Characterize With Confidence

Multiple Characterizations and Applications on ONE Platform

CE-SDS • cIEF • CZE • Glycans • Cell and Gene Therapy

SCIEX

Answers for Science.
Knowledge for Life.™

Consistent, Compliant Analysis Faster than Ever.

Confidently safeguard the success of your biologics with the SCIEX PA 800 Plus system that fully enables regulatory compliance.

Repeatability Matters

Even small variations in temperature can affect migration time. PA 800 Plus delivers repeatable results with exclusive recirculating liquid coolant to precisely control separation temperature.

Portability Matters

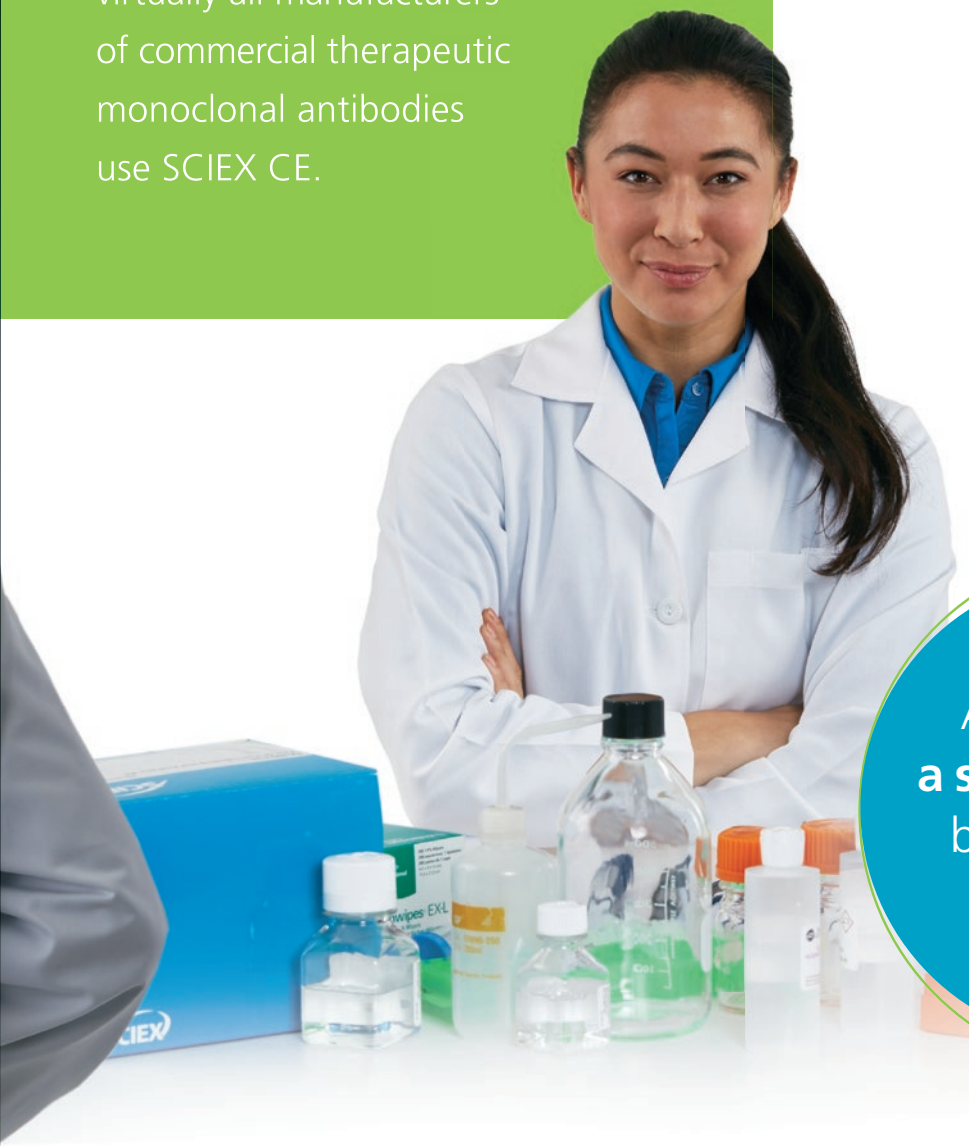
Develop and lock-down methods applicable to QC or regulated environments. PA 800 Plus easily transfers methods using robust, automated assays with proven portability – perfect for global multi-user, multi-instrument organizations.

RAW Data Matters

Data acquired by some technologies is often manipulated. However, only raw, unprocessed data can provide the confidence critical to both you and regulatory agencies for product submission and commercialization. The PA 800 Plus supports 21CFR211.194 compliance by providing raw, unmanipulated data. Regulatory requirements can be easily met where unmanipulated raw data may be required.

Results You Can Trust

With SCIEX, you can characterize any molecule with industry and regulatory accepted CE technology. That's one of the many reasons why virtually all manufacturers of commercial therapeutic monoclonal antibodies use SCIEX CE.



I can do ALL this

on my PA 800 Plus

- **Monoclonal Antibody Applications**
  - > Purity/Heterogeneity with Gold Standard CE-SDS in minutes
  - > Glycan Analysis with award-winning Fast Glycan Technology
  - > Charge Heterogeneity with fast and simple CZE or with hi-res cIEF
- **Cell and Gene Therapy Applications**
  - > Capsid Protein Purity
  - > Nucleic Acid and Plasmid Analysis

... with Expert Worldwide Support

Rely on SCIEX to provide world-class global support, delivered consistently across all geographies. Let SCIEX help you develop your next breakthrough therapeutic.

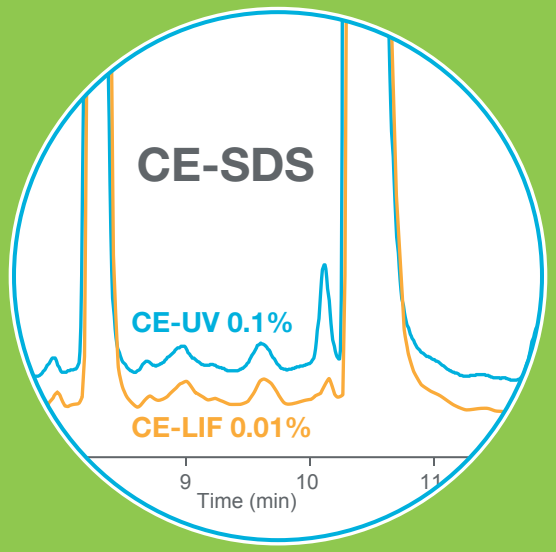
All possible on **a single platform** biopharma labs depend on.

I can do more...

Accurate • Reliable • Consistent

Purity/Heterogeneity with Gold Standard CE-SDS

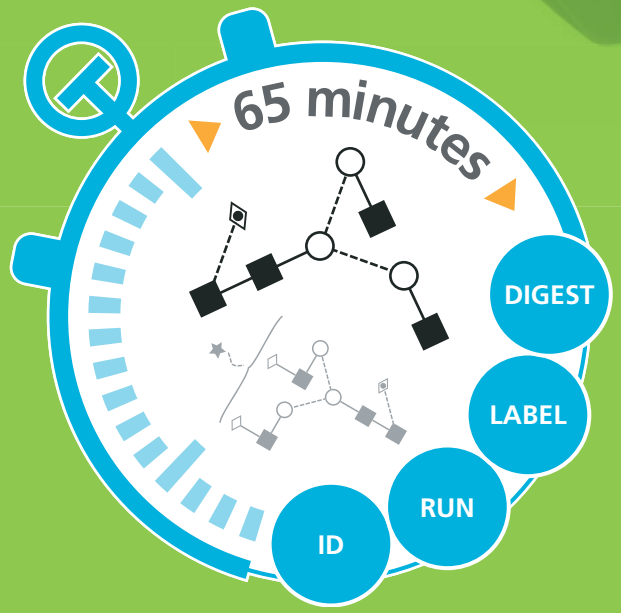
Reduced <15 min. / Non-reduced <18 min.



- Fastest CE-SDS separation time (12-18 minutes)
- Quantitation of impurities down to 0.01%
- Reproducible to 3 or more orders of magnitude sample concentration

Glycan Analysis with Award-Winning Fast Glycan Technology

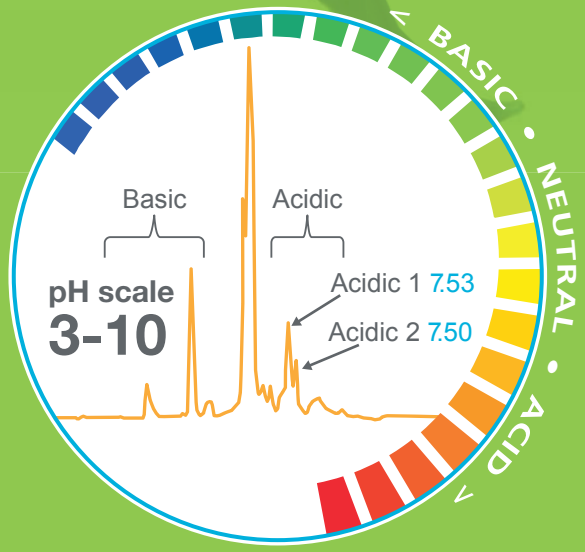
Glycoprotein to glycan ID in 65 min.



- Up to 5X faster than HILIC
- 1-hour sample prep
- Automated Glycan ID
- Cost and resource effective

Protein Charge Heterogeneity with Ultra Hi-res cIEF

pI range and accuracy in 1 run



- High pI accuracy on extreme acidic and basic variants
- High resolution throughout the pI range

with incredible flexibility.

Robust • Fast • Quantitative • Automated • Stress-Free

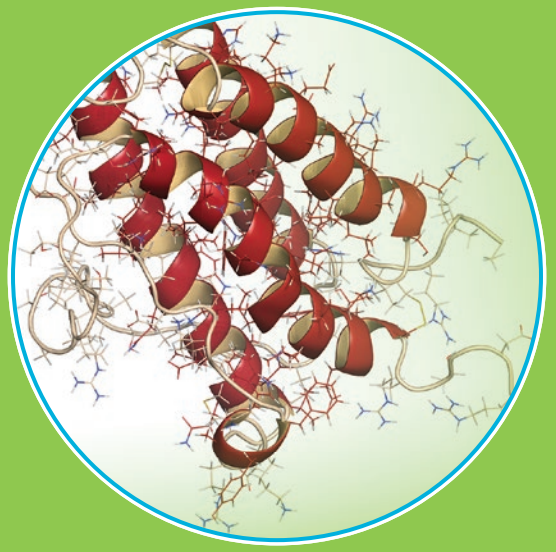
Charge Variant Analysis by CZE

Quick and simple

- Screen charge variants in 10 minutes
- Save time with fast, straightforward sample preparation
- Same method applies to a wide range of pI

Pharmacopoeial Protein Characterization

Beyond monoclonal antibody characterization



- Increased confidence in regulatory submissions using Pharmacopoeia methods
- Automated, quantitative, and sensitive profiling of Erythropoietins (EPO), Somatropin (Human Growth Hormone), Aprotinin using Pharmacopoeia methods

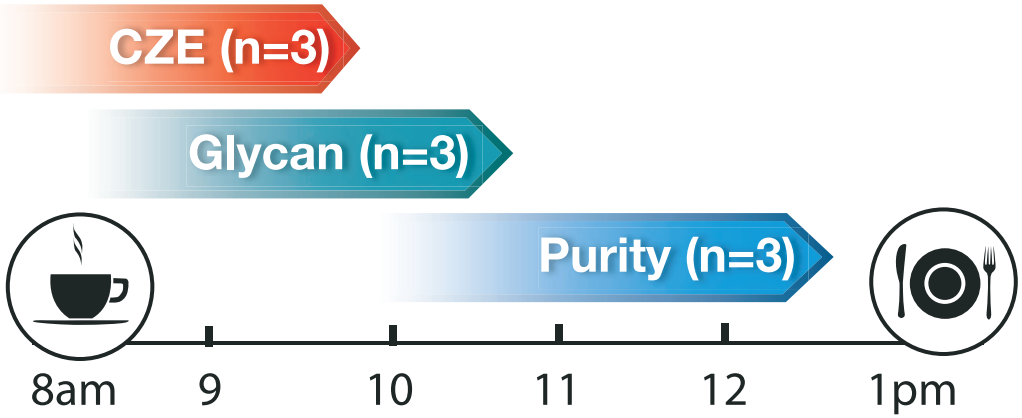
Cell and Gene Therapy

Robust, flexible solutions

- Assess size, purity, and capsid protein ratios
- Multiple kit-based chemistries available to assess the quality and impurities of nucleic acids through the use of ultra-sensitive fluorescence detection

I can get the job done...

Quick • Easy • Cost-effective



Flexible Workflows to Help You do More

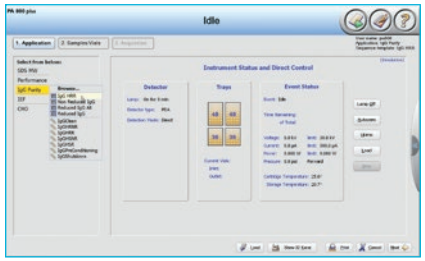
When you can do it all on a single instrument you know well, you can accomplish a lot before noon.

One Cartridge, Multiple Applications

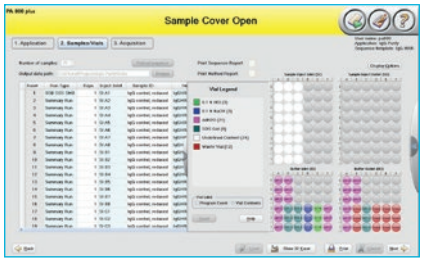
The agile EZ-CE cartridge functions across multiple applications streamlining your workflow and simplifying your inventory process.

Software As Easy As 1, 2, 3...

SCIEX software reduces operational complexity so you achieve more faster, for exceptional productivity.



1 Select application



2 Load samples and reagents

3 Acquire data

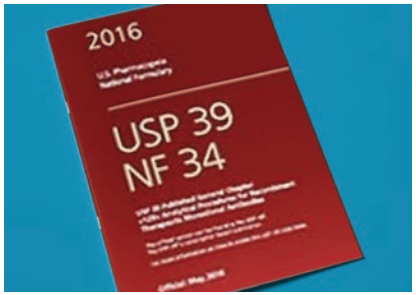
and trust my results.

Industry and Regulatory Proven CE Technology

Extensive intercompany studies have assessed the practical application of CE-SDS, cIEF, CZE and glycan analysis performed across the biopharmaceutical industry, demonstrating the methods are validation-ready.

The Best Technology Application

"This year's winner is SCIEX's high-throughput glycosylation analysis... it is a fully automated sample preparation for ultrafast N-glycosylation analysis of antibody therapeutics." – BioProcess International



USP Referenced

USP 39 NF 34 Chapter <129> recognizes SCIEX CE-SDS as "a sensitive, analytical method for quantitative estimation of product-related impurities such as nonglycosylated molecules, half antibodies, and fragments..."

http://www.usp.org/sites/default/files/usp/document/our-work/biologics/GC-129.pdf#page=9

Held to the Highest Quality Standards

SCIEX Capillary Electrophoresis systems have earned a global reputation for consistently meeting or exceeding our customers' quality expectations. Our commitment to excellence and continuous improvement is reflected in our comprehensive Quality Management System which complies with the requirements of ISO 9001:2008.

Multi-Site N-glycan mapping study 1: Capillary electrophoresis–laser induced fluorescence.

http://www.tandfonline.com/doi/abs/10.1080/19420862.2015.1107687

CLICK

Evaluation of capillary zone electrophoresis for charge heterogenity testing of monoclonal antibodies.

http://www.sciencedirect.com/science/article/pii/S1570023214007764

CLICK

A series of collaborations between various pharmaceutical companies and regulatory authorities concerning the analysis of biomolecules using capillary electrophoresis.

http://link.springer.com/article/10.1007%2Fs10337-011-2017-3

CLICK

Intercompany study to evaluate the robustness of capillary isolectric focusing technology for the analysis of monoclonal antibodies.

http://link.springer.com article/10.1007%2Fs10337-011-2017-3

CLICK

Need to Connect to a Mass Spec?

CESI 8000 Plus

With CESI-MS you can effectively integrate high-efficiency capillary electrophoresis (CE) with electrospray ionization (ESI) into a single dynamic process – *within the same device*.

Supplies and Resources

Items can be ordered at sciex.com/contact-us/ce-ordering

Reagents

Purity	
IgG Purity and Heterogeneity Assay	A10663
SDS-Gel Multipack (4 bottles)	A30341
10 kD Protein Standard	A26487
IgG Control Standard (3-pack)	391734
Purity/Sizing	
SDS-MW Assay Kit/ Purity/Sizing	390953
MW Sizing Standard	A22196
Glycan	
Fast Glycan Labeling and Analysis Kit	B94499PTO
Carbohydrate Labeling and Analysis Assay	477600
N-CHO Capillary	477601
Charge Heterogeneity	
Advanced cIEF Starter Kit	A80976
cIEF Peptide Marker Kit (pI Marker Kit)	A58481
Neutral Capillary	477441
Cell and Gene Therapy	
eCAP ssDNA 100-R Kit	477480
dsDNA 1000 Kit	477410

Supplies and Accessories

Universal Vials	A62251
200 µL Microvials (pkg of 100)	144709
Universal Vial Caps	A62250
Electrode Replacement Kit	A47775
Vial Cap Opener	A95348
Buffer Vial Tray (36 vials)	A58254
Buffer Vial Tray (48 vials)	A58255
nanoVials (pkg of 100)	5043467
Cartridge Assembly, 30 cm Capillary	A11147
Blank Cartridge Assembly Kit	144738
Cartridge Rebuilding Kit	144645
Cartridge Tubing Kit	144689
Capillary Coolant (450 mL)	359976
EZ-CE Capillary Cartridge (CE-SDS, Fast Glycan, CZE)	A55625
Bare Fused Silica 50 µM x 67 cm Capillaries 3-pack	338451

Hardware and Consumables are manufactured under ISO 9001:2008

Fast Glycan Labeling and Analysis Kit

EZ-CE Cartridge

Specifications and Ordering Information

Reach out to your local SCIEX representative to order today.

System Specifications

Dimensions:

Height: 29.2 in (74.2 cm)

Door Open: 38.8 in (98.6 cm)

Width: 25 in (63.5 cm)

Depth: 28.4 in (72.1 cm)

Weight (uncrated): 188 lbs (85.3 kg) (includes photodiode array detector)

Electrical Requirements:

Voltage: 100 - 240 V; 50/60 Hz

Voltage Range:

1 to 30 kV programmable in 0.1 kV increments

Current Range:

3 to 300 µA programmable in 0.1 µA increments

Pressure Delivery Range:

-5 to +100 psi

Sample Temperature Control:

4 - 60° C

Capillary Temperature Control:

15 - 60° C

System Capacity

Sample Trays:

2 x 96-well plates

2 x 48 universal vials

Buffer Tray:

2 x 36 universal vials

Detection Capability

UV/Vis

200, 214, 254, 280 nm standard filter

190 - 600 nm (custom filter option)

Diode Array:

190 - 600 nm (programmable)

0.5 - 32 Hz scan collection frequency (programmable)

Laser Induced Fluorescence (LIF):

300 - 700 nm excitation range

350 - 750 nm emission range

0 - 1000 RFU

Source Lasers with 3 mW Power Output:

488 nm solid-state laser (included in A66528)

Ordering Information

A66528
PA 800 Plus Pharmaceutical Analysis System

Includes separation module with UV, photodiode array and LIF detection; system controller with PA 800 Plus software

A66527
PA 800S Plus Pharmaceutical Analysis System

Includes separation module with photodiode array detection; system controller with PA 800 Plus software

Network Your Way to Success

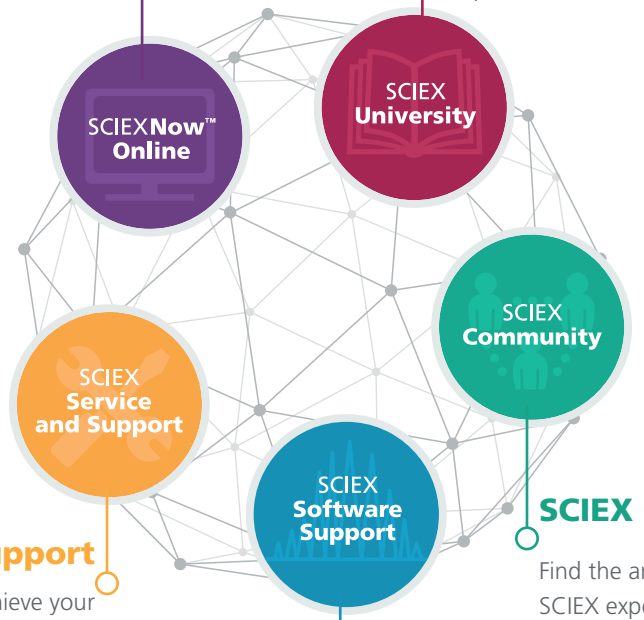
Discover How the SCIEX Success Network Speeds and Simplifies Your Path to Answers

SCIEXNow™ Online

The everything, anytime destination for all your SCIEX support needs

SCIEXUniversity

The most diverse and flexible learning options available



SCIEX Service and Support

We're here to help you achieve your goals quickly and efficiently

SCIEX Community

Find the answers you need from SCIEX experts as well as your peers

SCIEX Software Support

Get the latest software, so your instruments run at peak performance

Start Your Path to Success Now: sciex.com/support

Answers for Science.
Knowledge for Life.™

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