

AES Products and Technologies Introduction

CE Pharm 2022

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CCO

Innovations Make Breakthrough Solutions



CE Infinite

Multi-function iCIEF Platform



iCIEF-MS online coupling

Robust and simple characterizations

Fractionations

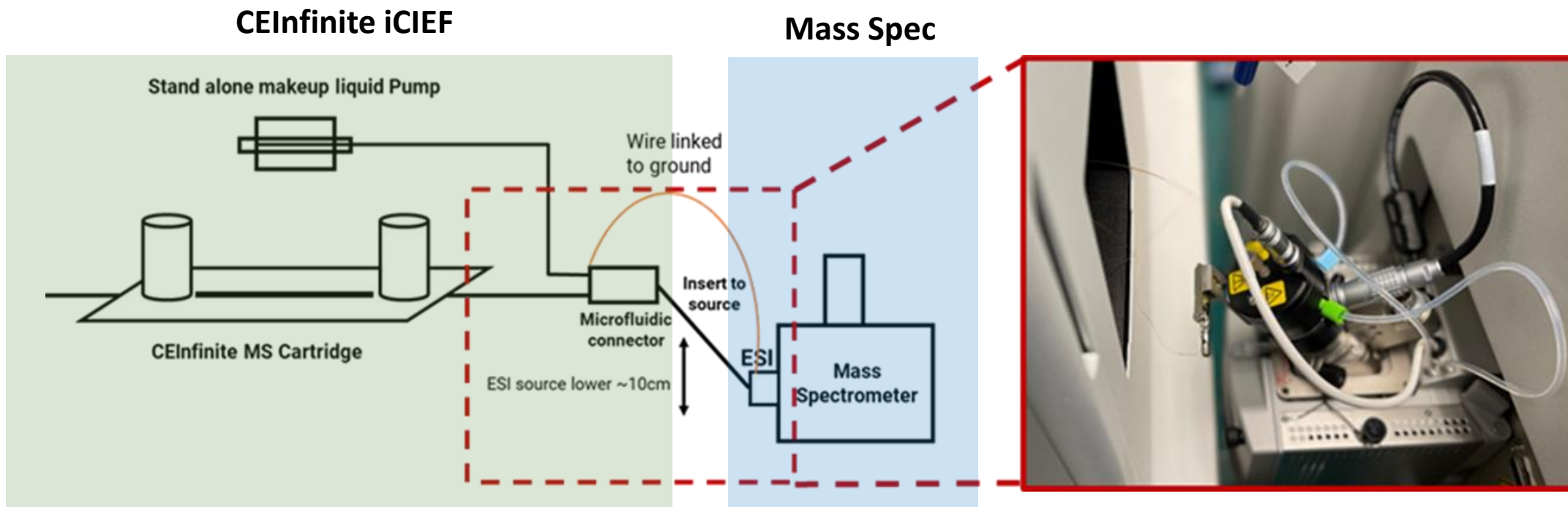
An automated preparative iCIEF.

Analytical iCIEF

Superior performance for QA/QC

iCIEF- Mass Spec online coupling

iCIEF- Mass Spec online coupling



- ✓ ICIEF-MS cartridge and connector allow fast connection without modification
- ✓ Directly couple with major brands of mass spectrometer on the market, ex. Thermo Fisher orbitrap
- ✓ Unique coatings and chemicals accelerate the drug development process, no methyl cellulose needed.
- ✓ Rapidly and cost-effectively obtain detailed characterization information at different stage of development
- ✓ Provides significant information about the quality of the drug substance within 30mins.

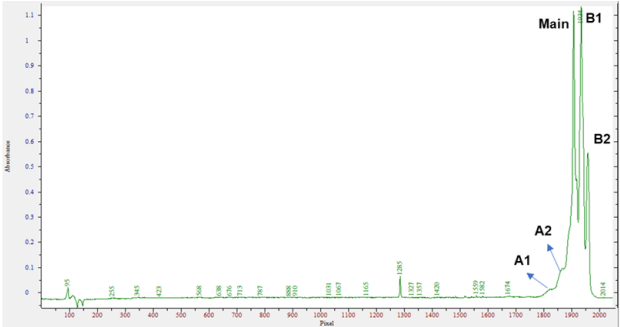
iCIEF-MS online example: intact BsAb

iCIEF

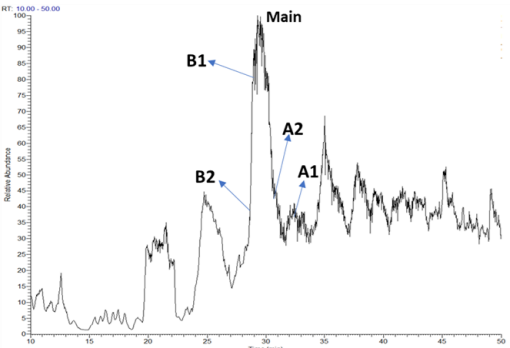


TIC

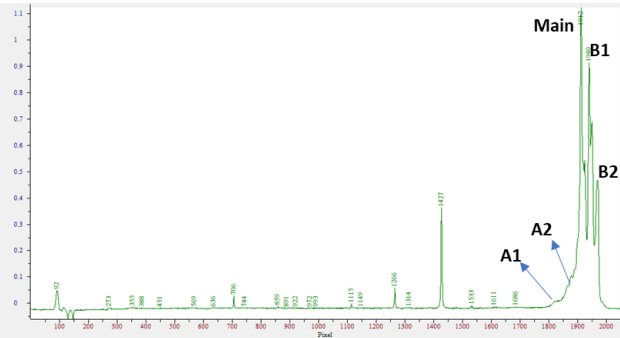
Run-1 (UV)



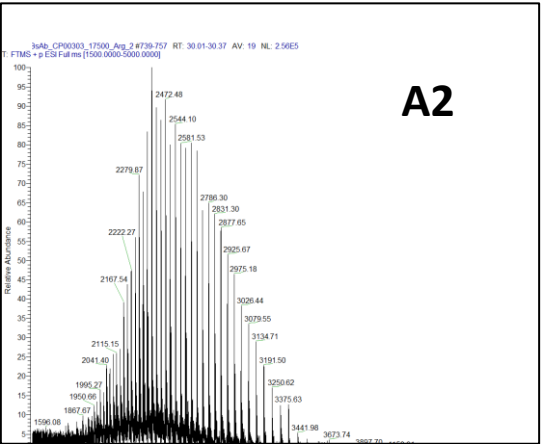
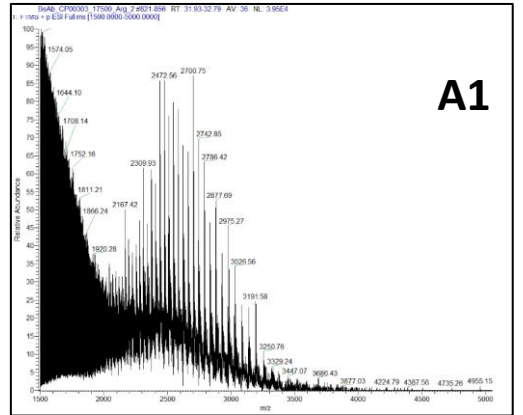
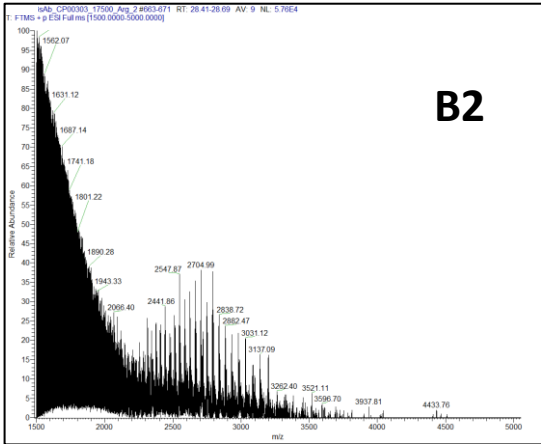
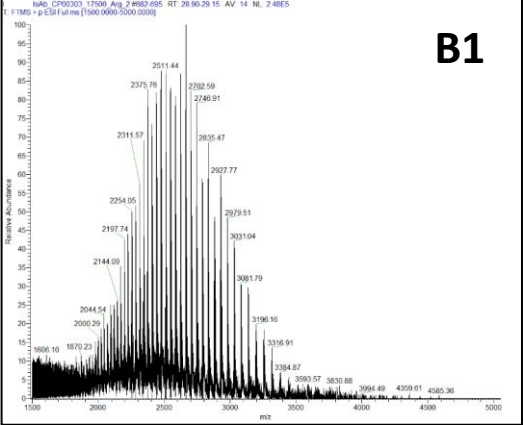
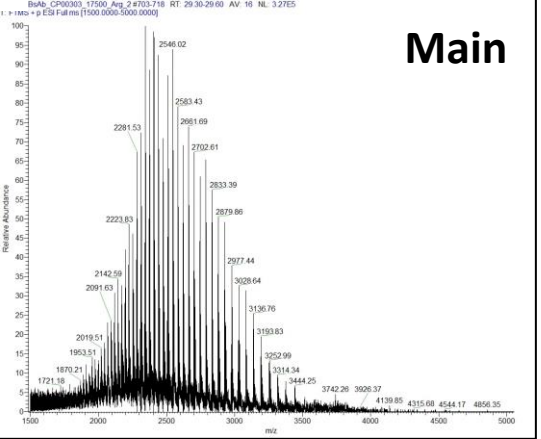
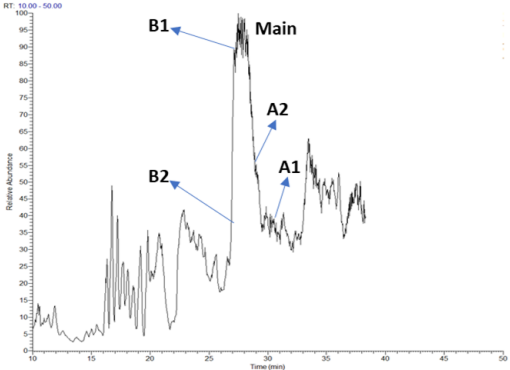
Run-1 (TIC)



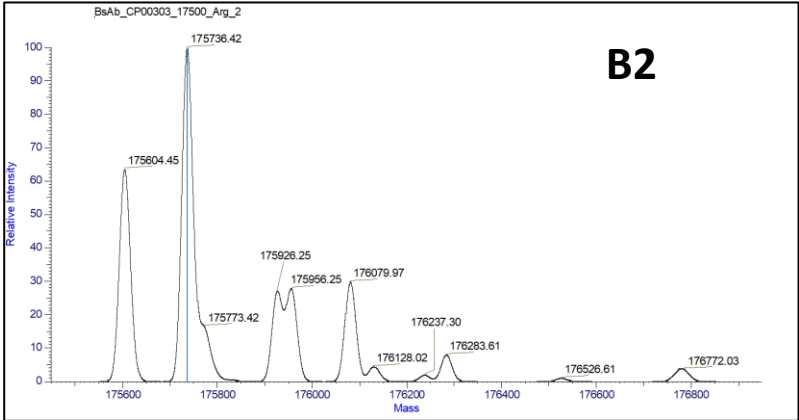
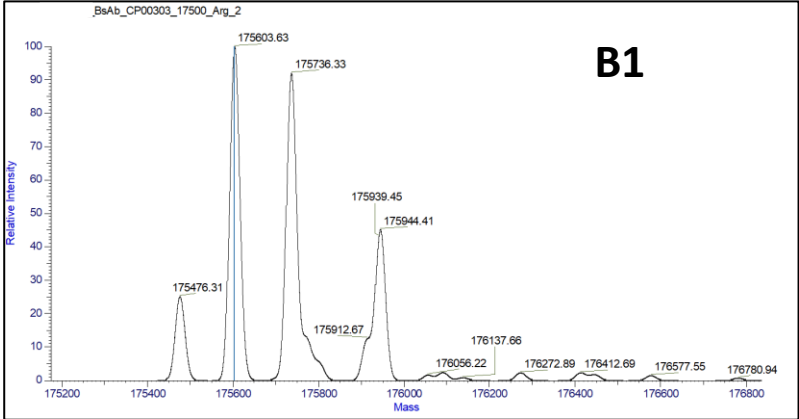
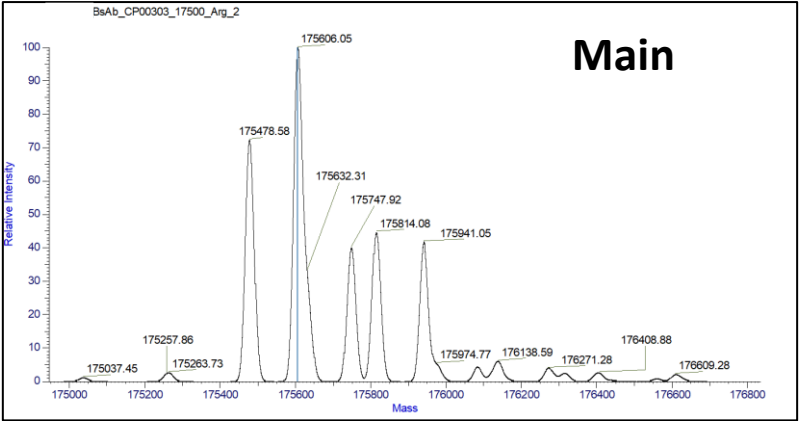
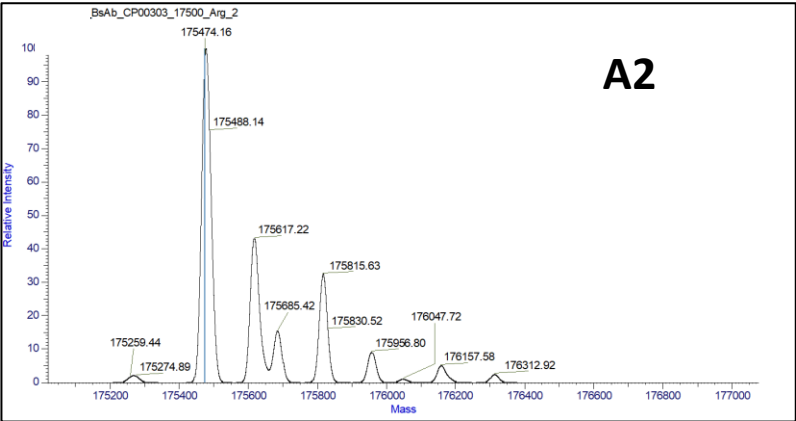
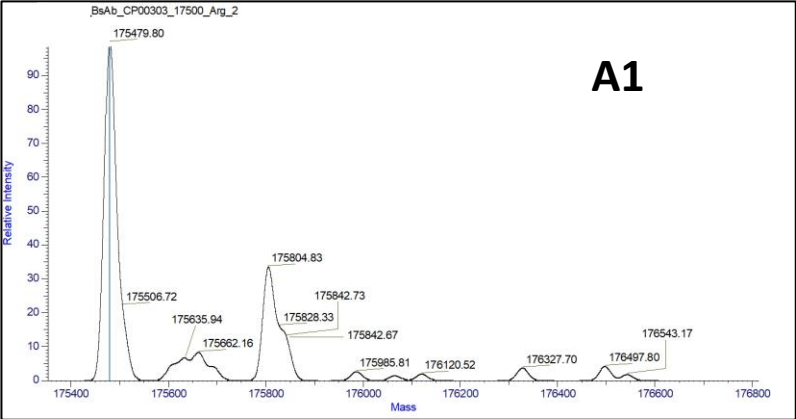
Run-2 (UV)



Run-2 (TIC)

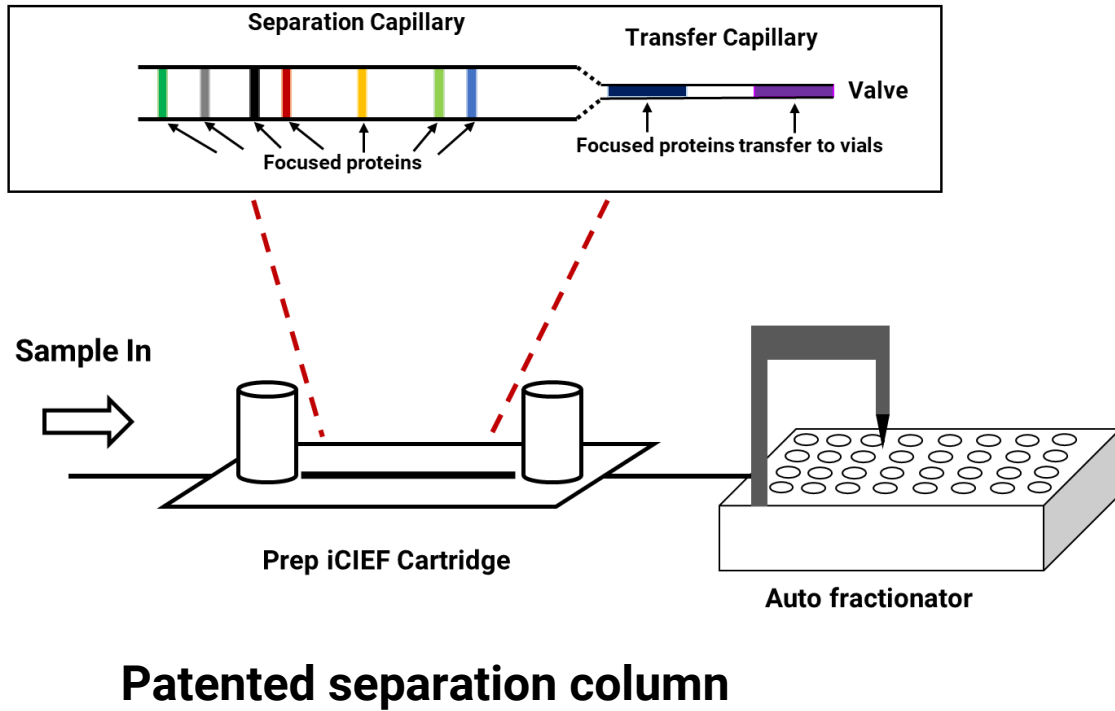


Deconvoluted results



iCIEF automated fractionations

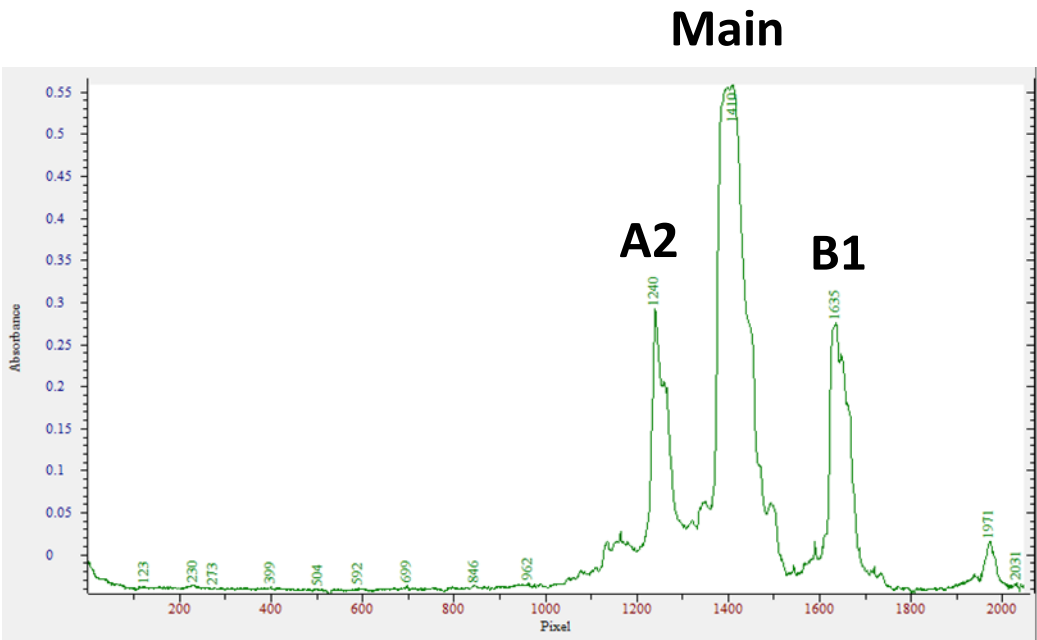
CEInfinite iCIEF Auto fractionation model **Upgraded!**



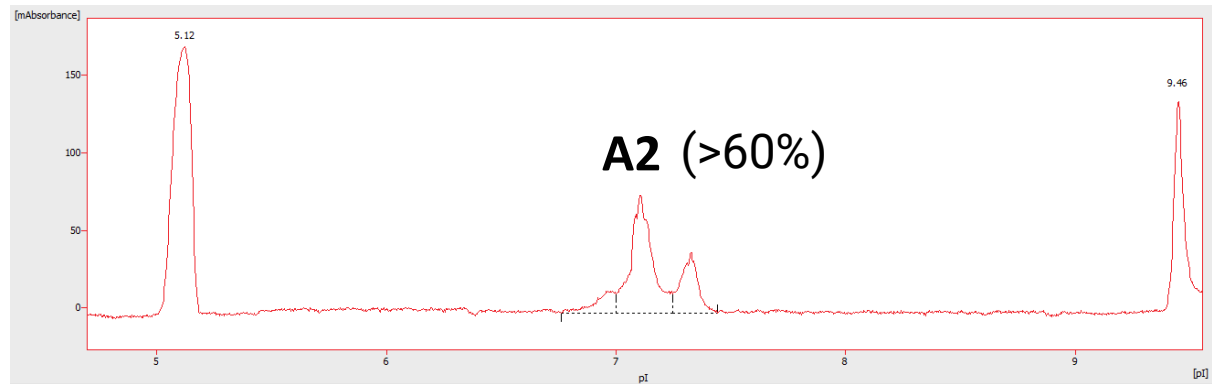
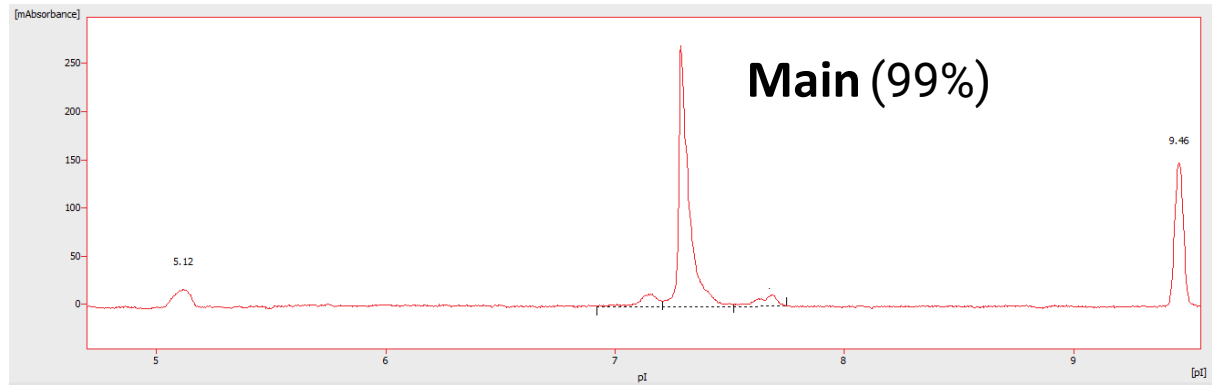
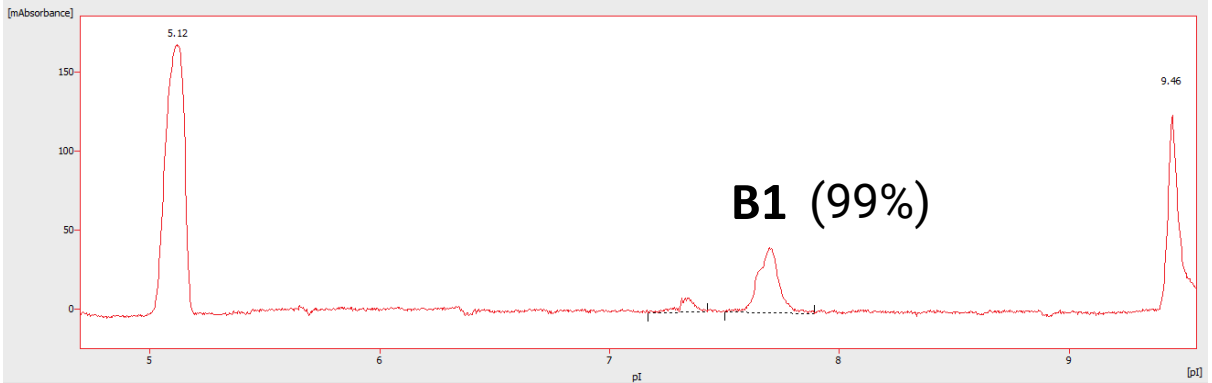
Highlights:

- Fractionation resolution: **<0.1 pI** difference.
- Achieve charge isomer as high as **90%** purity.
- Temperature controlled, automated system allows up to **96** fractions per run.
- Get as high as **8 µg** isomer per run. **~100 µg** collections per day.
- **Minimum** requirement of additional R&D derived from iCIEF platform method.

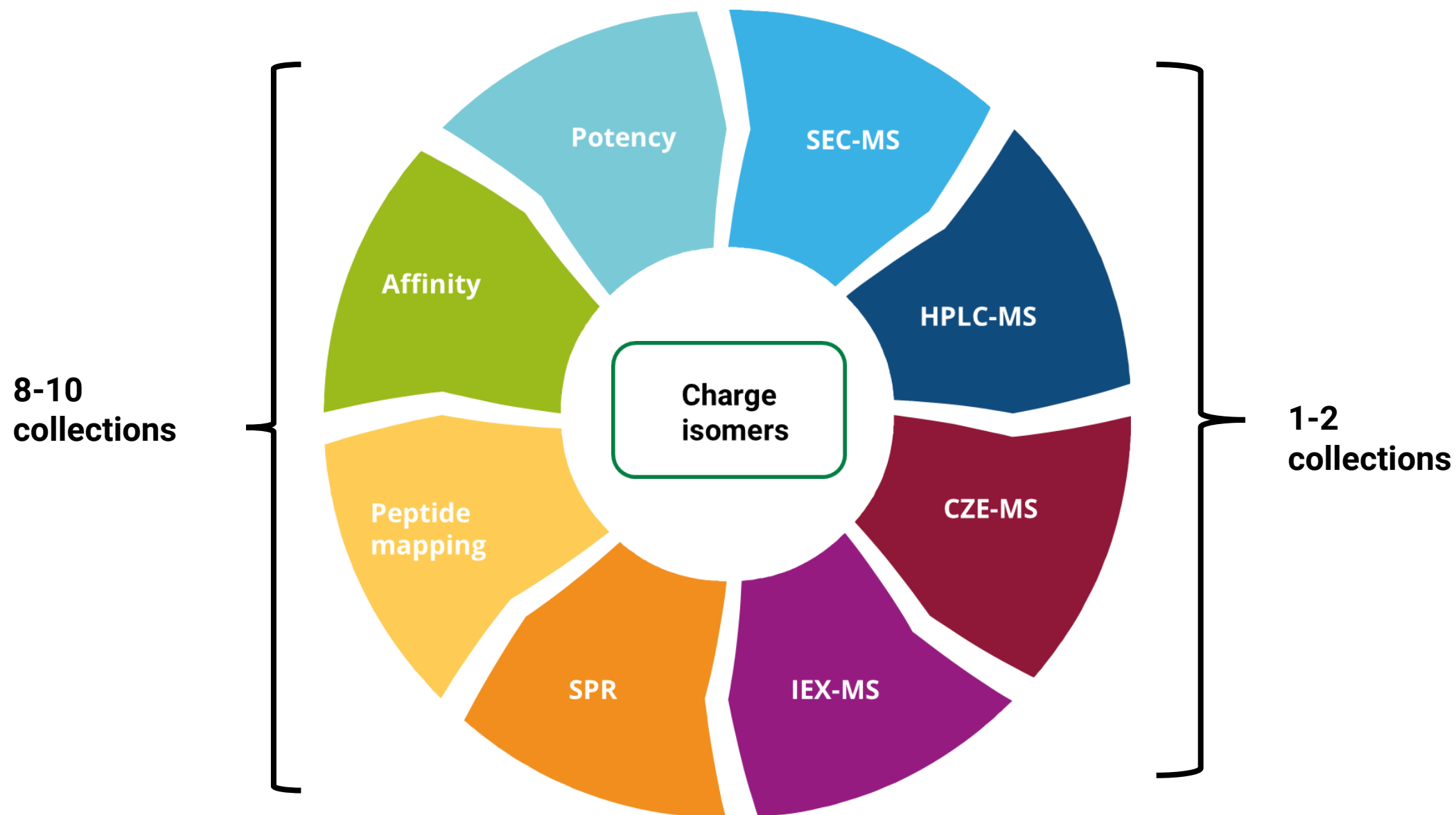
Fractionation example: Mab



Mab iCIEF profile in preparative mode



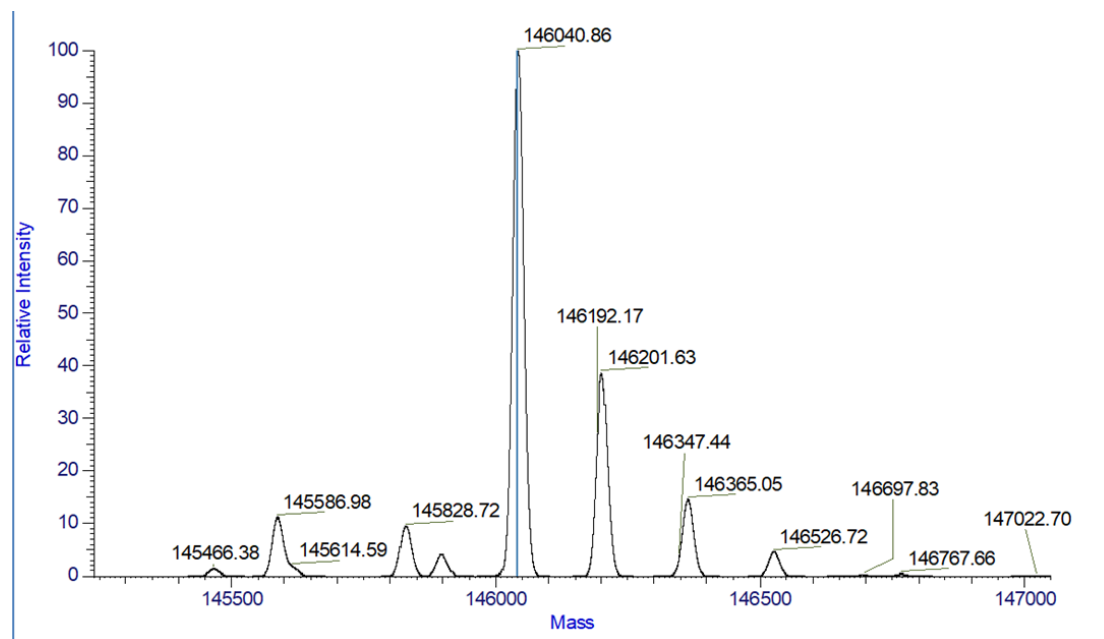
In-depth characterization with intact protein charge isomers



Comparison between iCIEF-MS online characterization and offline fractionation

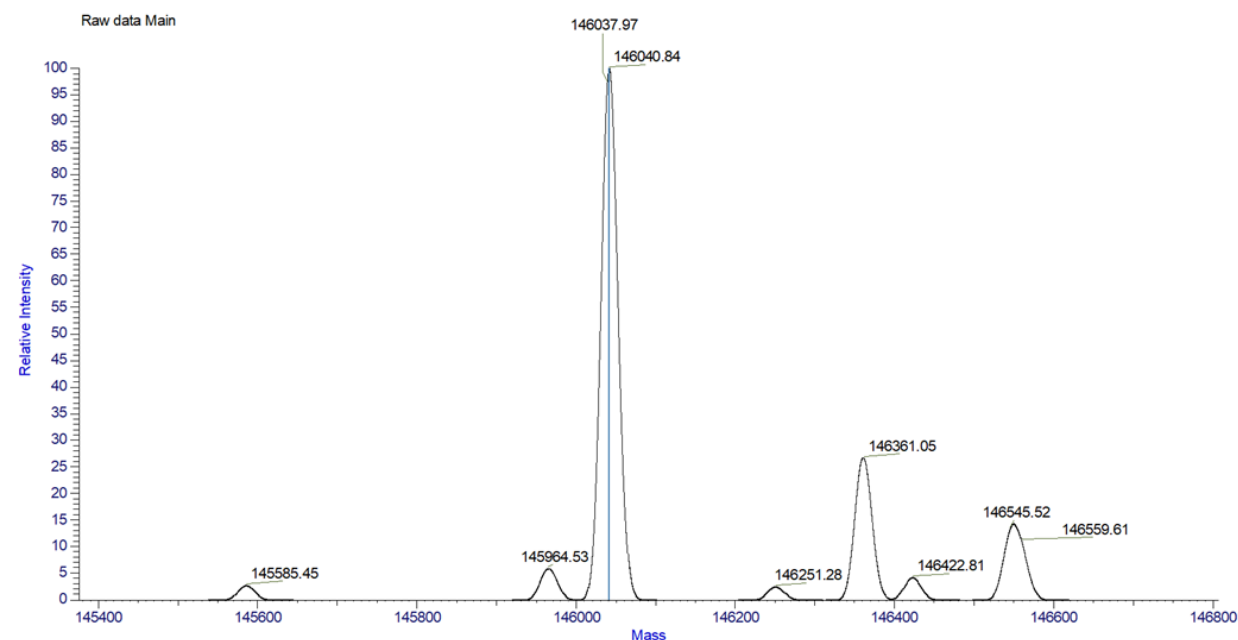
Intact mass

Main MW: 146040.86



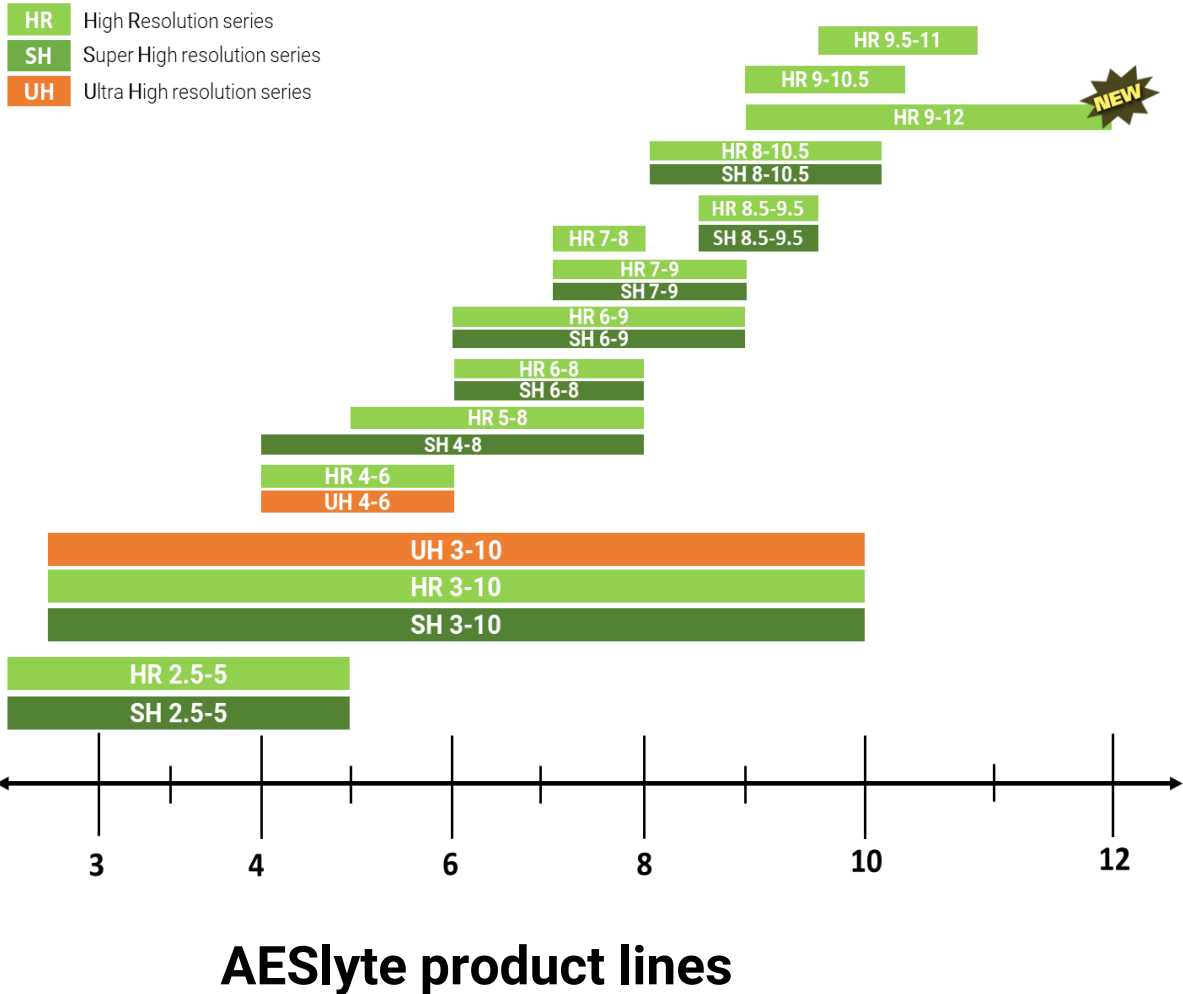
iCIEF-MS online coupling

Main MW: 146040.84

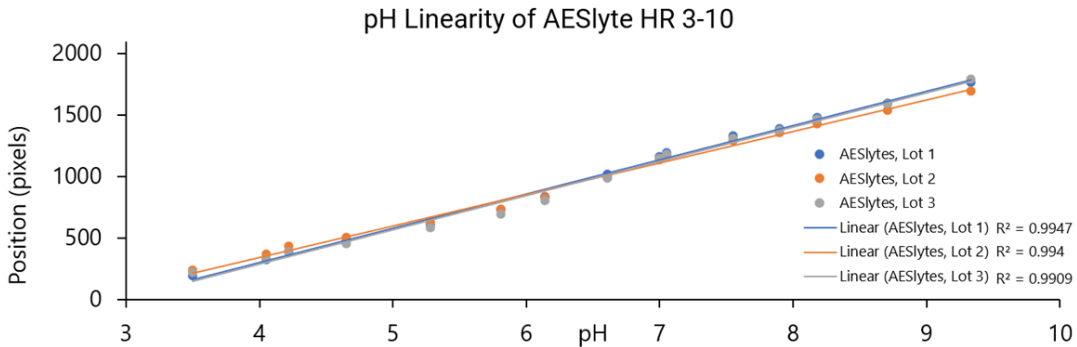


iCIEF fraction then HPLC-MS

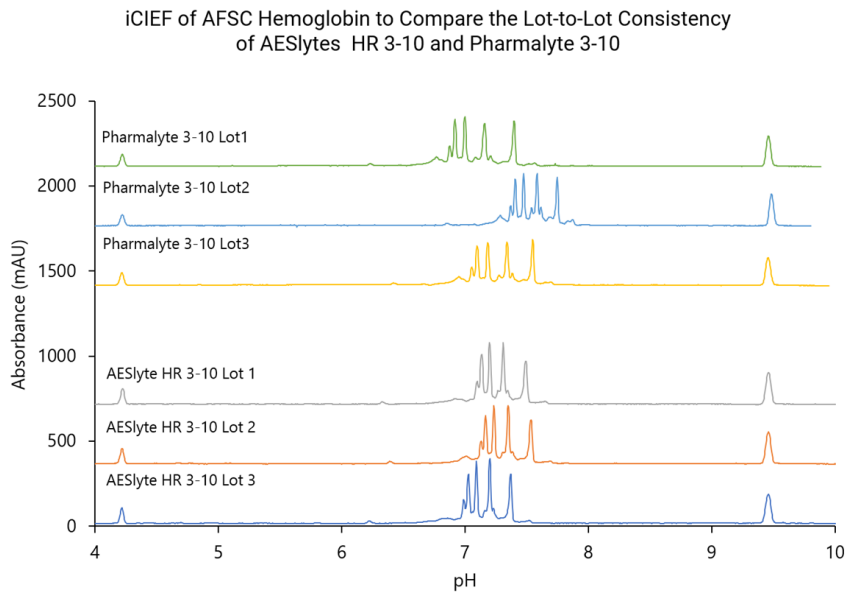
Analytical iCIEF with optimized reagents and coatings



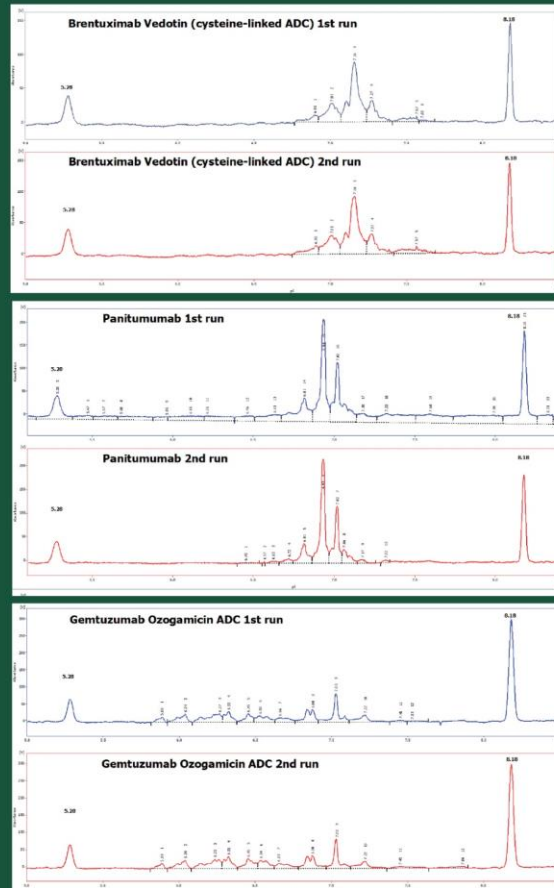
Good pH gradient linearity



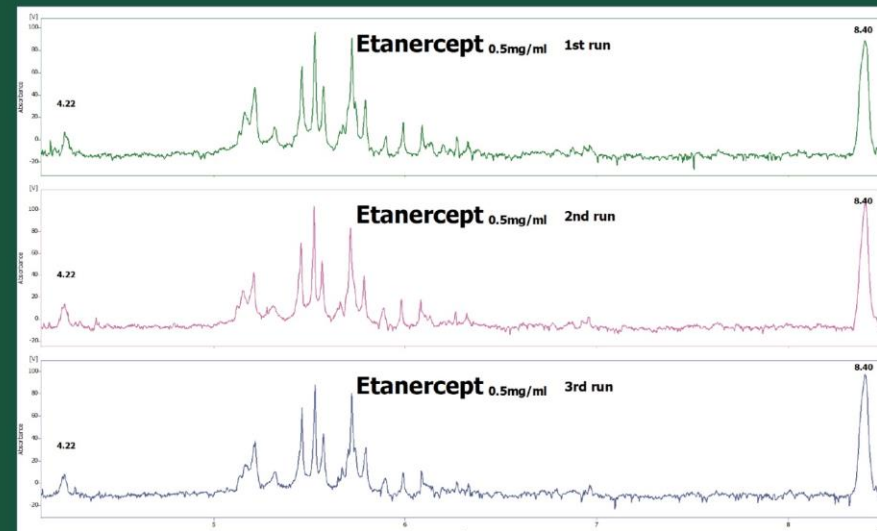
Good lot to lot sample egram consistency



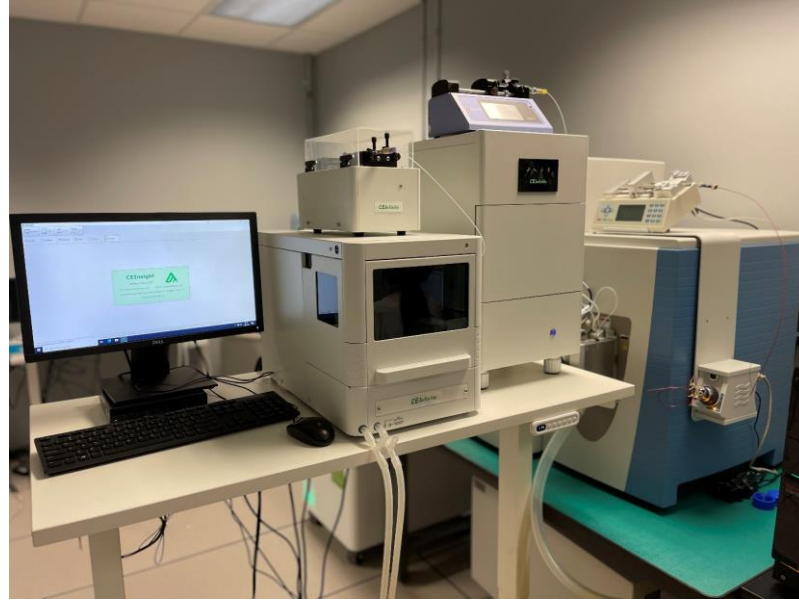
Superior performance iCIEF for Next Generation Therapeutics:



- Gene Therapy
- Cell Therapy
- Enzyme
- mRNA
- Lentivirus vector
- AAV
- mAbs
- ADCs
- Fusion proteins
- BsAbs
- LNP



AES Service



6000 sqft lab: for fractionation and iCIEF-MS online service and demo



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