CEInfinite

Accelerate Your Biologics Development and

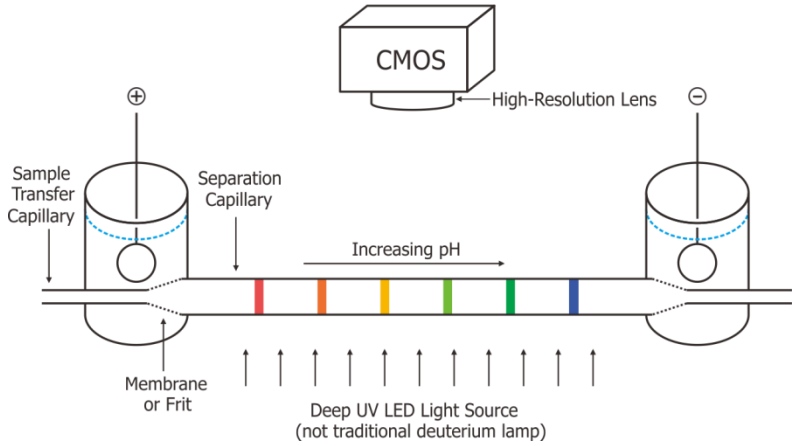
Protein Characterization

The Next Generation of iCIEF

The CEInfinite Instrument

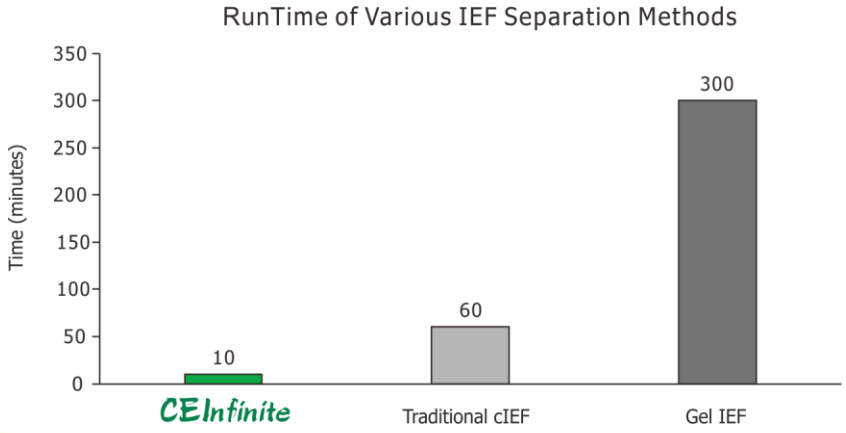
Imaged Capillary Isoelectric Focusing (iCIEF)

The CEInfinite system is based on proprietary whole column imaging detection (WCID) technology. A pH gradient is created using an electric field and carrier ampholytes, allowing proteins to separate along the capillary according to their isoelectric points (pIs). Highly efficient separation is achieved when proteins are focused into narrow zones in the pH gradient. An advanced scientific CMOS (sCMOS) image sensor and a deep UV LED light source is used to monitor real time separation in the column.



High Separation Efficiency

In comparison to traditional CIEF and gel electrophoresis, proteins separated with the CEInfinite instrument do not need mobilization and post-run staining steps which greatly shortens sample analysis time. Each run takes approximately 10 minutes, streamlining method development from months to hours and separation resolution can be as low as 0.01 pH.



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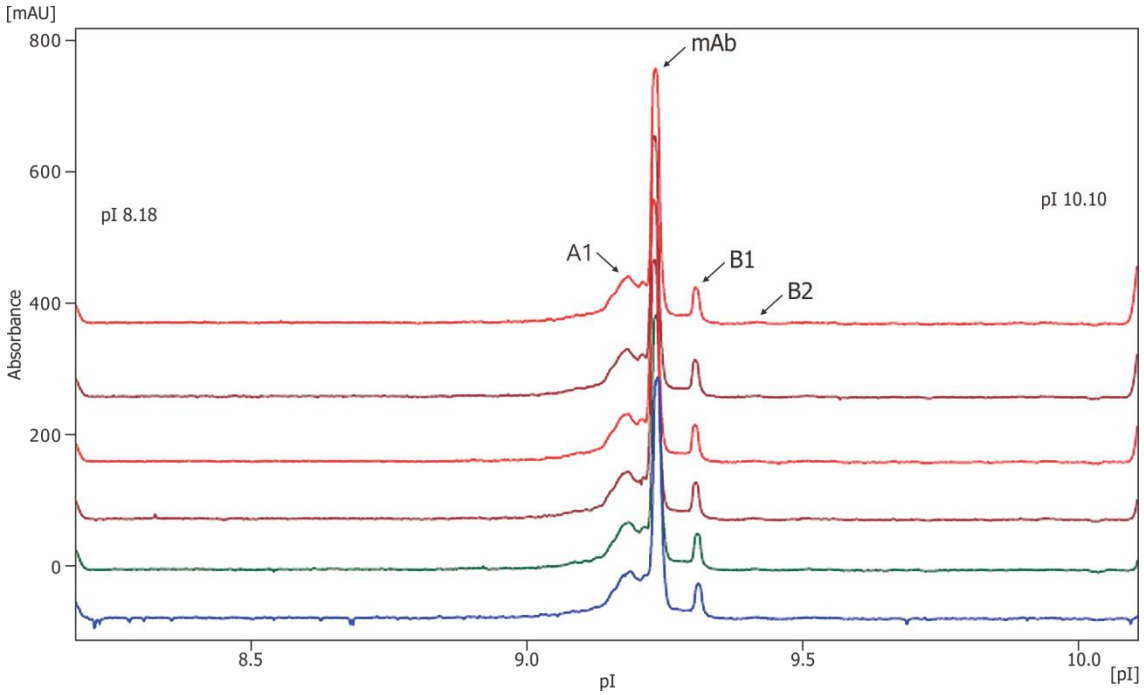
Protein Charge Heterogeneity Analysis

Protein charge heterogeneity profiling and characterization is essential to biologics development. This assay is performed quickly and easily, with little method development required, with the CEInfinite system. Results are generated with great reproducibility not only from within the same sample vial, but also across several sample vials, ensuring precision during both analysis and fractionation.



	pI		Peak Area	
	Average	% RSD	Average	% RSD
A1	9.18	0.06	32.67	1.63
mAb	9.23	0.00	59.62	0.82
B1	9.31	0.07	6.83	2.56
B2	9.41	0.05	0.92	13.42

iCIEF of NIST mAb taken from six different vials and the distribution of charge profiles

Total Solutions

Support for your CEInfinite instrument is available and includes novel applications such as high-resolution iCIEF fractionation, iCIEF coupling to MS, protein interaction studies, and Taylor dispersion rapid measurement of protein hydrodynamic radius.

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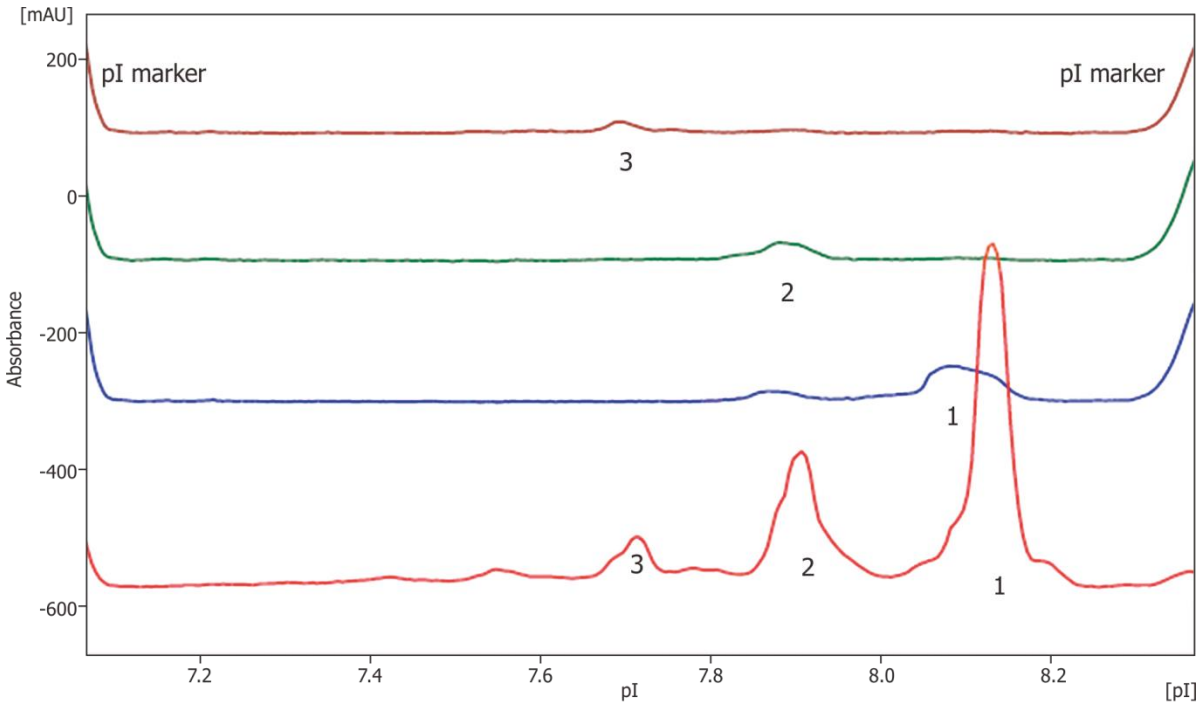
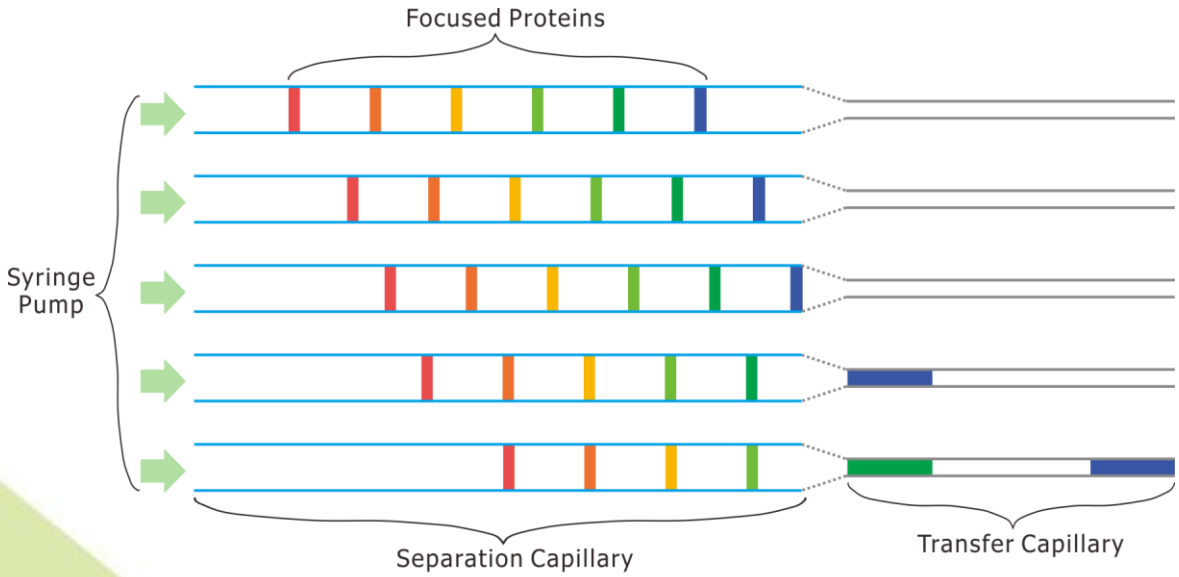
Isolate Products for Protein Characterization (Patent Pending)

The high resolution of the CEInfinite iCIEF system translates to the utmost purity of the final protein product. For example, proteins with a difference in pI of 0.2 or greater can be fractionated with greater than 80% purity. With the new CEInfinite 320 µm cartridge, one 45-minute run can yield up to 40 µg of purified protein.



iCIEF separation of mAb charge variants



Proprietary cartridges are designed to prevent peak remixing

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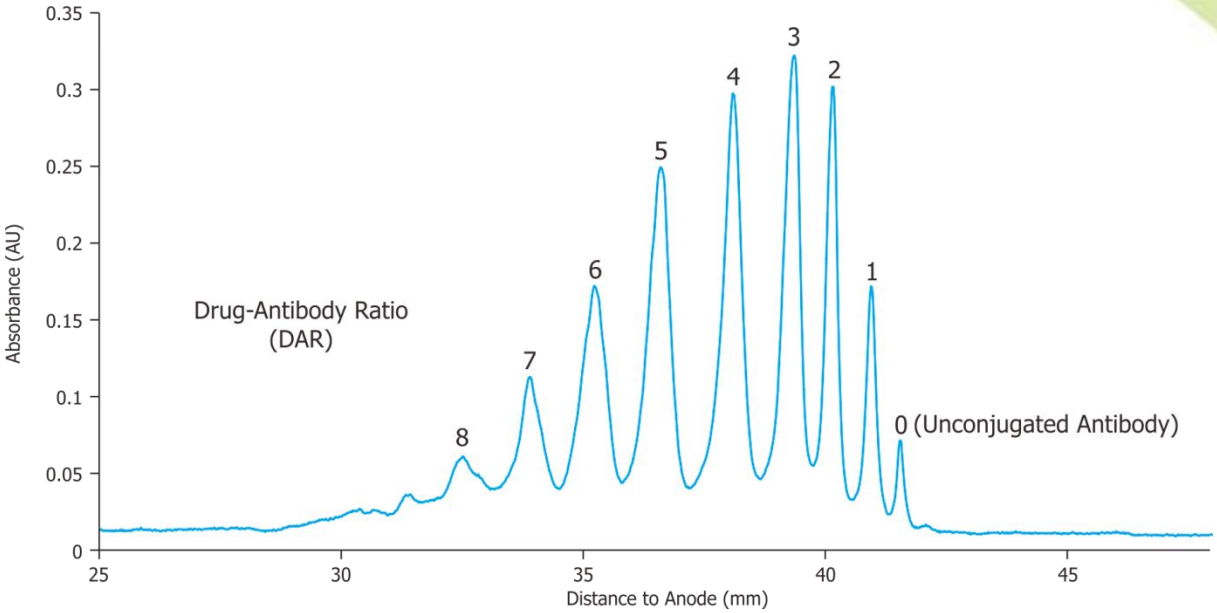
iCIEF Separation of Antibody-Drug Conjugates

The CEInfinite system also provides high-resolution separation of antibody-drug conjugates (ADCs).



Protein Molecular Characterization by iCIEF-MS

CEInfinite cartridges for iCIEF-MS preserve the great separation resolution of iCIEF. The use of a proprietary solvent during separation eliminates the need for urea and makes the protein fractions produced ready for MS with the interfacing technology available to connect the iCIEF-MS cartridge to an ESI source for MS.

CEInfinite Base, Analytical, and Preparative Systems

Three CEInfinite systems are currently available, each with high-performance iCIEF capabilities.

	Base	Analytical	Preparative
iCIEF Separation	✓	✓	✓
Whole Column Image Detection	✓	✓	✓
Autosampler	×	✓	✓
Pump	×	×	✓
Fractionation Capabilities	×	×	✓
iCIEF Coupled to Mass Spectrometry	×	×	✓

iCIEF Complete Consumable Product Line

Cartridges

CEInfinite cartridges are the world's first WCID imaging cartridges for direct coupling to a mass spectrometer. In addition to fluorocarbon (FC) and polyacrylamide (PA), proprietary acrylamide derivatives (AD) provide a highly reliable molecular layer coating suitable for separations between pH 2-11. These cartridges deliver high sensitivity and performance, and the easy flow along the capillary makes for simpler, faster sample injection with less clogging. Cartridges are available with various inner diameters for increased sensitivity and capacity.

AESlytes

AESlytes are synthesized strictly to ensure a high performance CIEF separation. Their low interaction with proteins increases resolving power and AESlytes do not strongly absorb UV, eliminating baseline noise. Finally, their linear pH gradient makes for a remarkably accurate pI calibration.

pI Markers

Reference standard isoelectric point (pI) markers are essential for calibrating your iCIEF. The CEInfinite system brings you the most comprehensive, evenly spaced, and thoroughly calibrated pI markers in the world. All CEInfinite pI markers come in a ready-to-use 100X concentration and have long shelf lives, reducing waste and saving you restocking time.

Electrolytes & Polymer Solutions

Manufactured under strict quality control guidelines, CEInfinite consumables will save you time as well and eliminate variability for a more reproducible result. All CEInfinite test kits, electrolytes, and methylcellulose solutions are fully tested and certified.

Product Specifications

iCIEF Instrument

Detection Mode	Whole column, sCMOS imaging technology
Height x Width x Depth	54 cm x 33 cm x 30 cm
Weight	30 pounds (14 kg)
Detection Dynamic Range	250 (0.004 – 1.0 AU, 280 nm)
High Voltage Range	0 – 3000 Volts (Continuously Adjustable)
Sample Throughput	Up to 12 injections per hour
Working Temperature	15 - 35°C
Humidity	20 - 80% RH
Electrical Requirement	100/240 VAC, 50 - 60 Hz
Exposure Time	0.02 – 99.9 ms
ADC Maximum	16386 AU
Operation Mode	Manual or Automatic
Detector Noise	Less than 0.001 AU, 280 nm
Separation pH Range	2.1 – 11.1

Autosampler

Model	840
Sample Capacity	84+3 vial tray, 96 well plate
Sample Tray Temperature	4 - 40°C
Typical Sample Volume	15 µL
Electrical Requirement	95 – 240 VAC, 50 – 60 Hz
Height x Width x Depth	36 cm x 30 cm x 57.5 cm
Weight	46 pounds (21 kg)
Working Temperature	10 - 40°C
Humidity	20 – 80% RH

Syringe Pump

Syringe Size	250 µL
Electrical Requirement	100 – 240 VAC, 50 – 60 Hz
Height x Width x Depth	12.14 cm x 10.8 cm x 24.1 cm
Weight	2.72 pounds (1.23kg)
Working Temperature	5 – 40°C
Humidity	20 – 80% RH

Software

CEInsight software fully controls the CEInfinite system with a user-friendly GUI. The CFR control and quantitation software provides reliable operation control, highly efficient data processing, and FDA Title 21 CFR Part 11 compliance.

Advanced Electrophoresis Solutions (AES) Ltd.

AES is a company dedicated to providing whole column imaging detection capillary electrophoresis systems, reagents and consumables. AES' total solution encompasses a variety of CEInfinite products and support, which enables clients to focus on protein separation, quantification, and characterization.

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