

# Characterize With Confidence

**Multiple Characterizations and Applications on ONE Platform**

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



The PA 800 Plus  
Pharmaceutical  
Analysis System



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

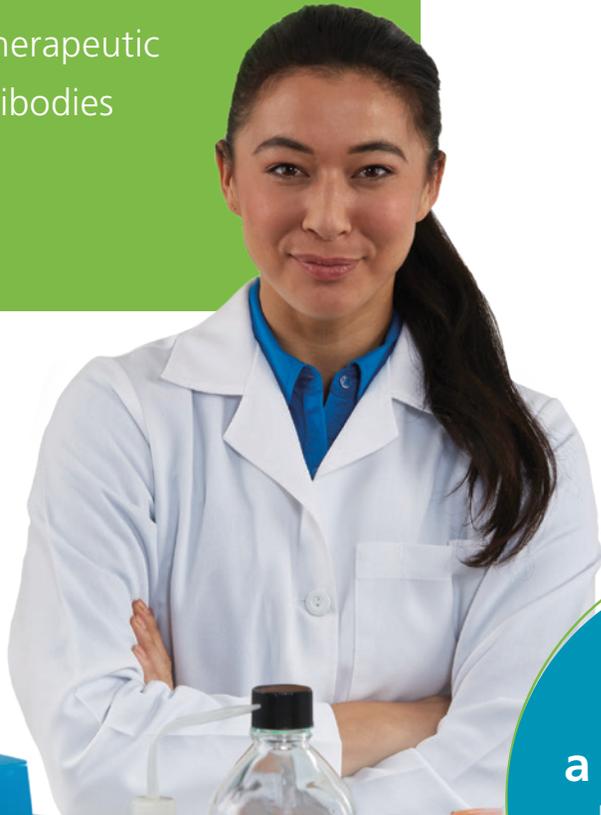
Develop and lock-down methods applicable to QC or regulated environments. PA 800 Plus easily transfers methods using robust, automated assays with proven portability – perfect for global multi-user, multi-instrument organizations.

ACEPTADO ✓



## 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 Proteins 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.

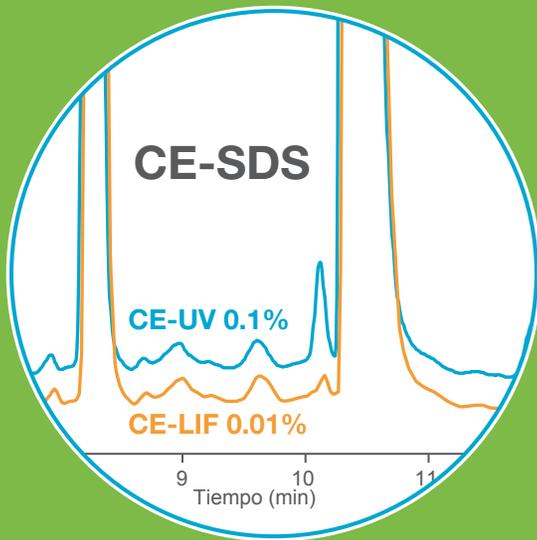
# I can do more...

**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

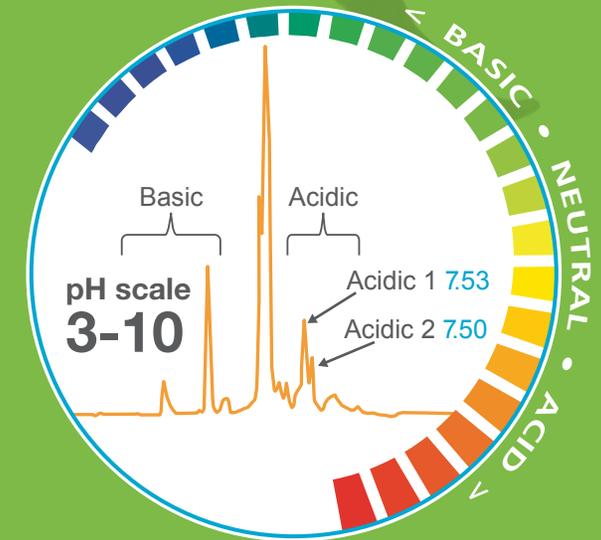
*Glycoprotein to glycan ID in 65 min.*



- Up to 2x 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

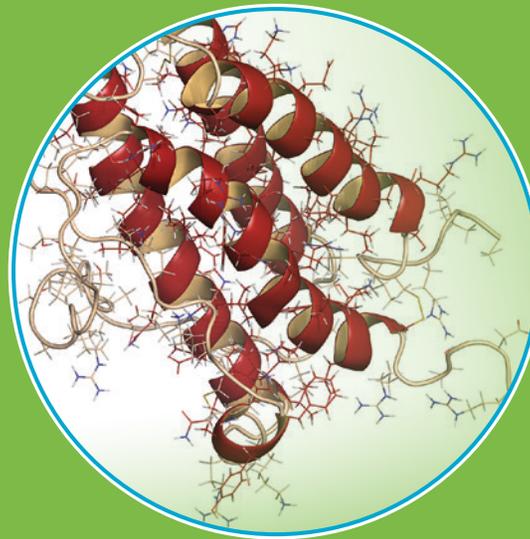
*Quick and simple*



- 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

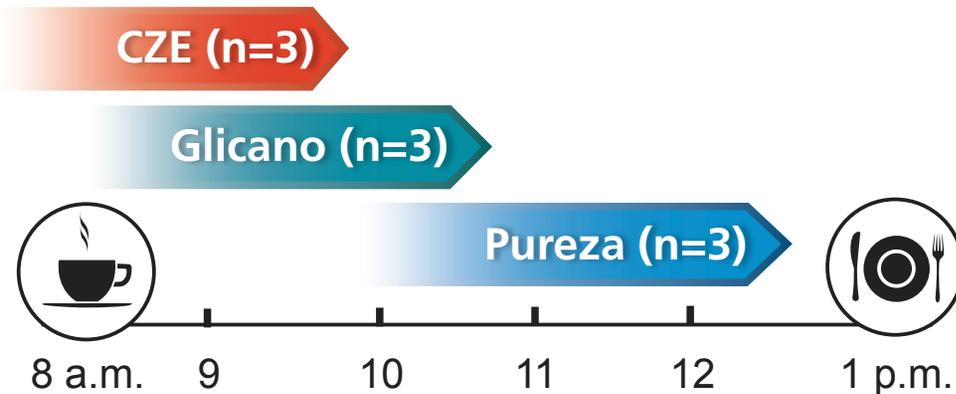
*Robust, flexible solutions*



- 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 ultrasensitive 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

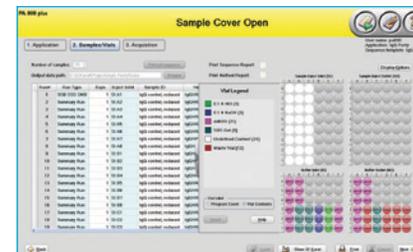
The agile EZ-CE cartridge functions across multiple applications streamlining your workflow and simplifying your inventory process.

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

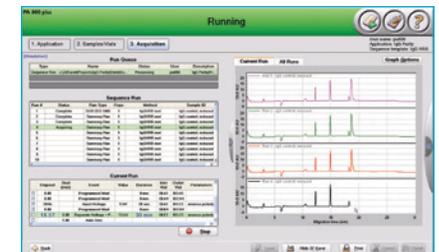
SCIEX software reduces operational complexity so you achieve more faster, for exceptional productivity.



1 Select application



2 Load samples and reagents



3 Acquire data

# and trust my results.

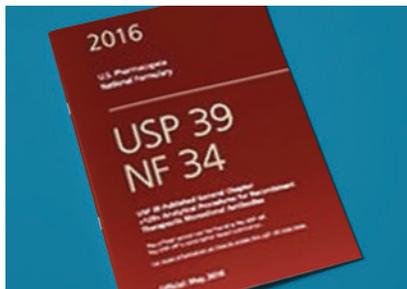
## Industry and Regulatory Proven CE Technology

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>



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

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



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>



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

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





## 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](http://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 $\mu$ L 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 $\mu$ M 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  $\mu$ A programmable  
in 0.1  $\mu$ A 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

### LUV/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

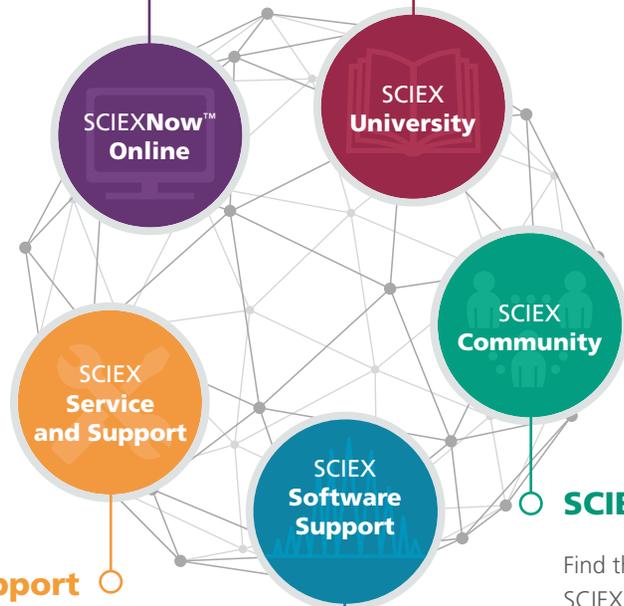
## Discover How the SCIEX Success Network Speeds and Simplifies Your Path to Answers

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#### Headquarters

500 Old Connecticut Path  
Framingham, MA 01701 USA  
Phone 508-383-7700  
[www.sciex.com](https://www.sciex.com)

#### International Sales

For our office locations please call the division headquarters or refer to our website at [www.sciex.com/offices](https://www.sciex.com/offices)

