CE-SDS Comparability Study

Maurice and MauriceFlex Systems for Biotherapeutic Analysis

The Maurice™ and MauriceFlex™ systems are capillary electrophoresis (CE) instruments designed for protein separation based on charge or size. The MauriceFlex system also enables the fractionation of individual protein charge variants for offline characterization using mass spectrometry and binding potency analysis using surface plasmon resonance. For size-based analysis, Maurice and MauriceFlex utilize capillary electrophoresis-sodium dodecyl sulfate (CE-SDS) to assess protein purity and fragmentation. This technical note presents a comparative study of CE-SDS performance between the Maurice and MauriceFlex systems across four different biotherapeutic modalities, including a bispecific antibody (BsAb), monoclonal antibody (mAb), a fusion protein, and an adeno-associated virus (AAV). Another study compares the performance of both these systems for protein charge (icIEF) analysis[1].

Materials

All materials used in this study are listed in **Table 1**

Material	Vendor	Catalog #
Lunsumio® (Mosunetuzumab)	Genentech	NA
Benlysta® (Belimumab)	GlaxoSmithKline	NA
Orencia® (Abatacept)	Bristol Myers Squibb	NA
AAV9 (2 x ^{10}13 VP/mL)	Virovek	NA
Maurice System	Bio-Techne	**090-000**
MauriceFlex System		**090-158**
Maurice CE-SDS PLUS Cartridge		**PS-MC02-SP**
Maurice Turbo CE-SDS™ Cartridge		**PS-MC02-TS**
Maurice CE-SDS PLUS Application Kit*		**PS-MAK03-S**
Maurice Turbo CE-SDS Application Kit*		**PS-MAK01-TS**
Acetone	Millipore Sigma	100014
Iodoacetamide (IAM)		16125
β-Mercaptoethanol (β-ME)		M-3148

Table 1. Materials and reagents used in this study.

*The Maurice CE-SDS PLUS and Turbo CE-SDS Application Kits contain all the necessary reagents for CE-SDS analysis with the CE-SDS PLUS and Turbo CE-SDS cartridges, respectively.

Methods

Details for each sample are provided in the Results section, along with their corresponding datasets. It should be noted that each prepared sample was split into two equal parts and loaded onto the Maurice and MauriceFlex systems respectively for parallel analysis. Samples were analyzed with the Maurice CE-SDS PLUS and Maurice Turbo CE-SDS cartridges, both of which were run on each instrument. Standard running conditions for each cartridge were used, as described below. Detection was in absorbance modes (220 nm) and all data were analyzed using Compass for iCE software v4.4. In this document, data generated with the CE-SDS PLUS cartridge are shown.

Run conditions:

CE-SDS PLUS: Injection for 20 seconds at 4600 V, then separation for 35 minutes (non-reduced) or 25 minutes (reduced) at 5750 V.

Turbo CE-SDS PLUS: Injection for 8 seconds at 3500 V, then separation for 8 minutes (non-reduced) or 5.55 minutes (reduced) at 4200 V.

Results

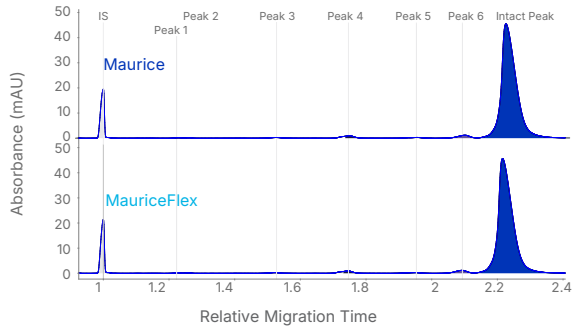
Mosunetuzumab (BsAb)

The BsAb sample was diluted to 0.5 mg/mL using the Maurice 1X CE-SDS PLUS Sample Buffer. The Maurice CE-SDS 25X Internal Standard (IS, 4%) was added to all samples, followed by the addition of 5% (V/V) of either IAM (250 mM) for non-reduced analysis, or β-ME (14.2 M) for reduced analysis. All samples were then heated for 10 minutes at 70°C, cooled on ice for five minutes, and finally subjected to centrifugation. Samples analyzed with Turbo CE-SDS were diluted with deionized water (1:1). Samples were loaded on to the Maurice and MauriceFlex instruments and run using standard conditions as described above.

CE-SDS PLUS

Figures 1A and **1B** show representative electropherograms of Mosunetuzumab analyzed with the CE-SDS PLUS cartridge under non-reduced and reduced conditions, respectively. Each figure allows for a comparison of profiles between Maurice and MauriceFlex, demonstrating similar inter-instrument results. The percent peak area (%PA) values for Mosunetuzumab are listed in **Tables 2** and **3** for non-reduced and reduced samples, respectively. **Tables 4** and **5** show %PA from the analysis of Mosunetuzumab with the Turbo CE-SDS cartridge on both instruments. %RSD values are shown for peaks that are >1% PA.

1A



1B

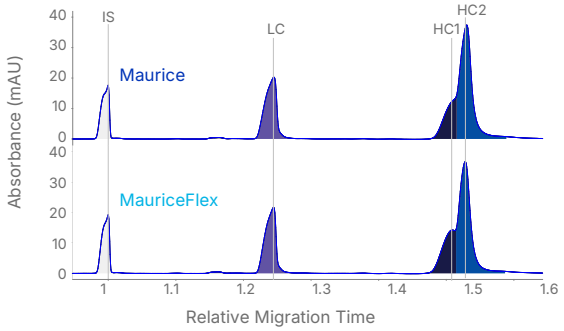


Figure 1. A comparison of Mosunetuzumab size profiles between Maurice and MauriceFlex systems using the CE-SDS PLUS cartridge. A. Analysis under non-reduced conditions shows the intact peak along with some minor peaks. **B.** Analysis under reduced conditions shows the light chain (LC) and a heavy chain which resolves into two peaks (HC1 and HC2). Under each running condition, the performance between the Maurice and MauriceFlex systems is highly comparable.

Mosunetuzumab Percent Peak Area (CE-SDS PLUS, Non-Reduced)							
Maurice (n=4)							
	Peak 1	Peak 2	Peak 3	Peak 4	Peak 5	Peak 6	Intact Peak
Average	0.26	0.20	0.54	2.09	0.59	2.17	94.15
Std. Dev	0.02	0.02	0.02	0.01	0.01	0.04	0.03
%RSD	-	-	-	**0.66**	-	**2.04**	**0.04**
MauriceFlex (n=4)							
Average	0.28	0.20	0.54	2.07	0.60	2.23	94.07
Std. Dev	0.02	0.03	0.02	0.03	0.01	0.09	0.15
%RSD	-	-	-	**1.24**	-	**3.86**	**0.16**

Table 2. %RSD values of intact Mosunetuzumab analyzed with CE-SDS PLUS under non-reduced across both systems are within acceptable ranges and comparable (highlighted in bold), indicating consistent performance.

Mosunetuzumab Percent Peak Area (CE-SDS PLUS, Reduced)			
Maurice (n=4)			
	LC	HC2	HC1
Average	32.55	50.90	16.55
Std. Dev	0.06	0.44	0.44
%RSD	**0.18**	**0.86**	**2.68**
MauriceFlex (n=4)			
Average	31.73	48.50	19.75
Std. Dev	0.15	0.16	0.10
%RSD	**0.47**	**0.34**	**0.51**

Table 3. %RSD values of Mosunetuzumab analyzed with CE-SDS PLUS under reduced conditions across both systems are within acceptable ranges and comparable for the LC and HC (highlighted in bold), once again demonstrating comparable performance of Maurice and MauriceFlex.

Mosunetuzumab Percent Peak Area (Turbo CE-SDS, Non-Reduced)							
Maurice (n=6)							
	Peak 1	Peak 2	Peak 3	Peak 4	Peak 5	Peak 6	Intact Peak
Average	0.23	0.68	0.53	1.98	0.58	2.63	93.38
Std. Dev	0.16	0.21	0.08	0.12	0.12	0.08	0.44
%RSD	-	-	-	**5.89**	-	**3.10**	**0.48**
MauriceFlex (n=6)							
Average	0.02	0.58	0.60	2.10	0.67	2.75	93.25
Std. Dev	0.04	0.08	0.06	0.06	0.05	0.05	0.14
%RSD	-	-	-	**3.01**	-	**1.99**	**0.15**

Table 4. %RSD values of Mosunetuzumab analyzed under non-reduced conditions across both systems are well within suitable ranges for the intact peak and comparable between both systems (highlighted in bold), indicating highly reproducible performance of the Turbo CE-SDS cartridge.

Mosunetuzumab Percent Peak Area (Turbo CE-SDS, Reduced)			
Maurice (n=6)			
	Peak 1	LC	HC
Average	0.98	35.43	63.27
Std. Dev	0.19	0.16	0.20
%RSD	-	**0.46**	**0.31**
MauriceFlex (n=6)			
Average	0.40	36.88	62.55
Std. Dev	0.09	0.53	0.33
%RSD	-	**1.43**	**0.53**

Table 5. %RSD values of Mosunetuzumab LC and HC peaks analyzed under reduced conditions across both systems are well within suitable ranges (highlighted in bold), indicating highly reproducible performance of the Turbo CE-SDS cartridge on both Maurice and MauriceFlex systems.

AAV9

50 µL of the AAV9 sample was mixed with cold acetone (250 µL) and incubated at -80°C for 1 hour. The sample was then centrifuged at 13,200 rpm for 10 minutes, and the supernatant was removed and discarded. The resulting pellet was air-dried and resuspended in 1X SDS CE SDS Sample Buffer (50 µL), followed by the addition of 2 µL of Internal Standard (IS, 4%) and 2.5 µL of β-ME (2.5%). The samples were heated at 70°C for 10 minutes, diluted with deionized water (1:4), cooled on ice for 5 minutes, and centrifuged at 13,200 rpm for 5 minutes. Samples were loaded on to the Maurice and MauriceFlex instruments and run under reduced conditions with both cartridges consecutively (see Methods section).

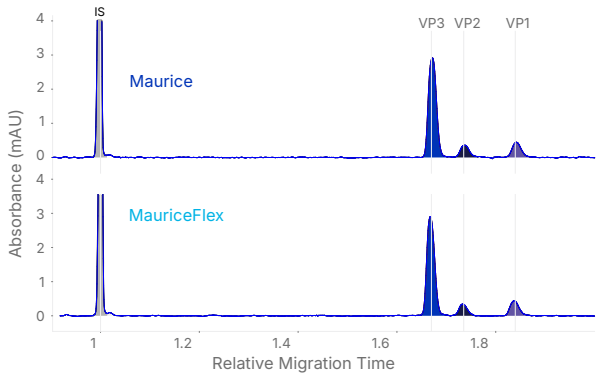


Figure 2. A comparison of AAV profiles between Maurice and MauriceFlex systems using the CE-SDS PLUS cartridge. Both systems result in similar AAV9 profiles, with distinguishable VP1, VP2, and VP3 peaks.

CE-SDS PLUS

Figure 2 shows the typical electropherogram of AAV9 obtained with the CE-SDS PLUS cartridge. Analysis on both instruments showed the expected, well-resolved viral protein peaks – VP1, VP2, and VP3. **Table 6** summarizes the results from this analysis, while **Table 7** summarizes the results for AAV9 analysis with the Turbo CE-SDS cartridge. Resolving viral proteins on Maurice with both CE-SDS cartridges has also been shown in another study, along with the determination of capsid protein ratios[2].

AAV9 Percent Peak Area (CE-SDS PLUS)			
Maurice (n=4)			
	VP3	VP2	VP1
Average	77.70	10.03	12.33
Std. Dev	0.42	0.28	0.19
%RSD	**0.55**	**2.75**	**1.54**
MauriceFlex (n=4)			
Average	77.93	9.60	12.48
Std. Dev	0.42	0.42	0.38
%RSD	**0.54**	**4.34**	**3.03**

Table 6. %RSD values of all three viral proteins detected with CE-SDS PLUS fall within acceptable ranges, and each viral protein demonstrates comparable average and %RSD values between instruments.

AAV9 Percent Peak Area (Turbo CE-SDS)			
Maurice (n=6)			
	VP3	VP2	VP1
Average	76.52	10.88	12.65
Std. Dev	0.34	0.21	0.23
%RSD	**0.44**	**1.96**	**1.79**
Capsid Ratio	6.03	0.85	1
MauriceFlex (n=6)			
Average	76.72	11.92	11.37
Std. Dev	0.35	0.28	0.23
%RSD	**0.45**	**2.34**	**2.06**
Capsid Ratio	6.7	1.06	1

Table 7. %RSD values for all three viral proteins detected using Turbo CE-SDS fall within acceptable ranges, with each viral protein exhibiting comparable average and %RSD values across instruments.

Belimumab (mAb)

Belimumab was diluted to 0.5 mg/mL using the Maurice 1X CE-SDS PLUS Sample Buffer (PN 046-567). Buffer exchange was performed using 0.25X phosphate-buffered saline (PBS). The Maurice CE-SDS 25X Internal Standard (IS, 4%, PN 046 144) was added to all samples, followed by the addition of 5% (V/V) of either IAM (11.5 mM) for non-reduced analysis or β-ME (650 nM) for reduced analysis. All samples were heated for 10 minutes at 70°C, cooled on ice for five minutes, and then subjected to centrifugation. Samples analyzed with Turbo CE-SDS were diluted with deionized water (1:1). Samples were loaded on to the Maurice and MauriceFlex instruments and run using standard conditions as described in the Methods section.

Figures 3A and **3B** show representative profiles of Belimumab under non-reduced and reduced conditions, respectively, analyzed with the CE-SDS PLUS cartridge. **Table 8** summarizes the %PA data from this analysis, while **Table 9** shows data for the same under reduced conditions. The results demonstrate high comparability between both instruments, rendering either of them suitable for CE-SDS analysis. Similarly, **Table 10** and **11** show data for Belimumab analyzed with the Turbo CE-SDS cartridge on both instruments, under non-reduced and reduced conditions respectively, once again highlighting comparability between the two systems.

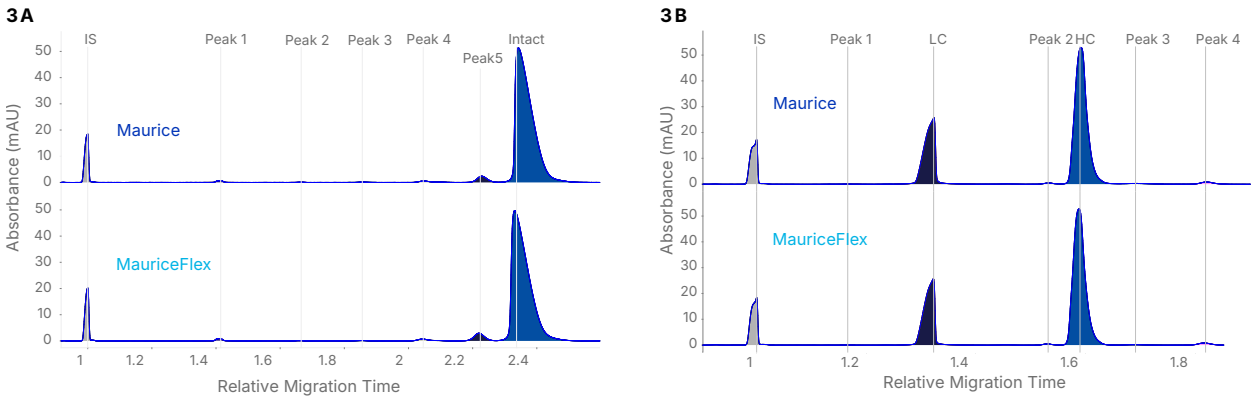


Figure 3. Comparison of Belimumab size profiles generated using the CE-SDS PLUS cartridge on both the Maurice and MauriceFlex systems. A. Under non-reducing conditions, the intact protein appears alongside minor species. **B.** Under reducing conditions, both LC and HC are detected. Across both conditions, the Maurice and MauriceFlex systems deliver highly comparable results.

Belimumab Percent Peak Area (CE-SDS PLUS, Non-Reduced)						
Maurice (n=4)						
	Peak 1	Peak 2	Peak 3	Peak 4	Peak 5	Intact Peak
Average	0.85	0.09	0.17	0.88	2.86	95.15
Std. Dev	0.02	0.01	0.01	0.02	0.09	0.15
%RSD	2.74	15.04	5.03	2.45	**3.12**	**0.15**
MauriceFlex (n=4)						
Average	1.27	0.09	0.19	1.22	4.23	93.01
Std. Dev	0.12	0.01	0.02	0.11	0.37	0.61
%RSD	-	-	-	-	**8.76**	**0.66**

Table 8. %PA of the intact peak for Belimumab analyzed with the CE-SDS PLUS cartridge is consistent across multiple injections and across both systems, as highlighted by low %RSD values for both Maurice and MauriceFlex.

Belimumab Percent Peak Area (CE-SDS PLUS, Reduced)						
Maurice (n=4)						
	Peak 1	LC	Peak 2	HC	Peak 3	Peak 4
Average	0.01	33.24	0.41	64.94	0.55	0.86
Std. Dev	0.00	0.03	0.01	0.02	0.03	0.01
%RSD	-	**0.08**	-	**0.04**	-	-
MauriceFlex (n=4)						
Average	0.03	33.09	0.39	65.48	0.16	0.86
Std. Dev	0.00	0.01	0.00	0.03	0.02	0.04
%RSD	-	**0.24**	-	**0.04**	-	-

Table 9. %PA data for Belimumab analyzed under reduced conditions are reproducible for both LC and HC across Maurice and MauriceFlex systems.

Belimumab Percent Peak Area (Turbo CE-SDS, Non-Reduced)						
Maurice (n=6)						
	Peak 1	Peak 2	Peak 3	Peak 4	Peak 5	Intact Peak
Average	0.57	0.10	0.32	0.95	2.32	95.78
Std. Dev	0.08	0.00	0.10	0.08	0.08	0.19
%RSD	-	-	-	-	**3.25**	**0.20**
MauriceFlex (n=6)						
Average	0.78	0.10	0.15	1.00	3.13	94.78
Std. Dev	0.08	0.00	0.05	0.09	0.08	0.13
%RSD	-	-	-	-	**2.61**	**0.14**

Table 10. The %PA of the intact Belimumab peak, analyzed using the Turbo CE-SDS cartridge, remains consistent across repeated injections and between both Maurice and MauriceFlex systems, as indicated by the low %RSD values.

Belimumab Percent Peak Area (Turbo CE-SDS, Reduced)					
Maurice (n=6)					
	LC	Peak 1	HC	Peak 2	Peak 3
Average	33.35	0.27	66.07	0.33	0.00
Std. Dev	0.22	0.10	0.19	0.08	0.00
%RSD	**0.65**	-	**0.28**	-	**-**
MauriceFlex (n=6)					
Average	34.23	0.35	64.88	0.13	0.42
Std. Dev	0.35	0.05	0.46	0.05	0.04
%RSD	**1.02**	-	**0.71**	-	-

Table 11. Under reduced conditions, Belimumab's light and heavy chains yield consistent %PA values across both Maurice and MauriceFlex systems. Reproducibility is supported by low standard deviations and %RSD values for each peak.

Abatacept (Fusion Protein)

250 mg of Abatacept was dissolved in 2 mL of H2O and stored in 20 uL aliquots at 125 mg/mL at -80°C. For analysis, Abatacept was diluted to 0.5 mg/mL using the Maurice 1X CE-SDS PLUS Sample Buffer. The Maurice CE-SDS 25X Internal Standard (IS, 4%, PN 046-144) was added to all samples, followed by the addition of 5% (V/V) of either iodoacetamide (IAM, 250 mM) for non-reduced analysis or β-ME (14.2 M) for reduced analysis. All samples were heated for 10 minutes at 70°C, cooled on ice for five minutes, and then subjected to centrifugation. Samples analyzed with Turbo CE-SDS were diluted with deionized water (1:1). Samples were loaded on to the Maurice and MauriceFlex instruments and run using standard conditions as described in the Methods section.

Figures 4A and **4B** show profiles of Abatacept analyzed on both Maurice and MauriceFlex with the CE-SDS PLUS cartridge. Instead of %PA, results for PA are reported because of the detection of a single, major peak for the molecule under both non-reduced and reduced conditions. **Table 12** presents the total PA for Abatacept analyzed using the CE-SDS PLUS cartridge on both Maurice and MauriceFlex systems, while **Table 13** shows the corresponding data generated with the Turbo CE-SDS cartridges. For each cartridge and under each running condition, the findings indicate strong agreement between the two instruments, confirming their suitability for CE-SDS analysis.

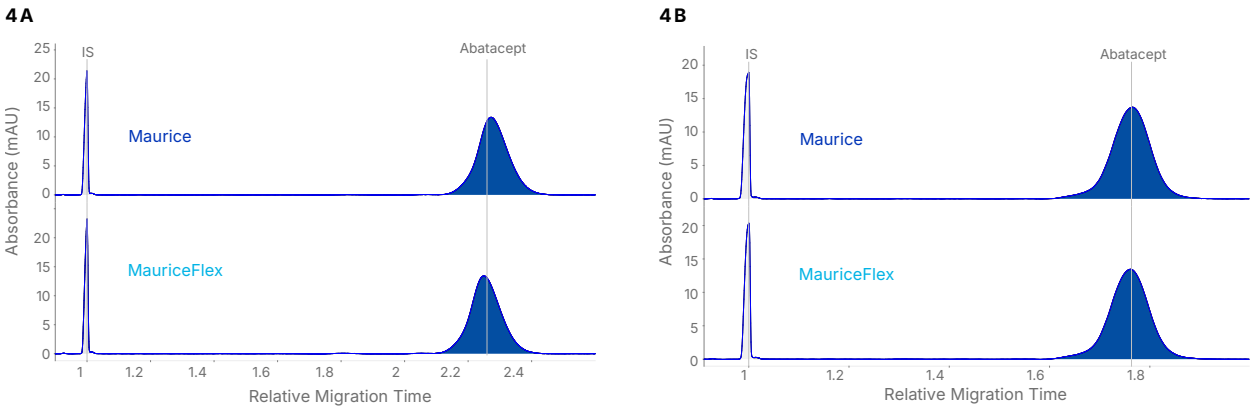


Figure 4. Comparison of abatacept size profiles using the CE-SDS PLUS cartridge on both the Maurice and MauriceFlex systems. A single, dominant peak is observed for both **A.** non-reducing conditions, and **B.** reduced conditions. In both cases, the Maurice and MauriceFlex systems produce highly comparable results to each other, as evidenced by comparable peak profiles.

Abatacept Total Peak Area (CE-SDS PLUS)		
	Maurice (n=4)	
	Non-Reduced	Reduced
Average	1367.00	1453.25
Std. Dev	10.47	4.82
%RSD	**0.77**	**0.33**
	MauriceFlex (n=4)	
Average	1336.98	1421.63
Std. Dev	21.95	8.21
%RSD	**1.64**	**0.58**

Table 12. Total peak area measurements for Abatacept with the CE-SDS PLUS exhibit comparable %RSD values across both Maurice and MauriceFlex, underscoring the consistency in quantitation between instruments.

Abatacept Total Peak Area (Turbo CE-SDS)		
	Maurice (n=6)	
	Non-Reduced	Reduced
Average	2326.18	2341.73
Std. Dev	29.29	20.90
%RSD	**1.26**	**0.89**
	MauriceFlex (n=6)	
Average	2174.03	2231.78
Std. Dev	15.67	45.73
%RSD	**0.72**	**2.05**

Table 13. Total peak area measurements for Abatacept with the CE-SDS PLUS exhibit comparable %RSD values across both Maurice and MauriceFlex, underscoring the consistency in quantitation between instruments.

Conclusion

This study demonstrates how both Maurice and MauriceFlex systems provide highly reproducible and comparable CE-SDS data across a range of biotherapeutic modalities, including bispecific antibodies, monoclonal antibodies, fusion proteins, and AAVs. Key metrics such as %PA and %RSD values, as well as peak area measurements, were comparable between the two systems, confirming their similarity in performance. Furthermore, the relative migration time of expected peaks for each molecule was also comparable between Maurice and MauriceFlex, as shown in **Figure 5**. The choice of instrument largely depends on analytical requirements of specific laboratories. Maurice enables protein charge (icIEF) and size (CE-SDS) analysis, while MauriceFlex offers icIEF, CE-SDS, and icIEF fractionation for further characterization. Both systems are suitable for comprehensive biotherapeutic development, from early-stage discovery to final product testing and are established analytical tools in the biopharmaceutical industry.

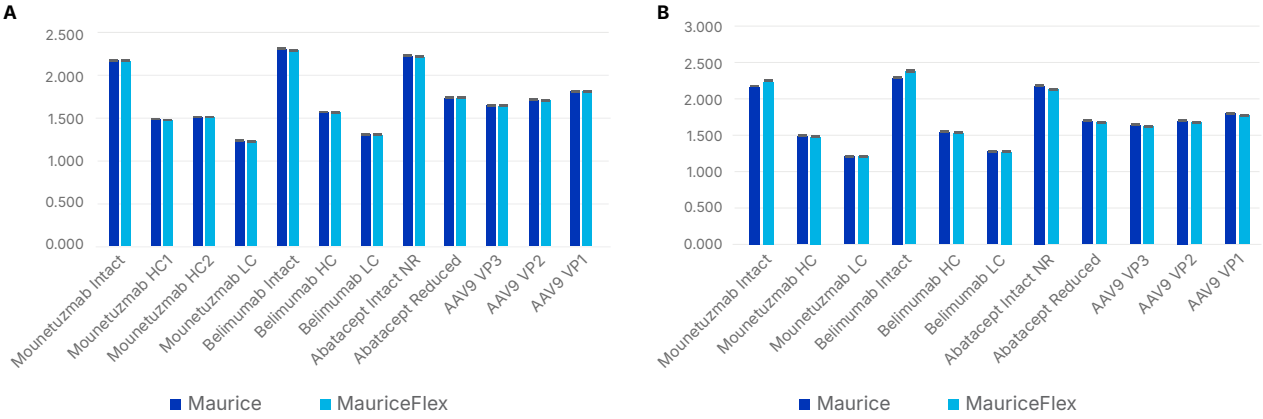


Figure 5. Bar graphs comparing the relative migration times of key peaks for Mosunetuzumab, Belimumab, AAV, and Abatacept, analyzed using A. CE-SDS PLUS and B. Turbo CE-SDS. Each pair of bars represents data from the Maurice and MauriceFlex, with results showing high comparability across instruments for each molecule. Error bars represent standard deviation, highlighting the reproducibility and consistency of migration times between both systems.

Learn more about CE-SDS

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REFERENCES

1. Application note: **Comparing the Performance of the Maurice and MauriceFlex Systems for Charge Heterogeneity Analysis**
2. Application note: **Viral Vector Characterization from Discovery to GMP Release with Maurice**