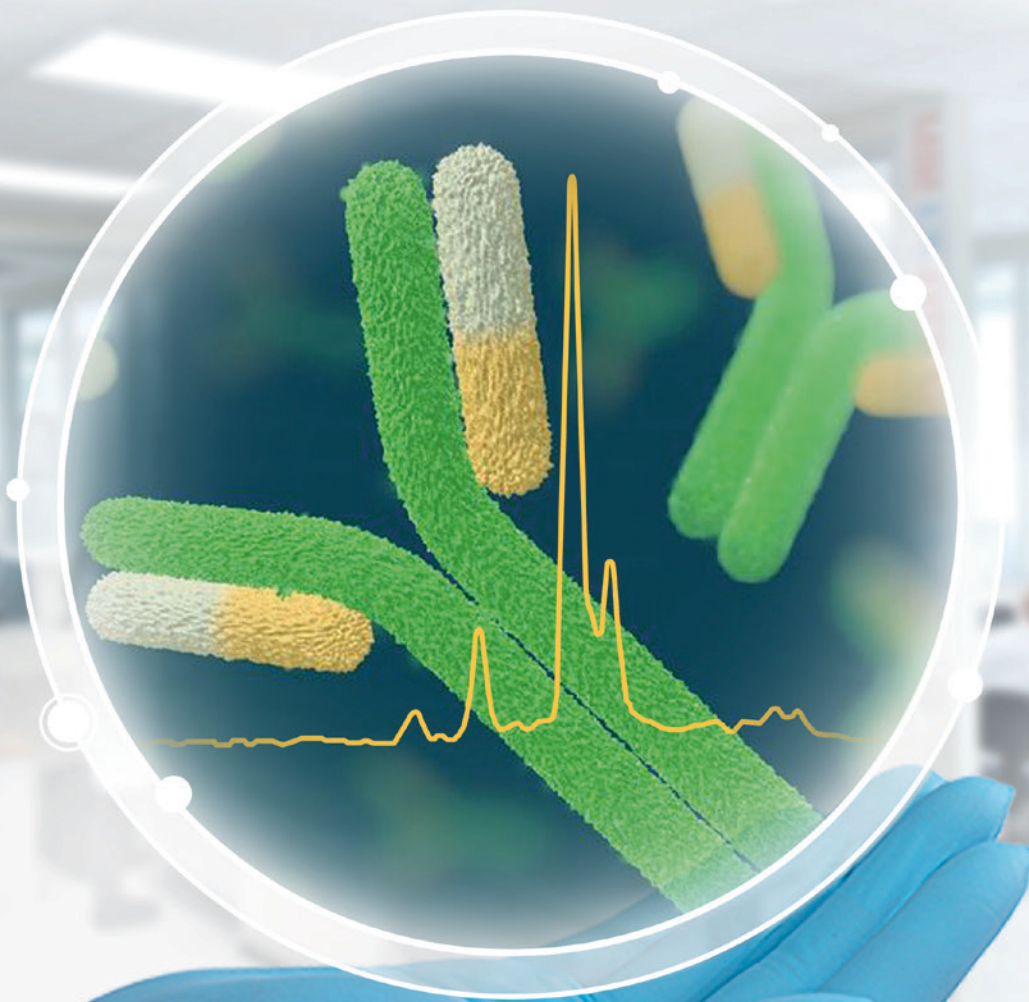


High Resolution, Sensitivity, and Speed.

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



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

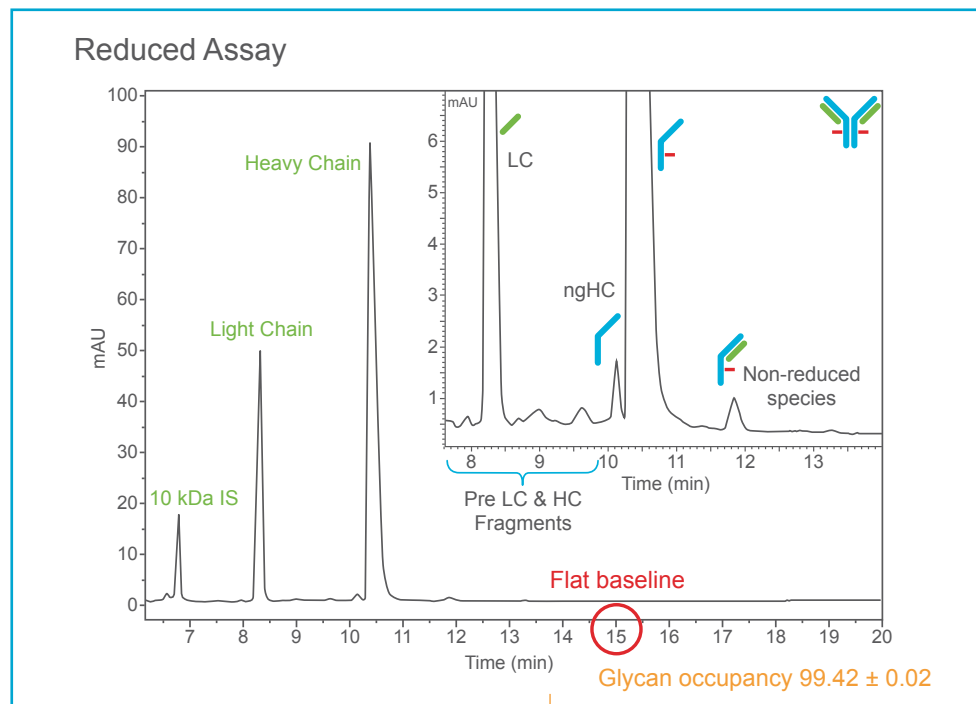
The PA 800 Plus Pharmaceutical Analysis System is a robust analytical platform that provides consistent, confident & compliant data, with easy-to-use software for the development and QC of biologics.

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.

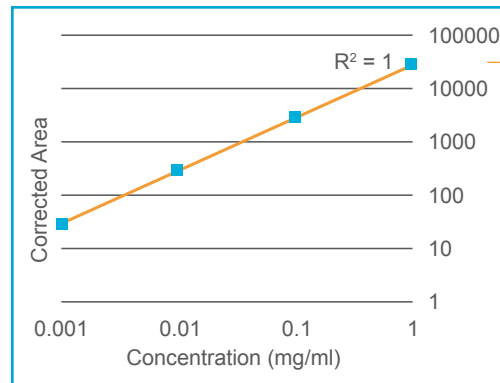
Contrary to slab gel, CE-SDS can resolve non-glycosylated heavy chain from glycosylated heavy chain, and can quantitate it too, as per regulatory requirements.

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.

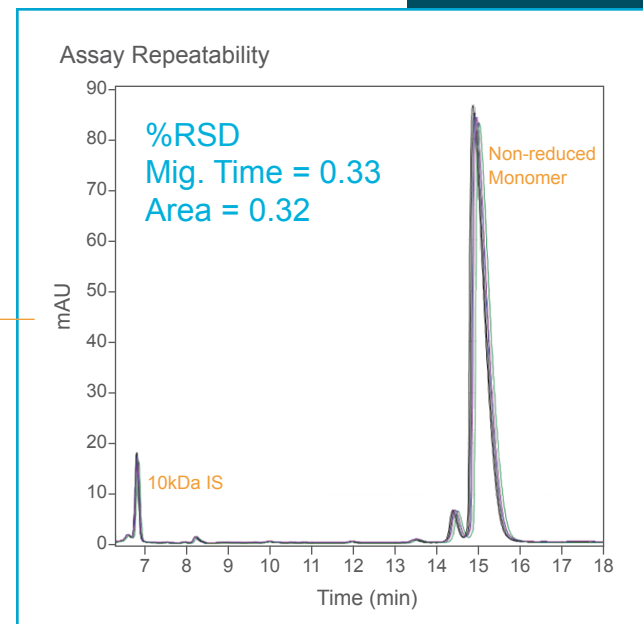
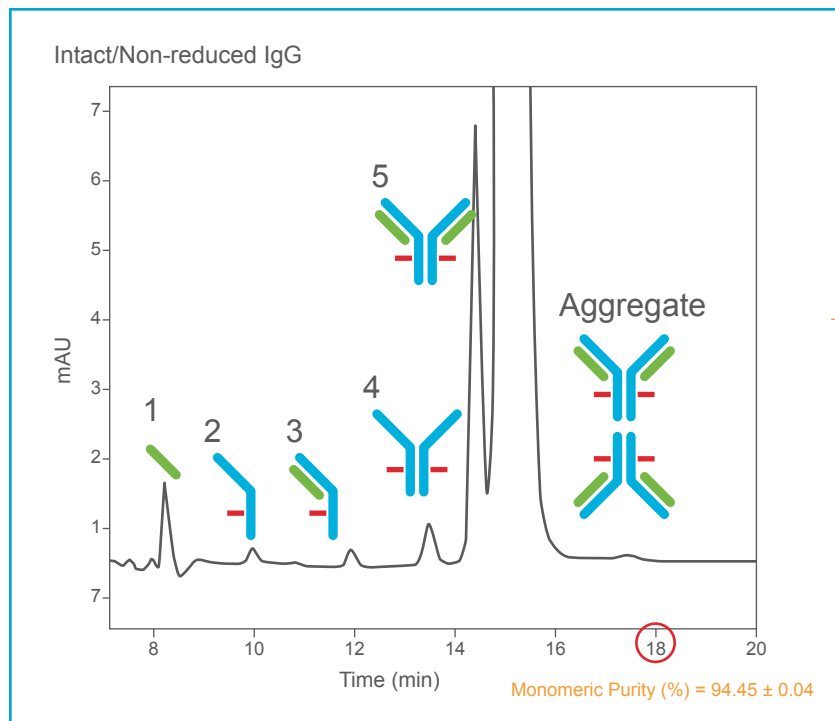
Protein Purity Characterization in <12-18 min.

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

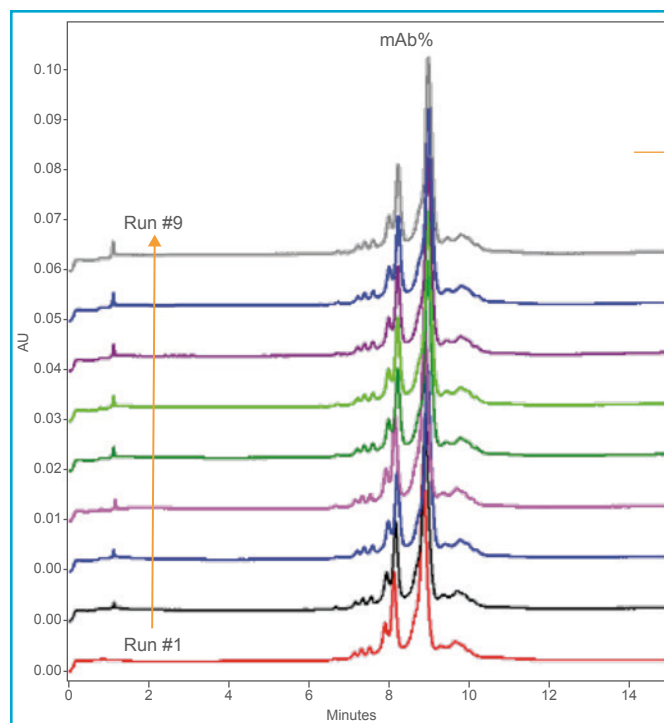


6 overlaid traces demonstrate the assay repeatability as the migration time and peak area RSDs are less than 0.5%

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.

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

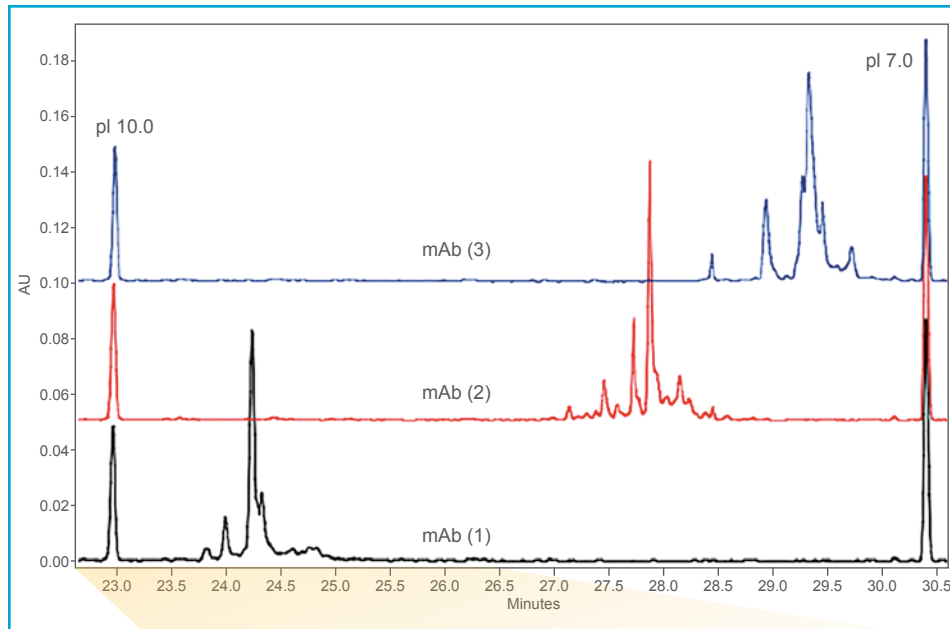
Parameter	SCIEX cIEF	CZE	non-SCIEX cIEF	CEX (pH gradient)
Resolution	Very good	Good to very good	Moderate to good	Good to very good
Analysis time	20-25 min	18-21 min (incl. rinsing)	20-25 min (incl. rinsing)	90 min
Applicability to mAbs without modification of the method	75%	100%	65%	~80%
Buffer consumption	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.

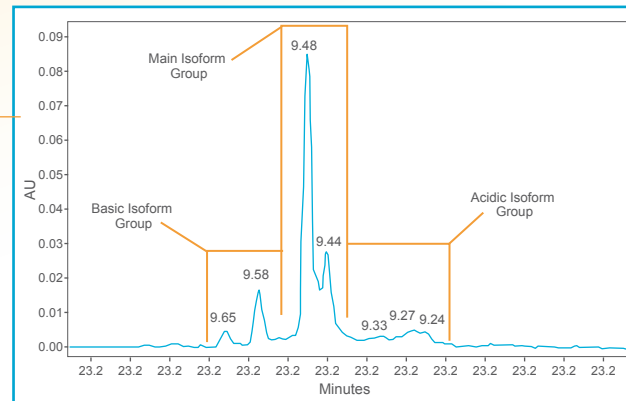


Figure 7: mAb (1) Peak Profile. A close up view of the mAb #1 cIEF separation.

"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.



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.

mAbs

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

Álvaro Sotekereyán, Sunguk Suh Park, Marcos Santos, Clarence Lim, Aled Jones, Ted Hans, Michael Kinszy, Shiva Fourouze, Slobodan Sabo, Zoran Sodic, Peng Feng, Csaba Várad, François de Escalibe, Jean-Bernard Fainnaghi, Fredi Szejtli, Thomas Niedringhaus, David Michels, Gordon Freckleton, Melissa Harms, Anusutay Marudikou, Melissa Schwartz, Jian-Kai Luo, Jonathan van Dyck, Pui King Leung, Marcell Olajos, Virginia Gu, Kai Gao, Wenbo Wang, Ja Wegstien, Sonmeeg Tey & Andros Gurtman

To cite this article: Sotekereyán, A., Sunguk Suh Park, Marcos Santos, Clarence Lim, Aled Jones, Ted Hans, Michael Kinszy, Shiva Fourouze, Slobodan Sabo, Zoran Sodic, Peng Feng, Csaba Várad, François de Escalibe, Jean-Bernard Fainnaghi, Fredi Szejtli, Thomas Niedringhaus, David Michels, Gordon Freckleton, Melissa Harms, Anusutay Marudikou, Melissa Schwartz, Jian-Kai Luo, Jonathan van Dyck, Pui King Leung, Marcell Olajos, Virginia Gu, Kai Gao, Wenbo Wang, Ja Wegstien, Sonmeeg Tey & Andros Gurtman. Multi-Site N-glycan mapping study I: Capillary electrophoresis - laser induced fluorescence. *mAbs*. DOI: 10.1081/15476312.2015.1107887

To link to this article: <http://dx.doi.org/10.1081/15476312.2015.1107887>

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mAbs, Volume 6, Issue 6, 2014

N-Glycan

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

B. Narayali,^{1,2} S.S. Park,³ K. Patel,⁴ M. Hong,⁵ X. Zhang,⁶ S.-X. Wong,⁷ B. Rowan,⁸ A. Bawolczyk,⁹ O. Solis-Soto,¹⁰ W. Li,¹¹ M. Gnanou,¹² H. Gamboa,¹³ A. Garcia-Caballero,¹⁴ C.C. Cheng,¹⁵ M. Zhang,¹⁶ N. Russo,¹⁷ R. Frazier,¹⁸ C. Johnson,¹⁹ K. Hristova,²⁰ K. Jasso,²¹ M. Sood,²² P. McGuffee,²³ S. Mochly,²⁴ S. Hiral,²⁵ & A. Bawolczyk²⁶

Abstract
 An international project involving members from US, Canada and UK has been formed to evaluate a number of intercompany studies assessing the practical application of CE-SDS, cIEF, and CZE that were performed across the biopharmaceutical industry effectively validating these assays. The results from the various studies are presented in this review. The results from the various studies are presented in this review. The results from the various studies are presented in this review.

Keywords
 CE, N-glycan, capillary electrophoresis, laser induced fluorescence, mAbs, glycan analysis, biopharmaceutical industry, regulatory authorities, USP, FDA, EMA, MHRA, Health Canada, Swissmedic, ANVISA, BfArM, EMA, MHRA, Health Canada, Swissmedic, ANVISA, BfArM.

Chromatographia 2016, 64, September (Vol. 54) 1137-1144
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Chromatographia (2011) 73:1137-1144

CE-SDS

Journal of Chromatography B

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

Bernad Morera^{1*}, Volker Schreiber¹, Steffen Kiering¹, Andras Hegny¹, Markus Wild¹, Christof Finkler¹, Stefan Christian¹, Kerstin Mueller¹, Li Zhang¹, René Farner¹, Marc Hussler¹, Melissa Harms¹, Richard Rostandi¹, Van Hai¹, Oscar Villa-Soto¹, Colin Whitmore¹, Sang Ae Park¹, Dietmar Hansen¹, Marcia Santos¹, Mark Lies²

Abstract
 Charge heterogeneity (CH) is a critical quality attribute (CQA) for monoclonal antibodies (mAbs). The evaluation of CH is a complex task that involves the use of various analytical techniques. This article describes the evaluation of capillary zone electrophoresis (CZE) for the analysis of CH in mAbs. The results show that CZE is a suitable method for the analysis of CH in mAbs.

Keywords
 CZE, mAbs, charge heterogeneity, capillary zone electrophoresis, monoclonal antibodies.

Chromatographia 2015, 88, September (Vol. 54) 101-110
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Journal of Chromatography B, 983-984 (2015) 101-110

CZE

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

Chuan Sufan Solis-Soto¹, Samuel Haber², Sunguk Suh Park³, Xinling Zhang⁴, Li Zhang⁵, Zoran Sodic⁶, Bodo Baumgart⁷, Ming Zeng⁸, Kang-Chun Cheng⁹, Angéla Rodóriguez¹⁰, Nancy Commins-Eitz¹¹, Kate H. Miller¹², Maura Parter¹³, Tamara Buzina¹⁴, Mingling Hong¹⁵, Steven Guo¹⁶, Margarete Rostand¹⁷, De-Mei Laney¹⁸, Irene Enghel¹⁹, Nicklas Löweny²⁰, Torsten Altmeyer²¹, Brian Nussler²²

Abstract
 Intercompany studies are essential to evaluate the robustness of capillary isoelectric focusing (cIEF) technology for the analysis of monoclonal antibodies (mAbs). This article describes the results of an intercompany study conducted across several laboratories to evaluate the performance of cIEF for the analysis of mAbs.

Keywords
 cIEF, mAbs, capillary isoelectric focusing, monoclonal antibodies, intercompany study, robustness, quality control.

Chromatographia 2011, 73:1137-1144
 DOI 10.1007/s00216-011-1137-1

Chromatographia (2011) 73:1137-1144

cIEF

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.

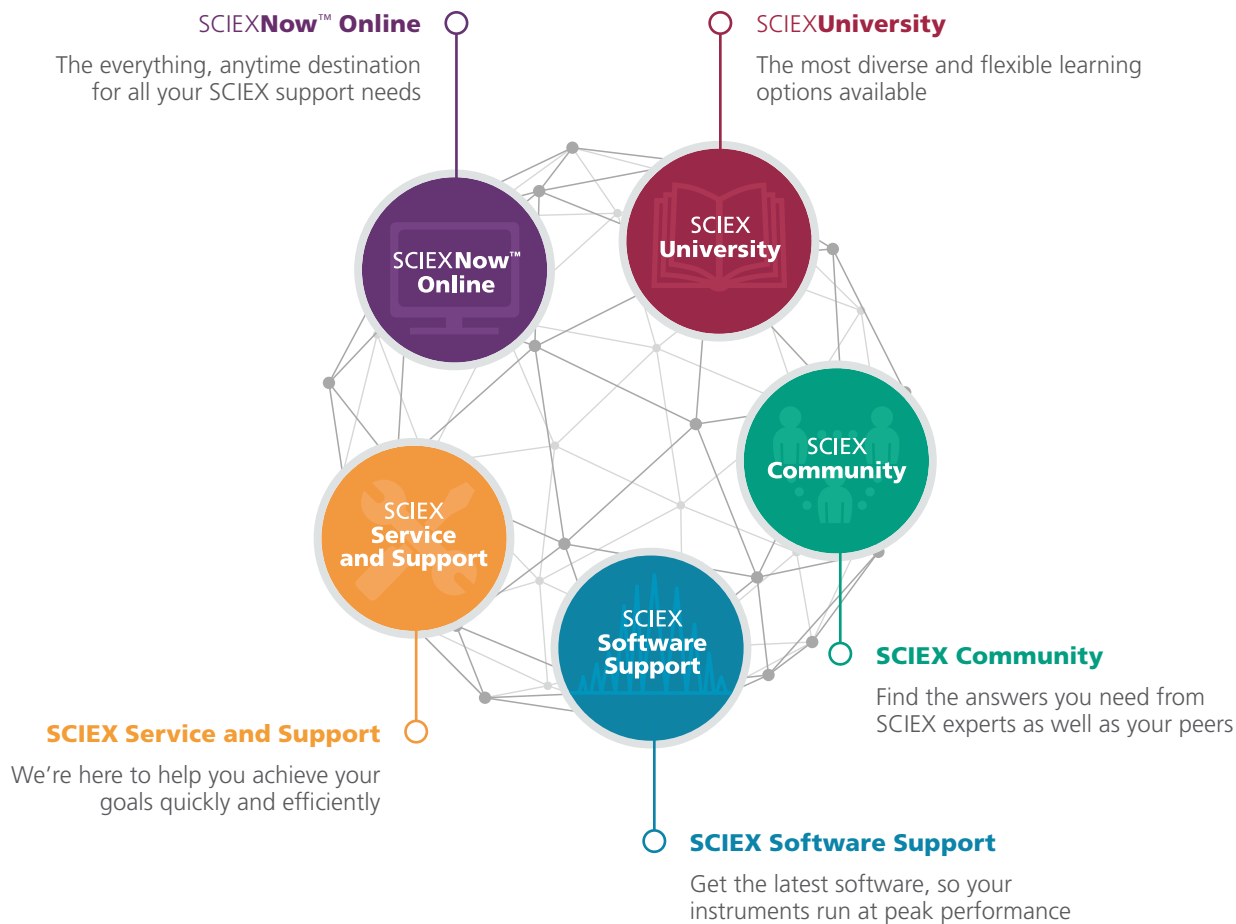
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