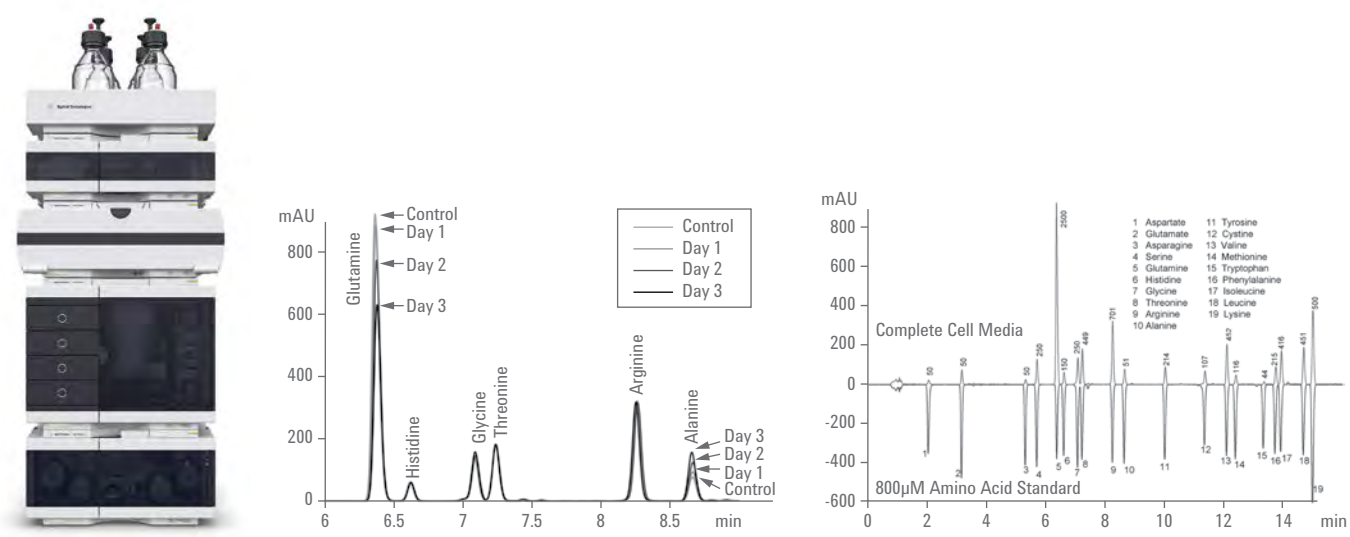


Results can be viewed in familiar gel view or Electropherogram view.

A FULL RANGE OF SOLUTIONS

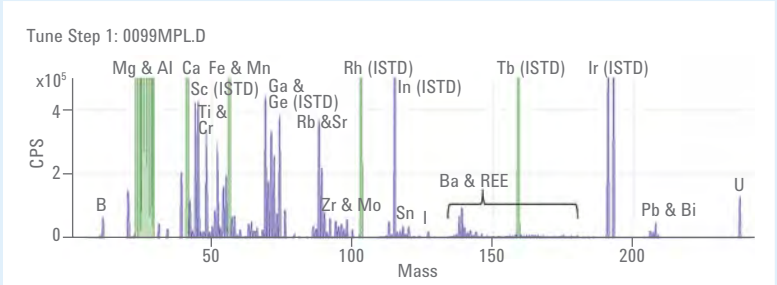
We have what you need for raw material, media, amino acid, and leachable and extractable analysis via UHPLC, GC, and ICP-MS

It's absolutely vital that you monitor various parameters in your fermentation broth—amino acids, sugars, organic acids—and use robust, well-established methods for analysis. You must be sure your final product is free of any leachable from any source. Metal contaminants from stainless steel fermenters, for example. Agilent has a comprehensive set of solutions that include GC, ICP-MS, and UHPLC instruments and software.



Agilent 1200 Infinity II UHPLC Series provides the power range and performance you require for amino acid analysis. Agilent ZORBAX Amino Acid Analysis (AAA) columns provide high resolution separations for amino acids.

The Agilent 7700x ICP-MS is well-suited for analyzing digested samples and analysis of elemental impurities according to USP <232>/<233>.



This full mass can of a commercial antacid sample illustrates the screening capability of the Agilent 7700x ICP-MS in helium mode.

По вопросам продаж и поддержки обращайтесь:

Алматы (7273)495-231
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89
Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Липецк (4742)52-20-81
Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Пермь (342)205-81-47
Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Тверь (4822)63-31-35
Томск (3822)98-41-53
Тула (4872)74-02-29
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Ярославль (4852)69-52-93

Россия (495)268-04-70
Киргизия (996)312-96-26-47
Казахстан (7172)727-132

afr@nt-rt.ru || https://agilent.nt-rt.ru/