

Answers, Simple and Streamlined

Solutions for Biotherapeutic Intact Mass Analysis



Answers for Science.
Knowledge for Life.™



Better Information for Better Biologics Decisions

Accelerate your standard intact biotherapeutic protein workflows with SCIEX X500B QTOF System, designed specifically for biologics. The ultra-compact and user friendly X500B system will speed your standard characterization workflows, while powerful BioPharmaView™ Software simplifies data processing to get you answers faster, so you can make better decisions about your biologic development.



Expert Functionality for Mass Spec Non-Experts

SCIEX OS on the X500B QTOF system dramatically improves the user experience, with a point-and-click interface that simplifies setup and operation, even for non-experts in LC-MS. High-performance methods for standard biotherapeutic analysis are just clicks away. The new Explorer view makes data review rapid and intuitive, and file format compatibility with BioPharmaView 2.0 software means fast, automated data processing and analysis are within reach for every operator.



No-worry sample queue:

Automated intact protein calibration seamlessly integrates mass calibration into your sample queue for rock-solid, accurate performance

Simple method building:

Build and optimize a high performance intact protein method with the easy-to-learn SCIEX OS user interface

Explore your data:

Quick look data visualization and review in real time using the Explorer window

Comprehensive Analysis:

Connect to BioPharmaView software for comprehensive data processing and analysis

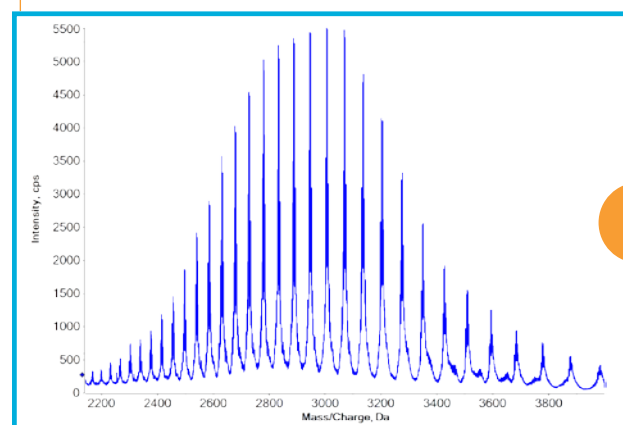
SCIEX OS user interface for method setup, batch submission, queue monitoring, including new tuning and service diagnostic tools

Mass Accuracy and Robustness You can Trust

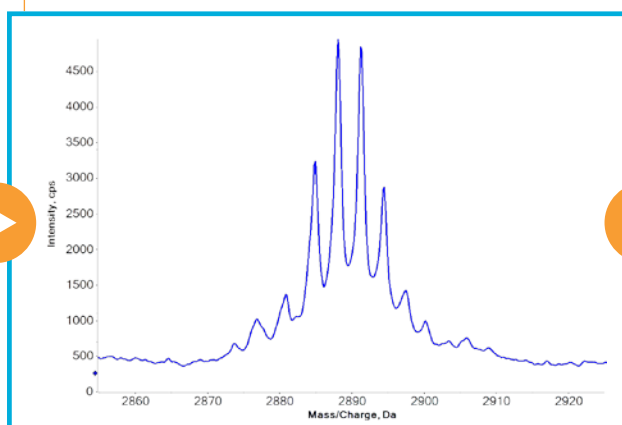
The key to high-quality results is high-quality data. You can be confident in the X500B QTOF system with the ability to see both major and minor isoforms of your intact biologic product with accurate mass assignments. Moreover, the combination of the industry-leading SCIEX Turbo V™ ion source and the heated TOF path in the X500B system result in maximized stability and robustness over time.

Identify major biotherapeutic isoforms and glycosylation distribution with efficient ionization from the Turbo V ion source. High mass accuracy ensures correct protein mass assignment.

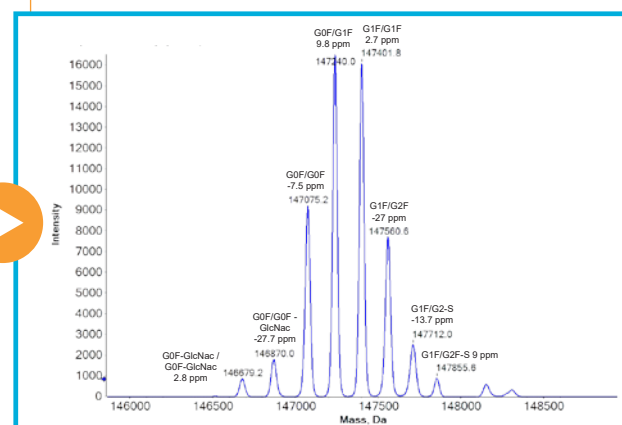
Intact rituximab analyzed on the X500B QTOF system, displaying high-quality Gaussian charge state distribution.



Individual, glycosylated isoforms can be viewed when the data is expanded for a single charge state series.

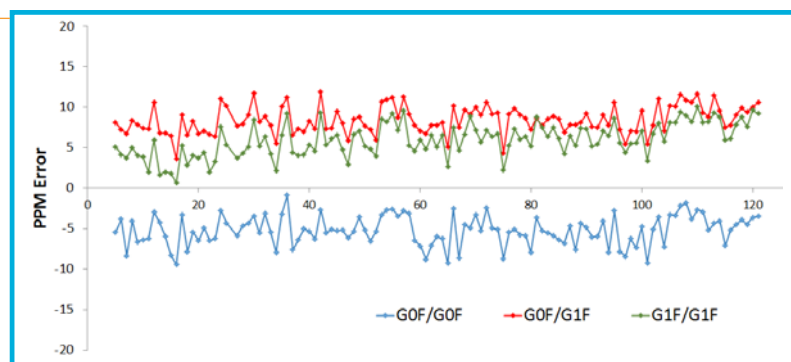


High mass accuracy of detected isoforms following protein deconvolution in BioPharmaView software



Excellent robustness for maximized stability over time: high quality mass accuracy that doesn't let you down.

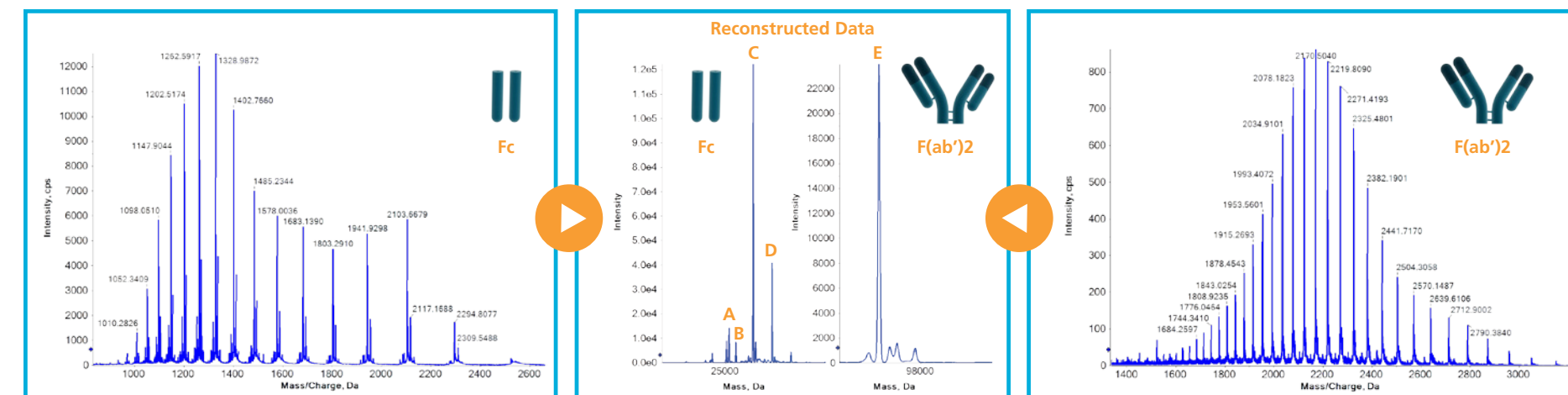
Deconvoluted intact mass analysis of rituximab monoclonal antibody (mAb) with 120 injections over the course of 24 hours resulted in mass error average <5.9 ppm for the three main glycoforms.



Pinpoint Your Glycans and PTMs

Glycan structures can be difficult to differentiate when performing intact mass analysis. The X500B QTOF system simplifies the characterization of glycans with subunit analysis: the result is more confident determination of glycosylation, including analysis of glycan clipping. Detect glycans, post translational modifications (PTMs), or C-terminal clipping quickly and easily.

Dig deeper and analyze glycosylation forms and PTMs with high-resolution subunit analysis



Product Form	Observed Mass	Reconstruction area	PPM error
(A) Fc- GOF less GlcNac, lysine loss	25028.4	99960	-13.7
(B) Fc- G0, lysine loss	25085.7	57082	-4.4
(C) Fc- GOF, lysine loss	25232.0	815710	-1.0
(D) Fc- G1F, lysine loss	25394.0	278735	-3.6
(E) F(ab')2	97627.5	162150	-6.0

Analysis of individual subunits of trastuzumab following IdeS protease digestion on the X500B QTOF system. Detection of F(ab')2 region (right graph) and Fc region (left graph) offers proper resolution to detect PTM presence such as glycosylation and terminal lysine loss. Deconvolution (center graph) with BioPharmaView software provides data with high mass accuracy (table) to ensure confidence of modified isoforms.

Visualize Your Path to Answers

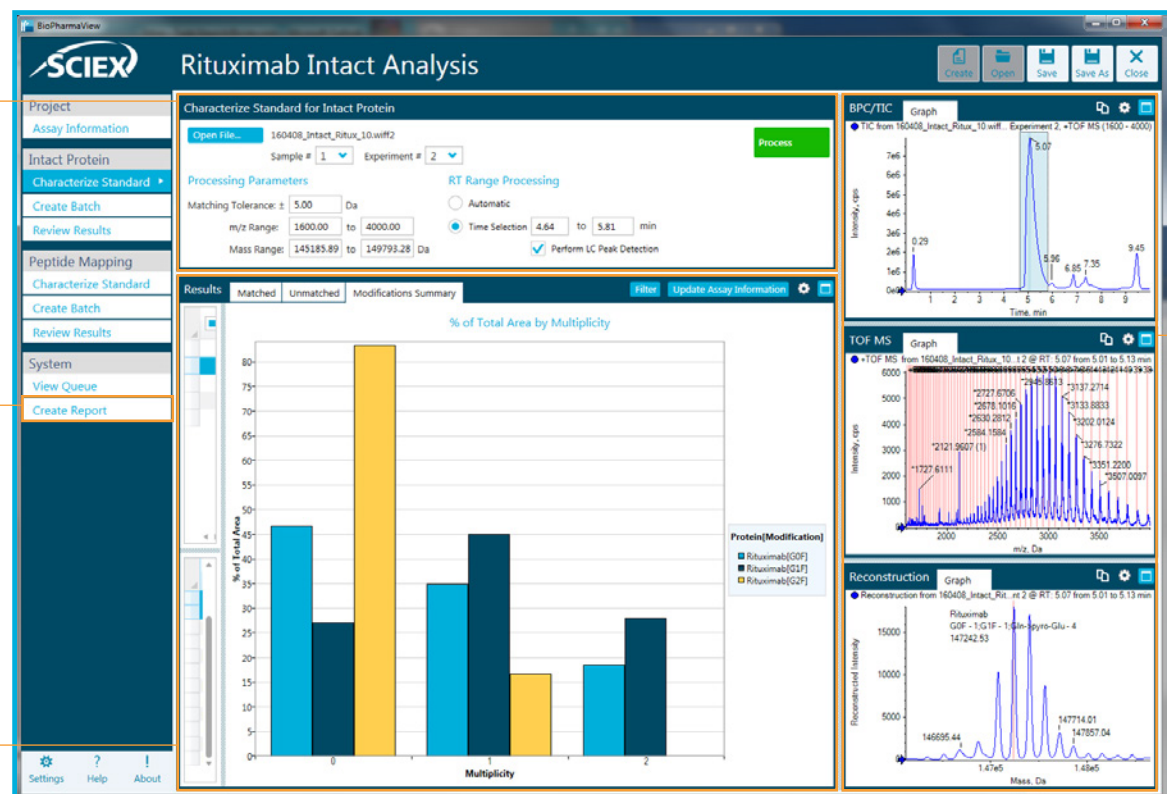
Data acquired on the X500B QTOF system is easily connected to SCIEX BioPharmaView 2.0 software, the leading solution for simple and automated biologics characterization data processing and analysis. You don't need to be an expert to accelerate your intact mass analysis: BioPharmaView software allows you to quickly understand your biologic product to ensure you're making the right decisions.

Simply provide protein sequence, potential modification information, and preferred processing parameters. BioPharmaView software automates intact protein deconvolution in seconds

Reduce variability and improve comparability by defining standardized deconvolution processing settings

Generate comprehensive reports in multiple output formats for easy integration with electronic notebooks

Quick interpretation with powerful graphical view of modification states, such as glycosylation



BioPharmaView software analysis of rituximab analyzed on the X500B system. Deconvolution parameters are defined and automated analysis is completed by the software to yield mass assignment, as well as detailed modification level summaries. All results are linked directly to the displayed raw data to ensure transparency and confidence.

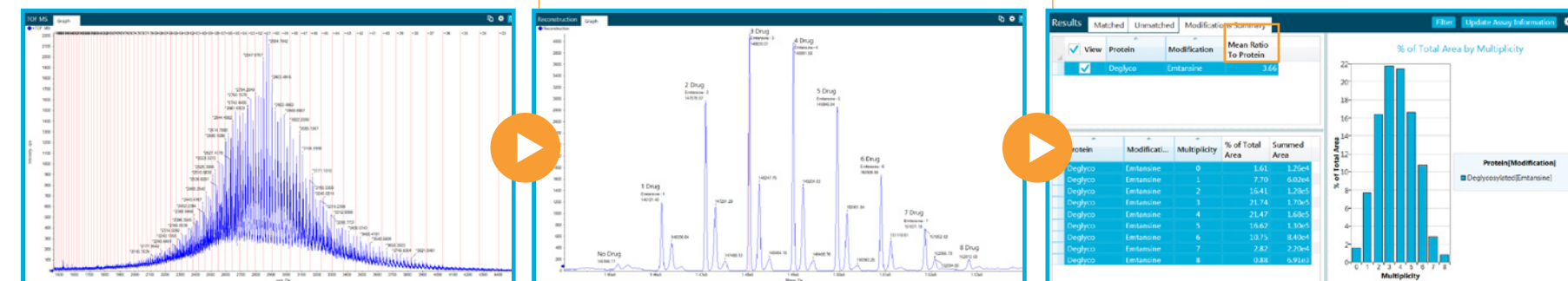
Increase your confidence in your answers with views of raw data linked to deconvoluted output

DAR at Your Fingertips

Simplified protein deconvolution and lightning fast drug-antibody ratio (DAR) calculations in BioPharmaView Software means you'll spend less time performing manual calculations. You'll see drug load and DAR across multiple samples, so you can focus on moving your antibody drug conjugate (ADC) through development.

Simplified protein deconvolution to view ADC drug states with high accuracy

Quickly visualize drug load on an ADC and calculate drug-antibody ratio with the automated DAR calculator

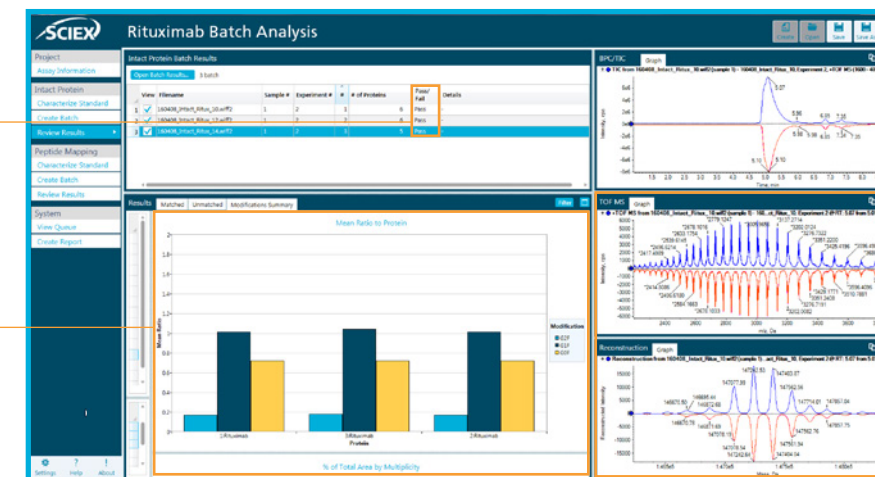


Comparability at a Glance

One-click batch processing and automated ratio calculations for post translational modifications--including glycosylation and drug conjugations--help you to compare multiple products quickly and efficiently. The multi-pane view in the main window shows you the processed and raw data from multiple samples side by side for greater confidence about your comparability conclusions.

Quickly find differences between samples with customized pass/fail flagging parameters

Visualize modification level differences between samples



Direct comparison of raw MS level spectra and protein deconvolution results from multiple samples

Intact analysis of a 3 lots of rituximab protein shows comparable quality attributes. Graphical view of the glycosylation levels indicates all three mAb samples have comparable glycosylation patterns.

Take Your Analysis to the Next Level with TripleTOF® 6600 Systems

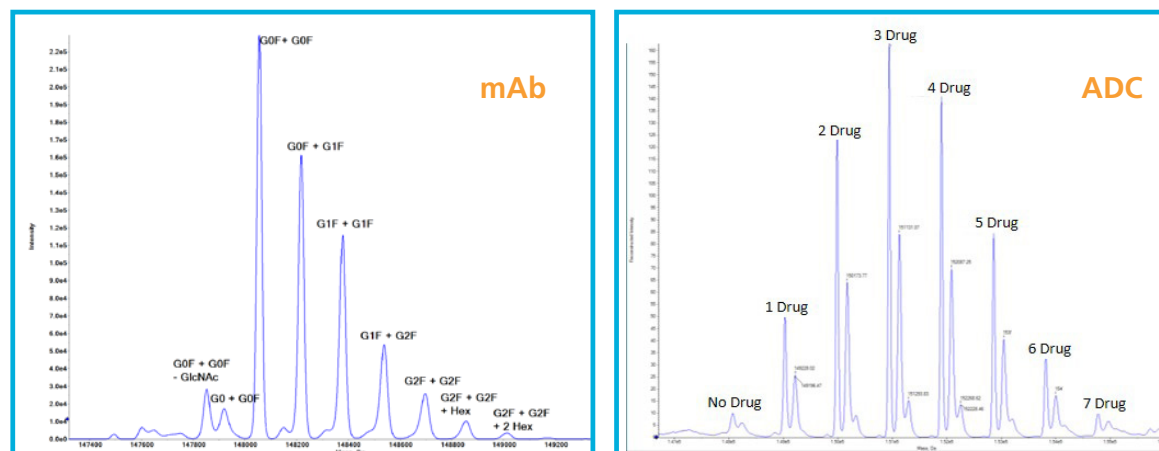
When the questions to be answered are more complex, and you need advanced capabilities, the SCIEX TripleTOF 6600 system, paired with orthogonal separation technologies, will help you get the answers you need.

See deeper into your biotherapeutic products and gain clarity that will help you make better decisions, confidently.

Find the Right Solution For Your Lab	TripleTOF 6600	X500B QTOF
Sensitive HRAM at Industry Leading Acquisition Rates	• •	•
Enhanced Linear Dynamic Range	• •	•
Advanced Orthogonal Separations with SelexION® Technology or CESI	•	
User-friendly SCIEX OS Interface for Simplified Setup and Use		•

You don't want to miss low abundance mAb or ADC isoforms:

Detect both high and low abundance molecular isoforms with the sensitivity and extended linear dynamic range of the TripleTOF 6600 LC-MS system.



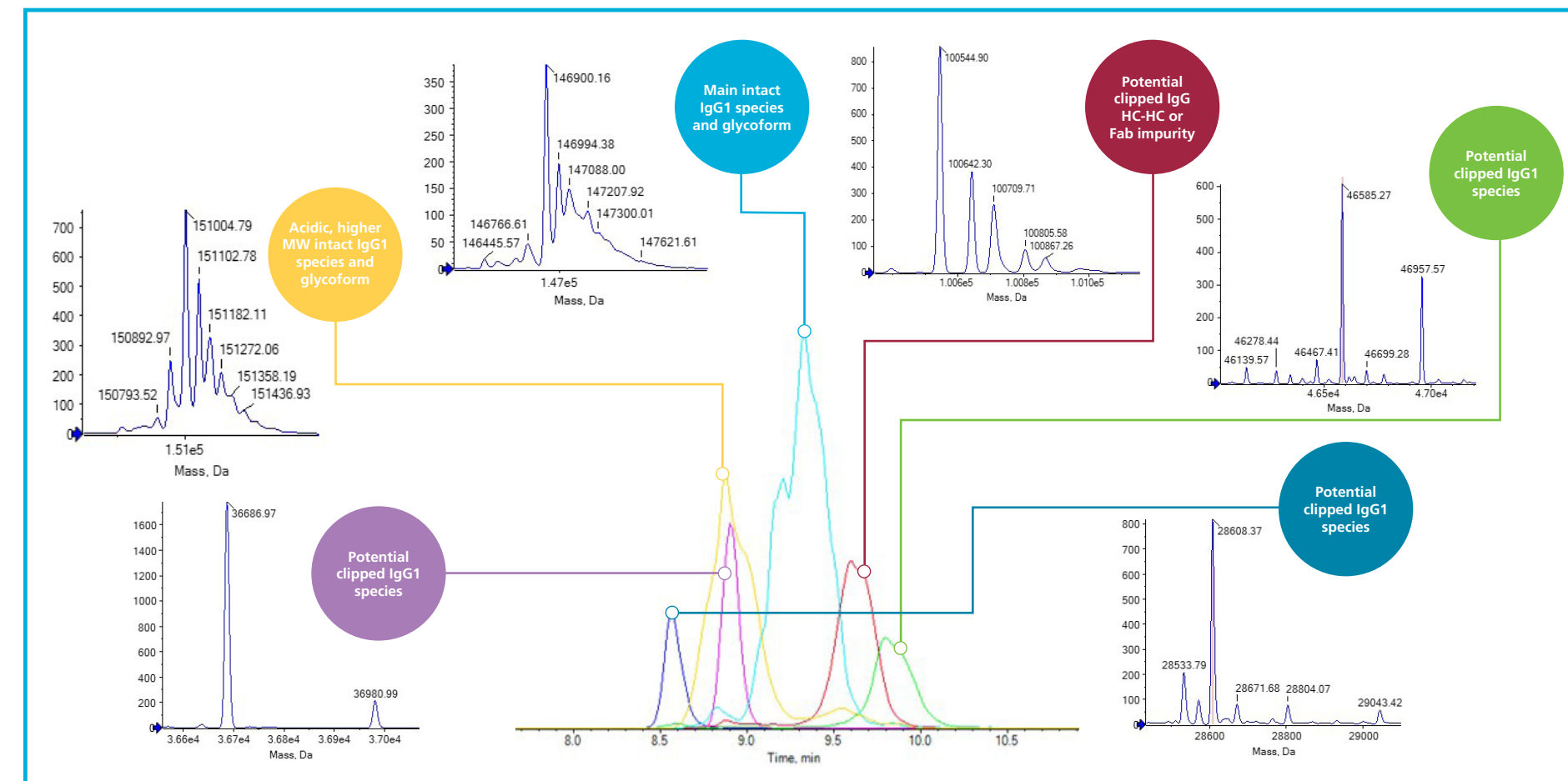
Detection of low abundance infliximab mAb isoforms (left) and an ADC drug-linked product (right) enabled by the high sensitivity TripleTOF LC-MS system.

Expand the Reach of Your TripleTOF System with CESI

Enhance your view of intact proteoforms by employing the high efficiency separation of capillary electrophoresis with the CESI 8000 Plus High Performance Separation-ESI Module, coupled to the TripleTOF 6600 system. High resolution separations enable a more thorough characterization of your intact biologic product. Additionally, CESI-MS only requires limited sample volumes, making it a powerful option for ADCs and other toxic molecules.

Dive deeper into your intact biotherapeutic analysis

CESI separation shows multiple protein form variants identified by distinct electrophoretic peaks. The added separation capabilities allow for the fast visualization of impurities such as intact charge variants and clipped species in therapeutic preparation and stressed samples.



Analysis of a stressed IgG preparation using CESI 8000 Plus Module with TripleTOF 6600 system. Simple acetic acid based buffers are used for sample preparation and separations for multi-level characterization of mAbs and other biologics. SCIEX CESI separation systems can be used with a variety of industry-leading mass spectrometers. Contact your SCIEX Separations representative for details.

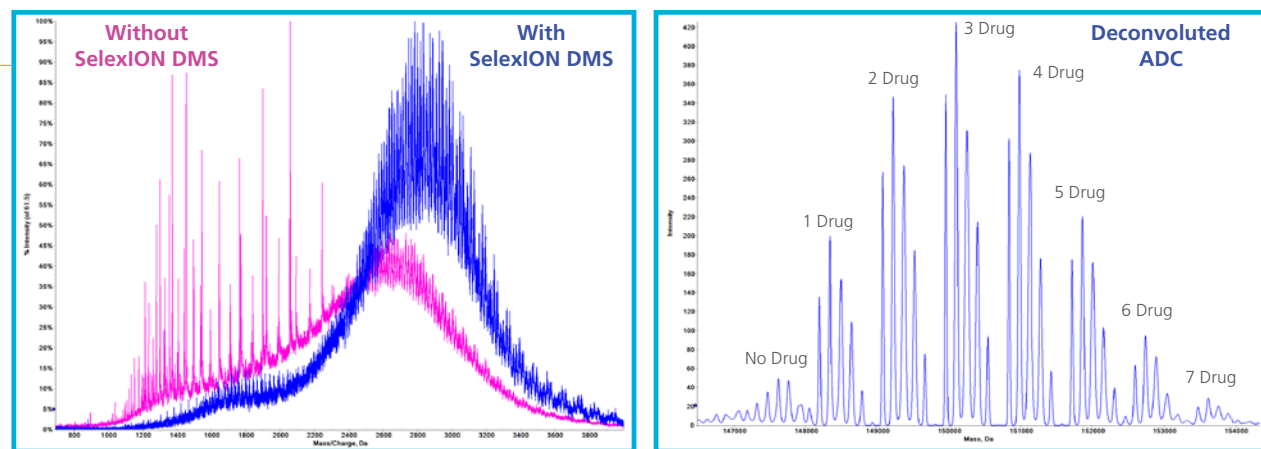


DAR, Demystified

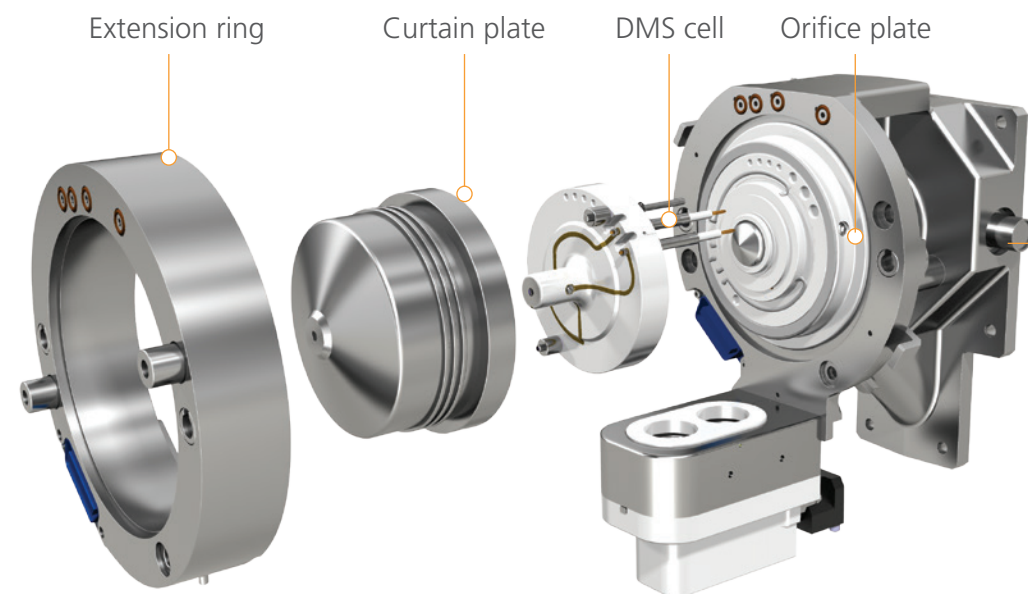
The inherent heterogeneity and high molecular weight of antibody drug conjugates (ADCs) can make characterization a difficult challenge. If your ADC is in a complex matrix, combining the TripleTOF 6600 with SelexION® Differential Mobility Technology reduces data complexity, yielding a clearer picture of your ADC. With the automated drug-antibody ratio (DAR) calculation capability in BioPharmaView software, you'll save significant time and effort.

See through complex matrices:

Reduce complexity in your ADC samples by using SelexION differential mobility separation technology



Analysis of glycosylated lysine linked ADC on TripleTOF platform. High complexity pink spectra is ADC sample analyzed without use of SelexION separation, and simplified blue spectra is with SelexION technology optimized for transmission of the ADC molecule, providing significant background reduction. Simplified and accurate determination of drug-to-antibody ratio (DAR) shown on the right.



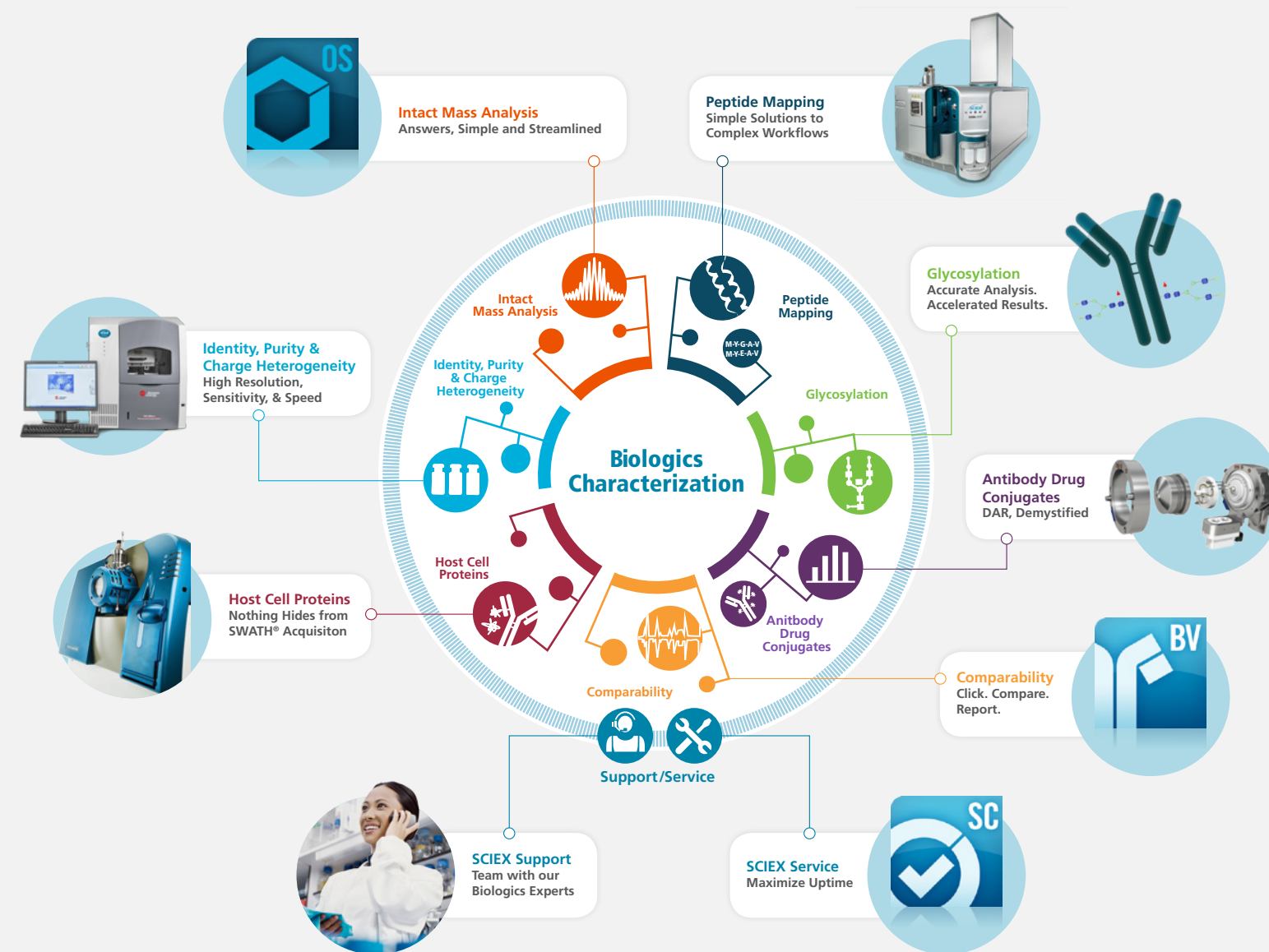
SelexION Differential Mobility Technology components

Simplify your mass spectrum:

Accurately determine your DAR in complex samples by removing interfering proteins using the SelexION device, which is simple to install on a TripleTOF System without breaking vacuum

It's Time to Reduce Complexity in Biologics Characterization

Simplified intact mass analysis on an X500B QTOF System is the newest innovation in the SCIEX 360° solution for Biologics Characterization. You can advance your characterization workflows with our full-circle product portfolio, including application-focused systems, software and services designed specifically for biologics analyses. SCIEX innovation can help you speed routine tasks as well as simplify your most complex characterization challenges, so you can achieve insights faster and with greater confidence than you ever thought possible. Find out more at sciex.com/biologics



Your Success is Our Success

We take it personally

As a SCIEX customer you have access to a world-class customer support organization. Wherever you are, we're there with you as a trusted partner to answer questions, provide solutions, and maximize lab productivity.

Our customer support organization has access to the latest product updates, software revisions, methods and repair procedures to make sure that you stay on top of your game.

When you have questions, we have answers.

Learn more at sciex.com/customersupport, or locate your local account representative at sciex.com/contactus

Answers for Science.
Knowledge for Life.™

AB Sciex is doing business as SCIEX.

© 2016 AB Sciex. For Research Use Only. Not for use in diagnostic procedures. The trademarks mentioned herein are the property of AB Sciex Pte. Ltd. or their respective owners. AB SCIEX™ is being used under license.

RUO-MKT-03-4645-A 09/2016

Headquarters

500 Old Connecticut Path
Framingham, MA 01701 USA
Phone 508-383-7700
sciex.com

International Sales

For our office locations please call the division headquarters or refer to our website at sciex.com/offices

