

# Risk Assessment for Critical Method Parameters in cIEF Method -Changes in Chemicals and Instruments

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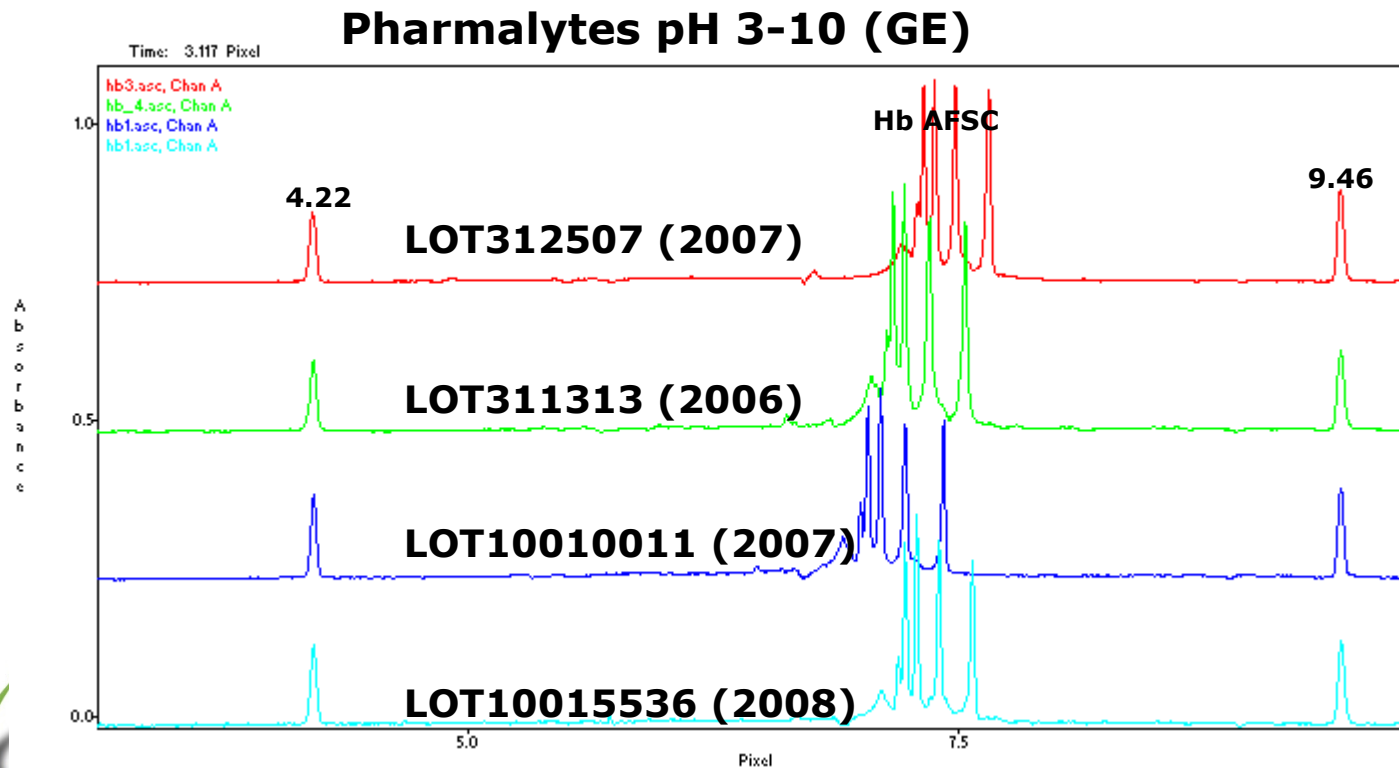
# Significant Changes

- Change is inevitable
- Identify significant changes
- Be prepared –If we can predict the changes based on knowledge and experience

# Changes in Reagents

- Carrier ampholytes
  - Different lots of the same brand names
  - Different brand names (one brand name was discontinued)
- pI markers
  - Protein markers
  - Small molecule markers
  - Different vendors

# Carrier Ampholytes -Different Lots, Same Brand Names

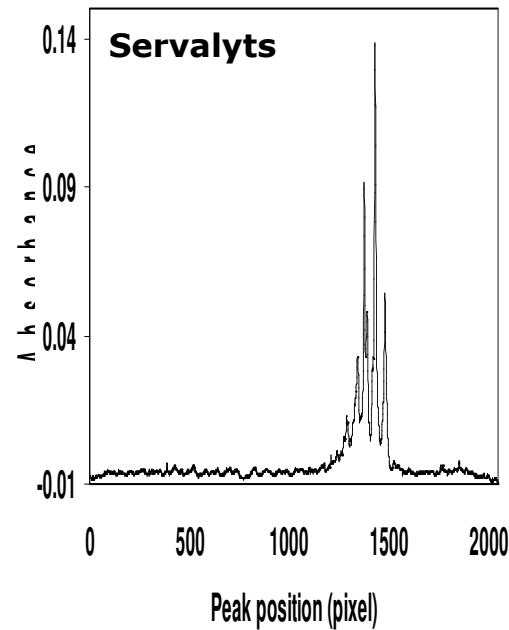
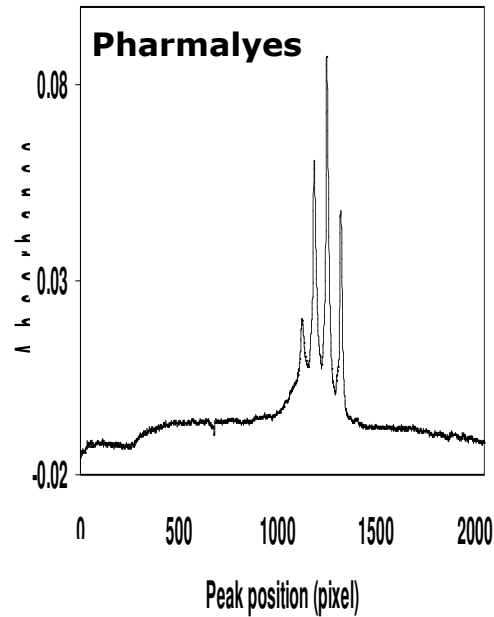


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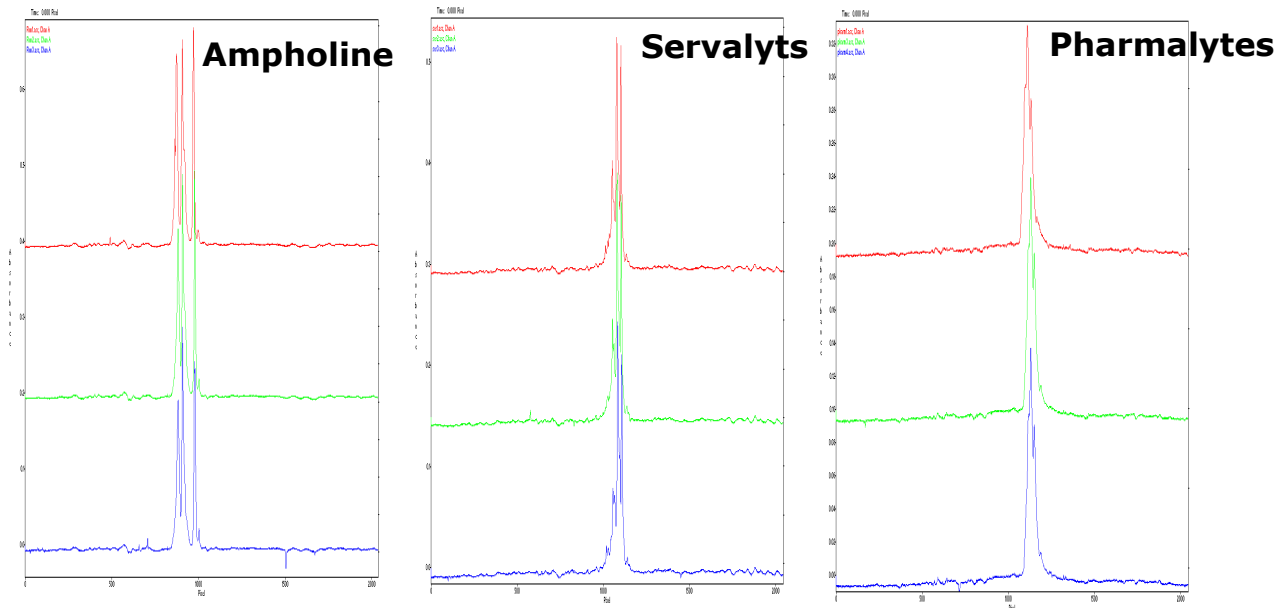
# Carrier Ampholytes -Different Brand Names

Sample: a mAb



# Carrier Ampholytes -Different Brand Names

Sample: a mAb



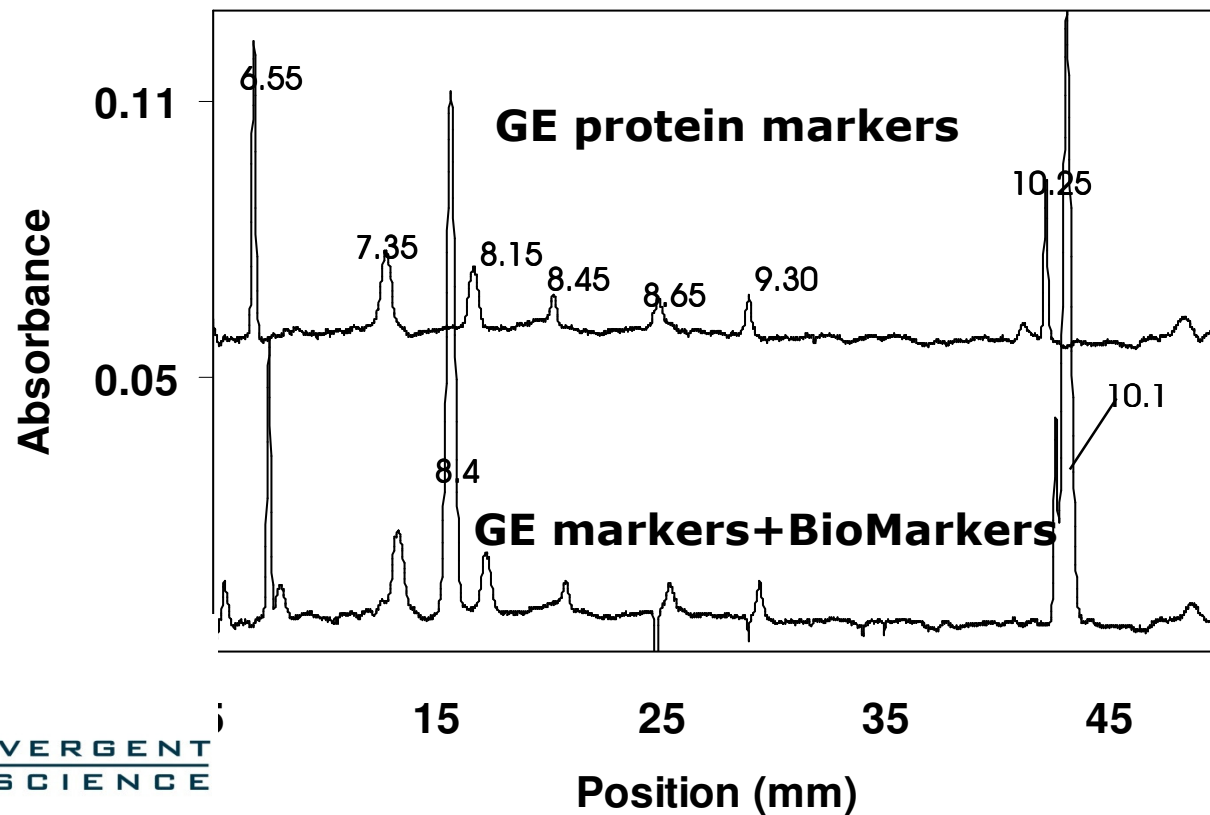
pI →



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# pI Markers -Protein vs Small Molecule



# pI Markers -Different Vendors

## Measured pI values of a mAb

	pI Markers 6.4, 8.6 (Bio-Rad)					6.14, 8.79 (Convergent Bioscience)				
Average (n = 9)	7.608	7.772	7.978	8.25	8.47	7.74	7.895	8.09	8.34	8.548
SD	0.004	0.004	0.004	0	0	0	0.005	0	0	0.004
%CV	0.053	0.051	0.05	0	0	0	0.063	0	0	0.047

# Changes in Chemicals -???

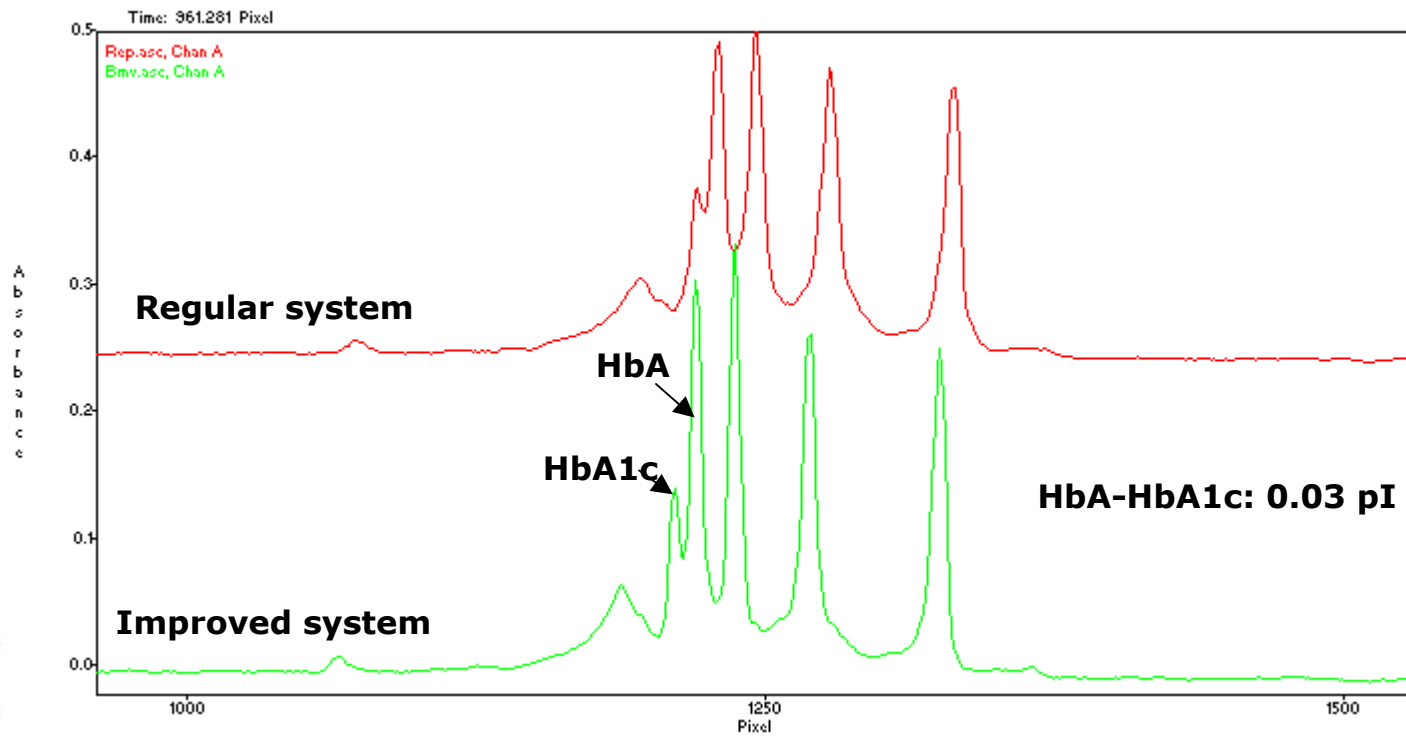
➤ ??

➤ ??

# Changes in Instruments

- Better (different) resolution
- Higher (different) sensitivity

# Better Resolution



# Higher Sensitivity

- May see things that could not seen before

# Other Changes in Instruments???

➤ ???

## Suggested Solutions

- Different lots of same brand names of carrier ampholytes
  - Leave enough room for pI specification
  - Always compare to ref
- Different brand name carrier ampholytes
  - Test all available CAs –ensure that more than one CAs give similar peak pattern
- Different pI marker systems
  - Leave enough room for pI specification
  - Always compare to ref



## Solutions? (cont'd)

- Higher resolution
  - Group peaks
  - ?
- Higher sensitivity
  - ?
- ?
  - ?

# Convergent Bioscience's Commitment

- System & Software Performance
  - Continuous and ongoing improvement
  - *Make the best better*



# Convergent Bioscience's Commitment

- Understand regulated environments
  - Recognize potential impacts
  - Respect the evaluation and implementation process
  - *Collaborate early and extensively*

