High Resolution, Sensitivity, and Speed.

Identity, Purity and Charge Heterogeneity with the PA 800 Plus Capillary Electrophoresis System

SCIEX

Answers for Science.
Knowledge for Life.™

Consistent, Confident and Compliant Data

Good analytical technologies provide comprehensive characterization and facilitate regulatory compliance.

Established techniques capable of generating results with a high level of accuracy, sensitivity, reproducibility, and flexibility are therefore, paramount to biopharmaceutical analyses within your lab.

Research analysts handling protein therapeutics need:

- Automated qualitative and quantitative analyses
- Proven functionality enabling maximum operational efficiency
- Flexible method development as well as simple routine operation across a range of molecules
- Robust, industry validated applications that are globally transferrable

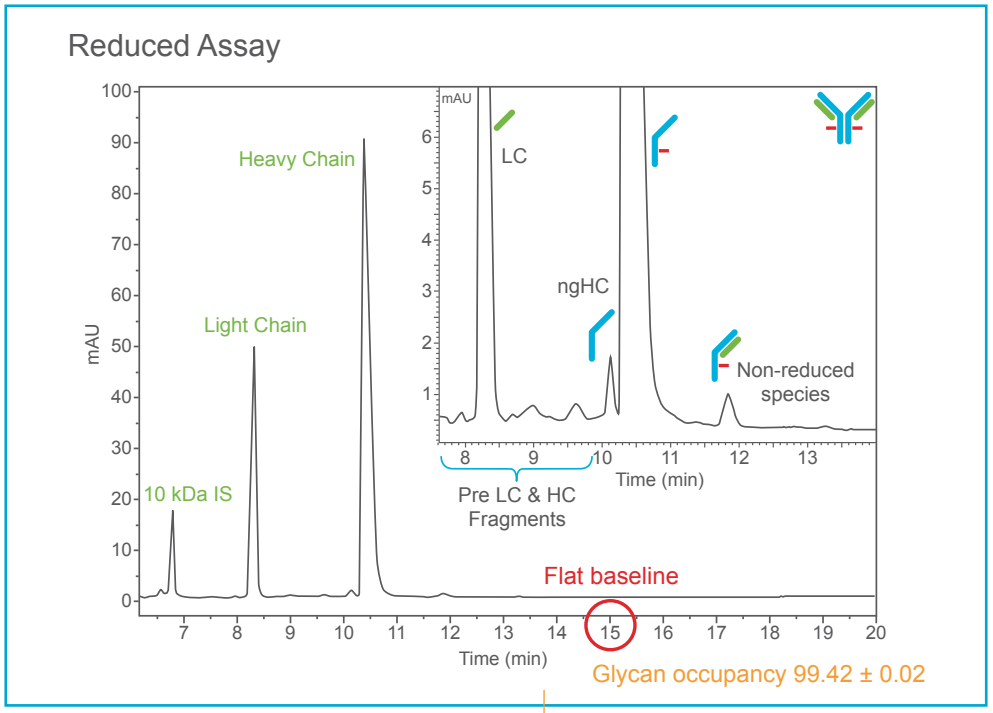
The PA 800 Plus Pharmaceutical Analysis System is a robust analytical platform that provides consistent, confident & compliant data, with easy-to-use software for the development and QC of biologics.

Exceed Sensitivity and Resolution Requirements

Protein Purity Characterization Below 0.1%

Association of low-level impurities with therapeutic proteins can mean the difference between the success and failure of a biotherapeutic.

Have confidence in your results with SCIEX CE-SDS, the gold standard adopted by biopharma for this application.



Capillary-based SDS method for separation of reduced NIST mAb, in less than 15 minutes.

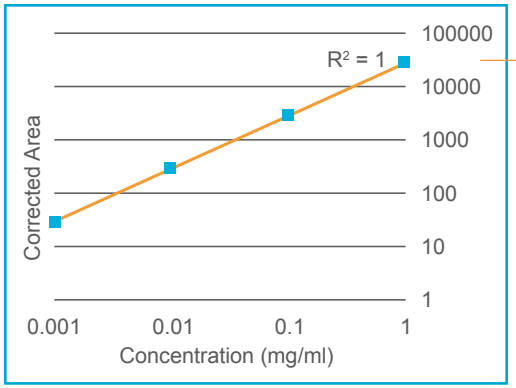
Contrary to slab gel, CE-SDS can resolve non-glycosylated heavy chain from glycosylated heavy chain, and can quantitate it too, as per regulatory requirements.

Complete Your Protein Purity Characterization in <18 Minutes

Time is of the essence. Workloads are high. Achieve more and make every minute count without impacting the quality of your data, with fast, accurate and reproducible separations.

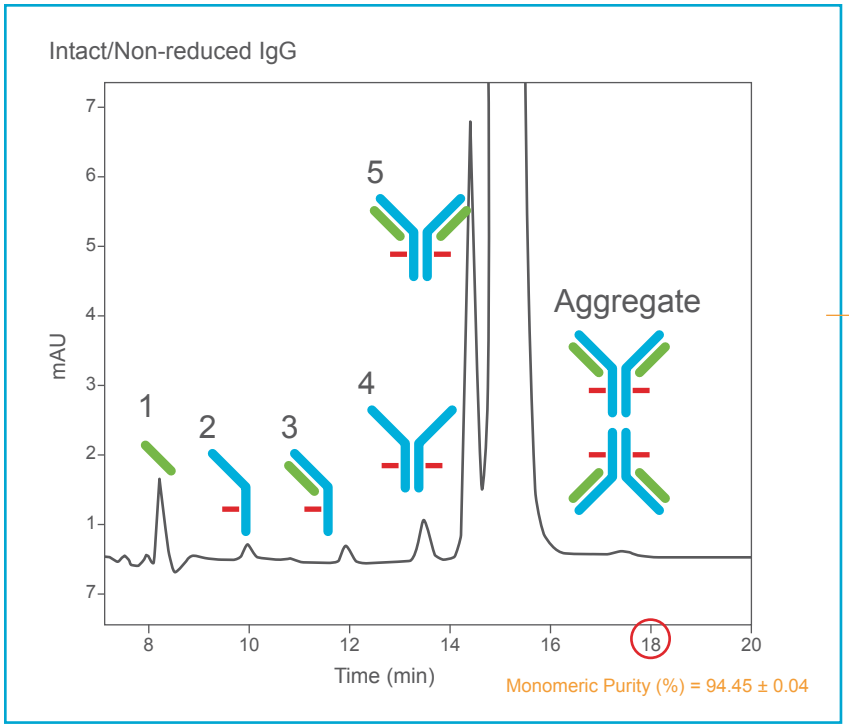
Protein Purity Characterization in <12-18 min.

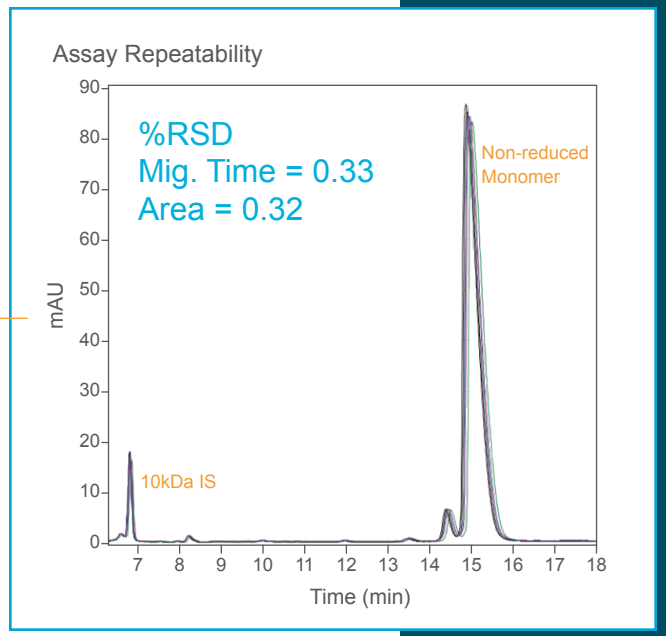
Gain excellent assay reproducibility for both reduced and non-reduced IgG analyses on the PA 800 Plus.



Achieve maximum sensitivity with the PA 800 Plus modular UV and Laser Induced Fluorescence (LIF) detection – providing at least three orders of magnitude of impurity detection – 0.1% and 0.01% respectively.

Rapidly Assess Monomeric Purity





6 overlaid traces demonstrate the assay repeatability as the migration time and peak area RSDs are less than 0.5%

Learn More. Watch the SCIEX Webinar Series.

MAb Charge Heterogeneity Analysis by CZE, Part 1: Results of an Intercompany Robustness Study

Dr. Bernd Moritz, Hoffman-La Roche, Pharmaceutical Division, Basel, Switzerland

MAb Charge Heterogeneity Analysis by CZE, Part 2: A Case Study from Merck Sharp & Dohme

Dr. Joop Waterval and Tijmen Verwij, Merck Sharp & Dohme, Netherlands

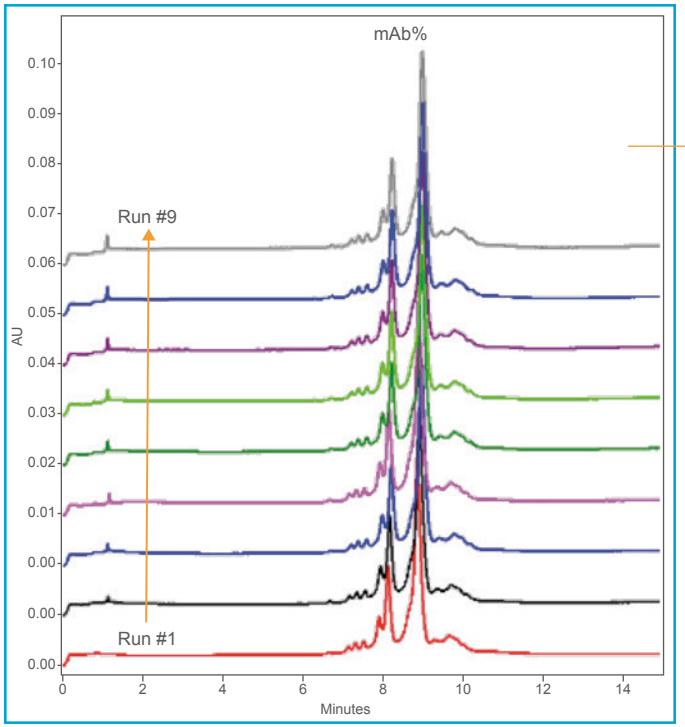
MAb Charge Heterogeneity Analysis by CZE, Part 3: A Test Method Fit for QC Testing

Dr. Marc Hassel, Novartis Pharma AG, Basel, Switzerland

High Throughput Charge Heterogeneity Made Easy

Rapid Charge Variant Analysis Made Easy

When used on the PA 800 Plus, Capillary Zone Electrophoresis (CZE) offers faster separation results than other LC and CE methods. Additionally, you'll find CZE offers many other advantages for your lab.



CZE separations are performed with high reproducibility and are ideal for multi-user/ multi-instrument environments.

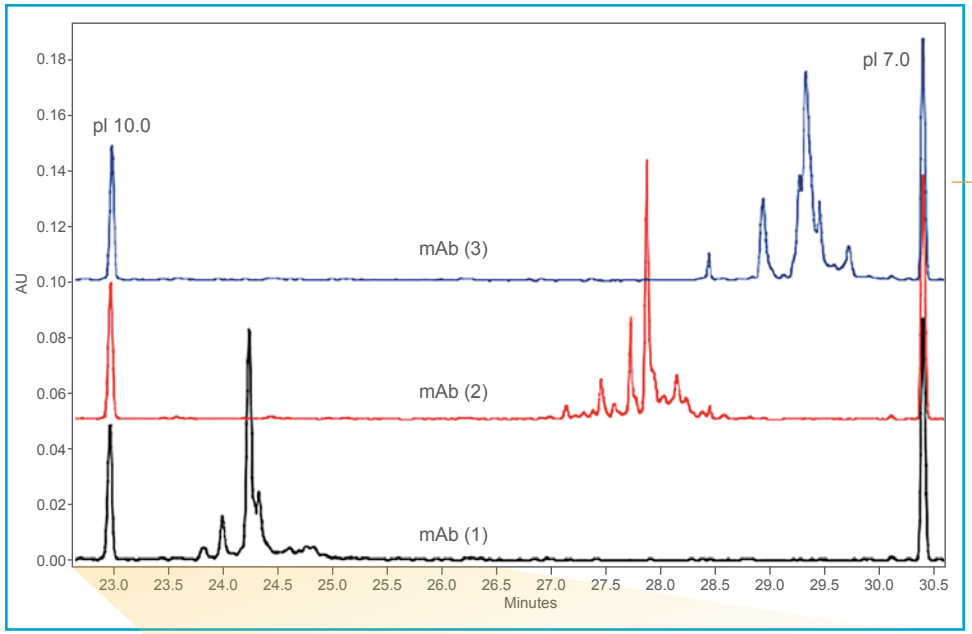
Parameter	SCIEX cIEF	CZE	non-SCIEX cIEF	CEX (pH gradient)
Resolution	Very good	Good to very good	Moderate to good	Good to very good
Analysis time	20-25 min	18-21 min (incl. rinsing)	20-25 min (incl. rinsing)	90 min
Applicability to mAbs without modification of the method	75%	100%	65%	~80%
Buffer consumption	Very low	Very low	Very low	720 ml / 8 runs
Injection concentration	0.3 - 04 mg/ml	0.009 - 3.6 mg/ml	0.3 - 0.4 mg/ml	0.006 - 3.6 mg/ml
	SCIEX data	Novartis data, see webinar		

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

Highest Resolution Charge Heterogeneity Capillary Isoelectric Focusing (cIEF)

Confidently Assess Protein Stability

The SCIEX cIEF workflow on the PA 800 Plus System has proven robust and portable. Universal or platform methods can also be created – significantly decreasing method development efforts and simplifying workflows with a single method for molecules across a wide pI range.



cIEF workflow can be established as a standard platform assay across a wide pI range, simplifying workflows.

Ultra high resolution cIEF is capable of achieving separation between isoforms as closely related as 0.03 pI units.

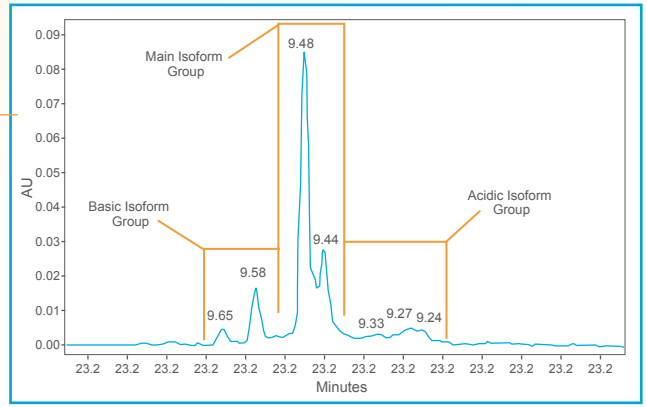


Figure 7: mAb (1) Peak Profile. A close up view of the mAb #1 cIEF separation.

“PA 800 Plus has been validated for ...”

Read extensive intercompany studies assessing the practical application of CE-SDS, cIEF, and CZE that were performed across the biopharmaceutical industry effectively validating these assays.

mAbs

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

mAbs. Volume 6, Issue 6, 2014

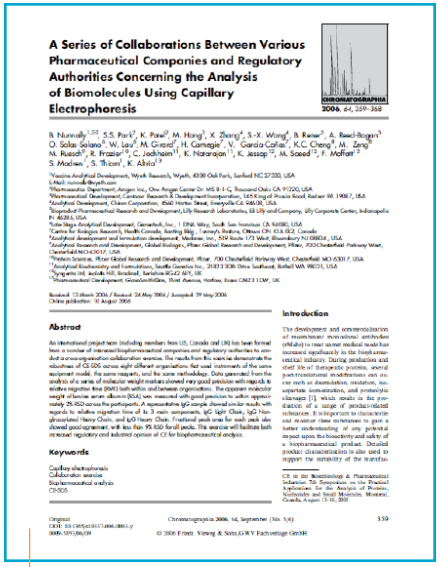
N-Glycan

Journal of Chromatography B

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

Journal of Chromatography B, 983–984 (2015) 101–110

CZE



A Series of Collaborations Between Various Pharmaceutical Companies and Regulatory Authorities Concerning the Analysis of Biomolecules Using Capillary Electrophoresis

Chromatographia (2011) 73:1137–1144

CE-SDS

Intercompany Study to Evaluate the Robustness of Capillary Isoelectric Focusing Technology for the Analysis of Monoclonal Antibodies

Chromatographia (2011) 73:1137–1144

cIEF

In 2016 the US Pharmacopeial convention (USP) published Chapter <129> describing the application of CE-SDS and glycan analysis for the characterization of monoclonal antibodies.

Notable Publications and Tech Notes

Proven CE Robustness for Biopharmaceutical Quality Control and Method Transfer

A Series of Collaborations between Various Pharmaceutical Companies and Regulatory Authorities Concerning the Analysis of Biomolecules Using Capillary Electrophoresis. *Chromatographia* 2006, 64, September (No. 5/6).

Salas-Solano O et al. (2011) Intercompany Study to Evaluate the Robustness of Capillary Isoelectric Focusing Technology for the Analysis of Monoclonal Antibodies. *Chromatographia*. 73:1137-1144

Evaluation of Capillary Zone Electrophoresis for Charge Heterogeneity Testing of Monoclonal Antibodies. *J Chromatogr B Analyt Technol Biomed Life Sci.* 2015 Mar 1;983-984:101-10.

Capillary Electrophoresis in Quality Control: PART I: Application for Therapeutic Proteins.

Capillary Electrophoresis in Quality Control: PART II: CE-SDS: Method Development and Robustness.

Quantitative and Automated Protein Purity & Heterogeneity Analysis by CE-SDS

IgG Purity/Heterogeneity and SDS-MW Assays with High-Speed Separation Method and High Throughput Tray Setup.

Assay of IGG Purity and Heterogeneity Using High-Resolution Sodium Dodecyl Sulfate Capillary Gel Electrophoresis.

Automation of CE-SDS Sample Preparation for PA 800 Plus IgG Purity/Heterogeneity Assays Using a Biomek 4000 Automation Workstation.

Quantitative & Robust Protein Charge Heterogeneity Analysis

Analysis of Monoclonal Antibody Charge Variants by Capillary Zone Electrophoresis. High-Resolution cIEF of Therapeutic Monoclonal Antibodies: A Platform Method Covering pH 4-10.

SCIEX Biologics Characterizations Solutions

For more information on SCIEX Biologics Characterization Solutions download the SCIEX Biologics Analytical Characterization Compendium.

For an extensive collection of recorded webinars and events on CE, click here.

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SCIEXUniversity

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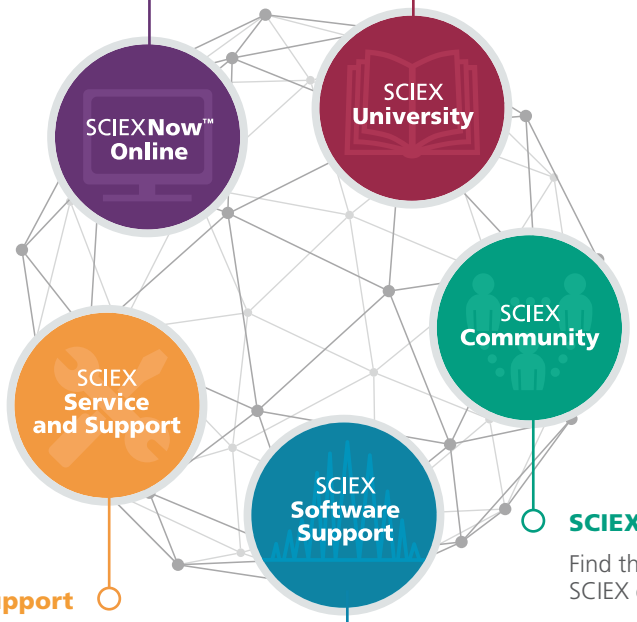

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Knowledge for Life.™

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