

A single, ready-to-use kit for fast, comprehensive analysis of both plasmid topological isoforms and linear sizing on a multi-capillary electrophoresis platform

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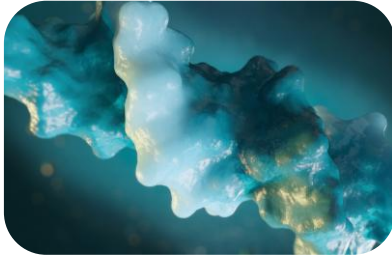
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pDNA analysis workflow



Easy sample preparation



Plasmid DNA sample/
dsDNA linear sample

Sample pretreatment

- Dilution with 1x sample buffer for analysis

CGE-LIF analysis



BioPhase 8800 system

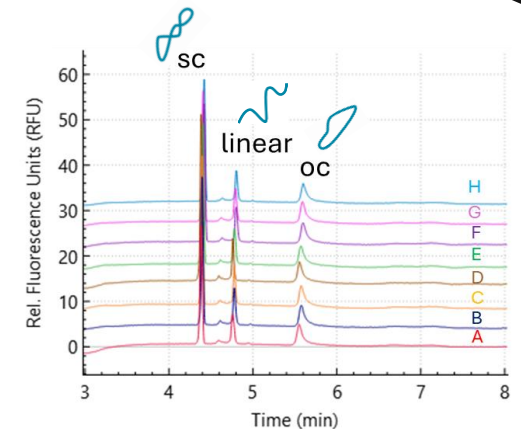


PA 800 Plus system



DNA 20 kb Plasmid and Linear kit
Pre-assembled BFS cartridge

Automated result generation

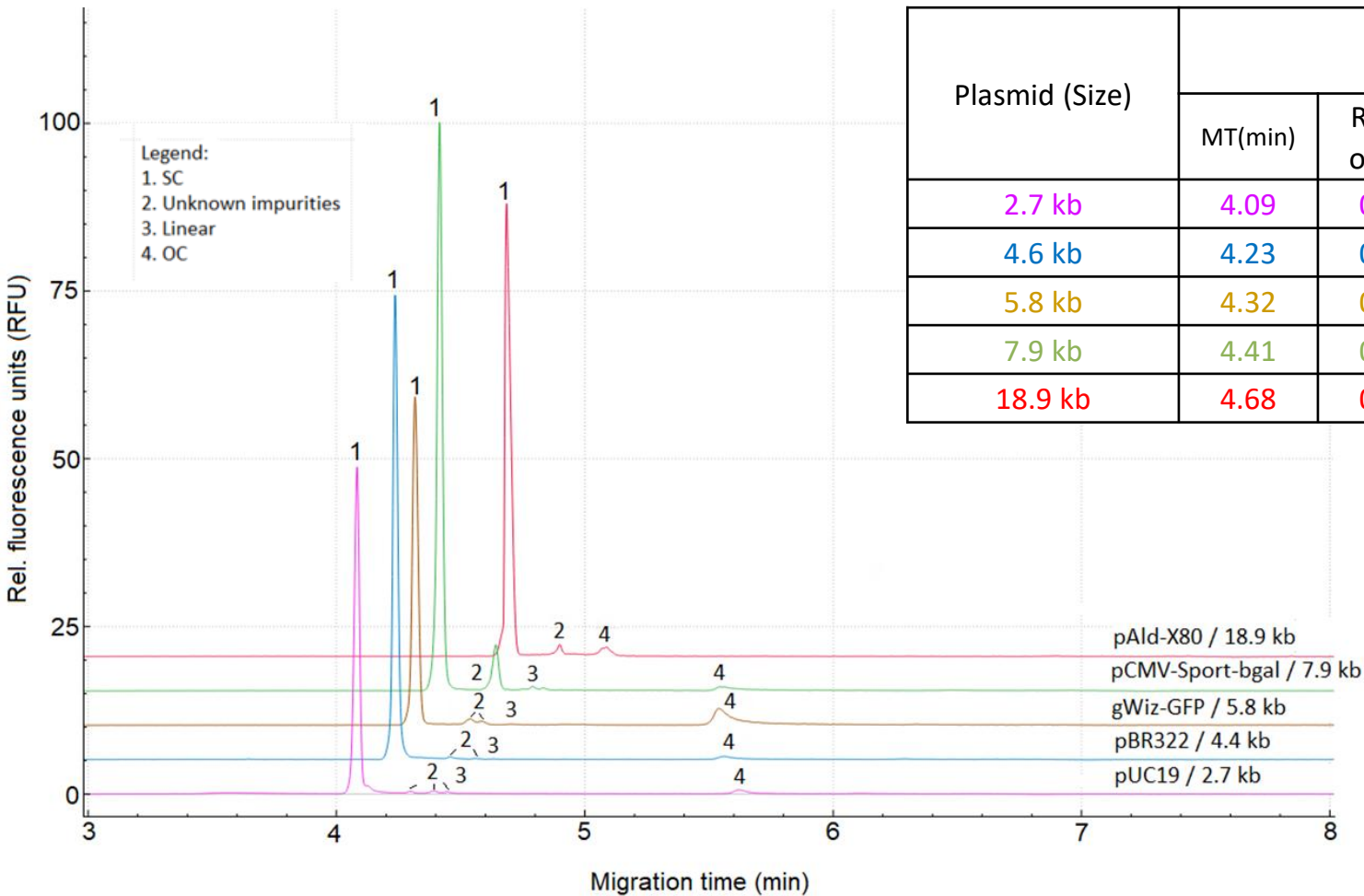


Evaluate pDNA critical quality attributes (CQAs)

- pDNA topological purity assessment
- Linear dsDNA sizing
- Identity confirmation with restriction digestion

Plasmid DNA purity analysis

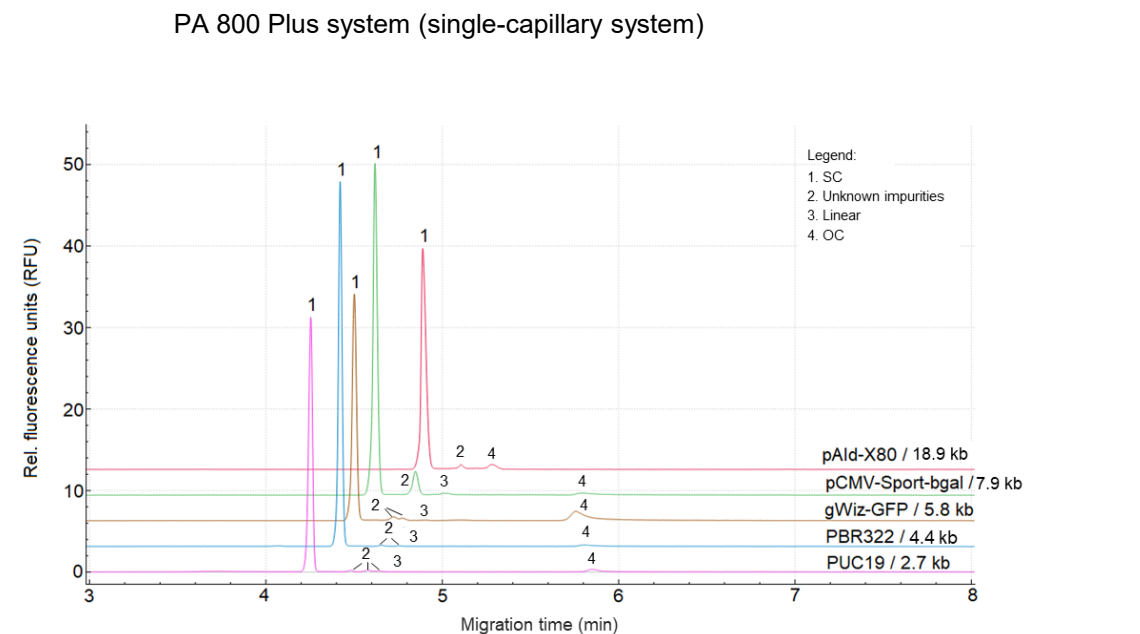
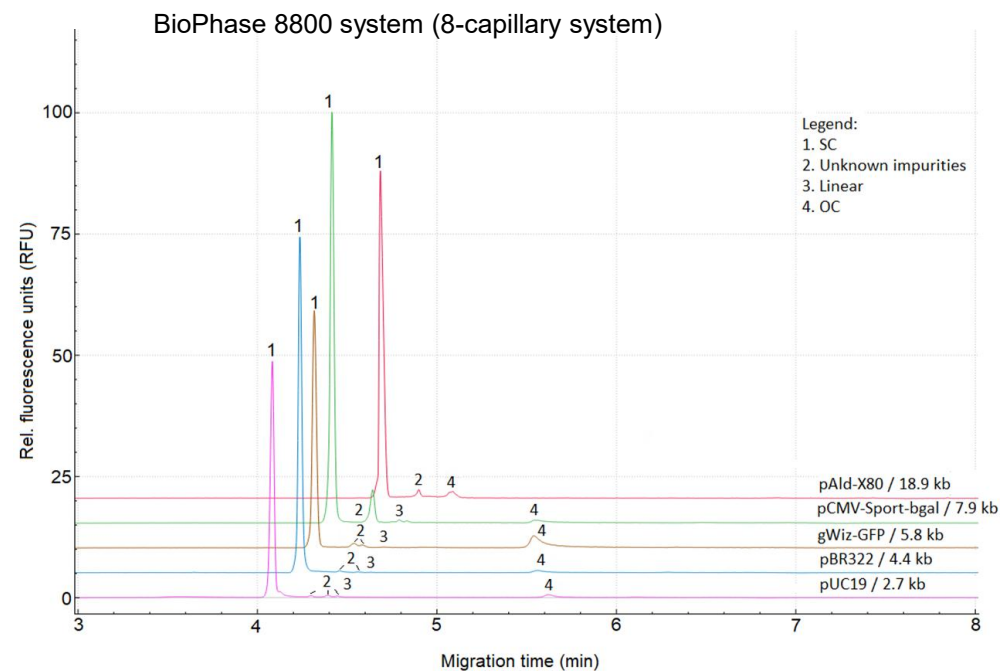
Looking at the repeatability of the assay (12 injections)



Plasmid (Size)	Supercoiled				Open circular	Other impurities
	MT(min)	RSD% of MT	CPA%	RSD% of CPA%	CPA%	CPA%
2.7 kb	4.09	0.21	94.92	0.13	2.05	3.03
4.6 kb	4.23	0.20	96.44	0.13	1.37	2.19
5.8 kb	4.32	0.19	83.05	0.65	12.47	4.48
7.9 kb	4.41	0.15	88.68	0.37	1.80	9.52
18.9 kb	4.68	0.11	93.48	0.40	3.72	2.80

Able to resolve the different topological isoforms of all 5 pDNA samples of varying sizes with high repeatability, where the RSD% of SC% (purity) is <1%

Break through the boundaries of throughput with a multi-capillary system

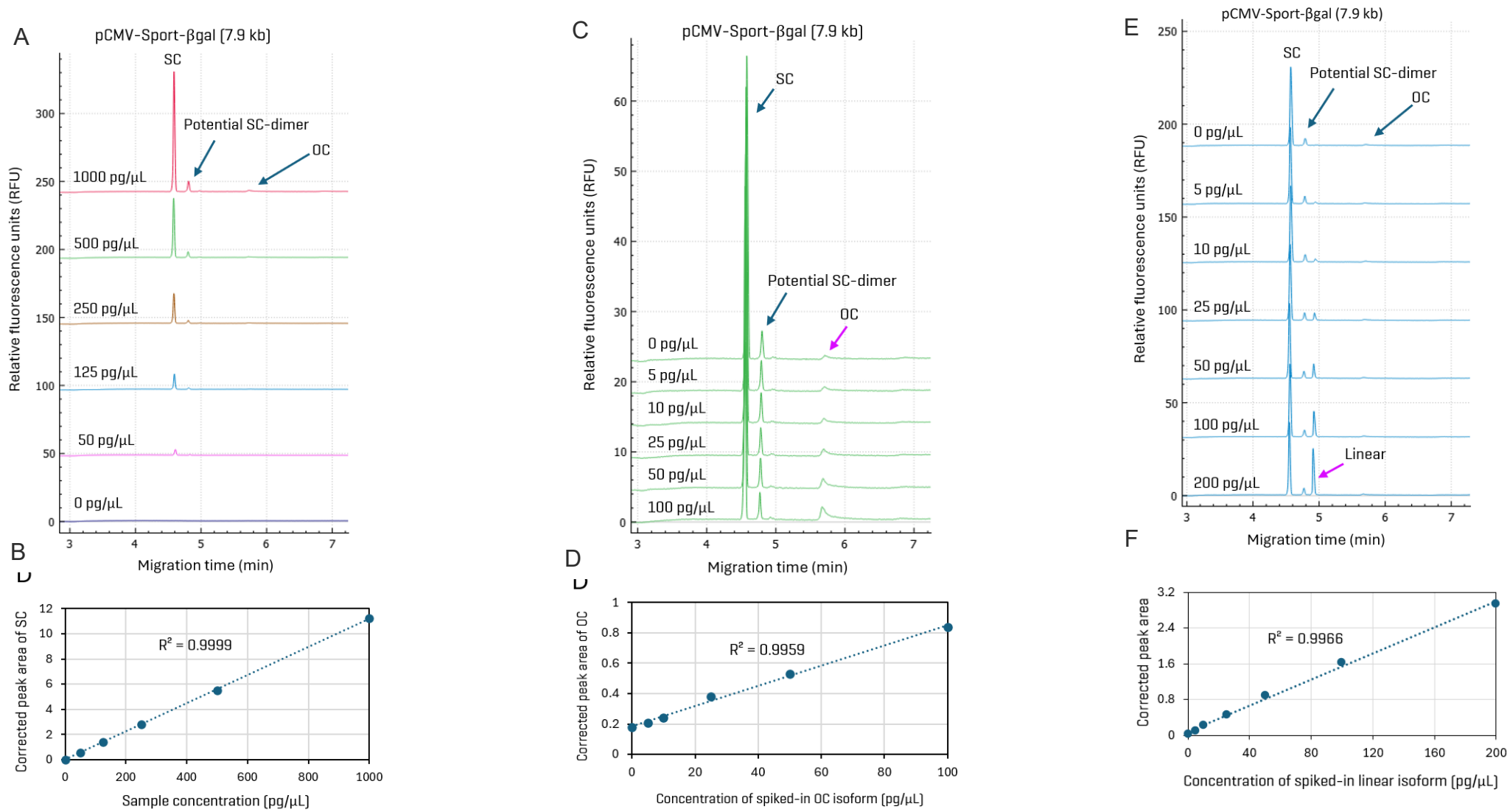


	BioPhase 8800 system (n = 3)				PA 800 Plus system (n = 3)			
	MT* (min)	RSD+% of MT	CPA^%	RSD% of CPA%	*MT (min)	RSD+% of MT	CPA^%	RSD% of CPA%
2.7 kb (PUC-19)	4.09	0.24	94.88	0.11	4.25	0.11	96.25	0.05
4.6 kb (PBR322)	4.23	0.03	96.63	0.20	4.42	0.09	98.36	0.03
5.8 kb (gWiz-GFP)	4.32	0.26	82.53	0.19	4.50	0.08	85.21	0.48
7.8 kb (pCMV-Sport-βgal)	4.41	0.07	88.48	0.22	4.62	0.07	89.45	0.21
18.8 kb (pAld-X80)	4.68	0.19	93.83	0.07	4.89	0.12	94.37	0.11



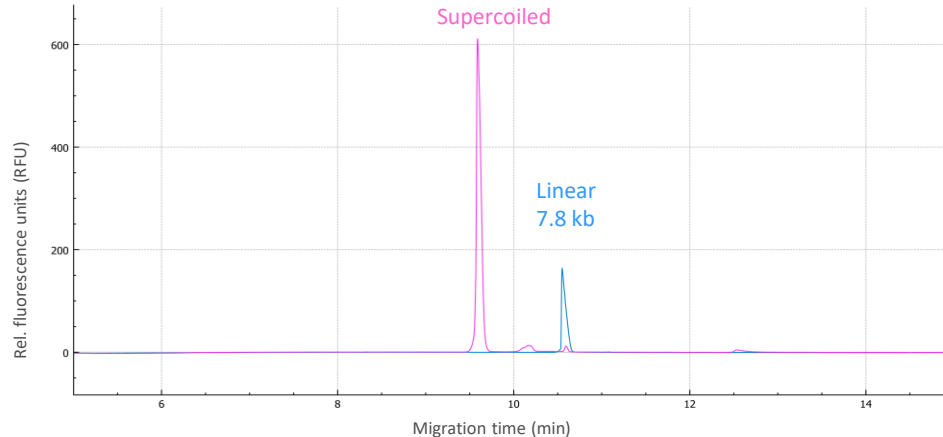
Seamless method transfer between single-capillary and multi-capillary systems (PA 800 Plus system to BioPhase 8800 system)

Highly sensitive and accurate quantitation of the topological forms



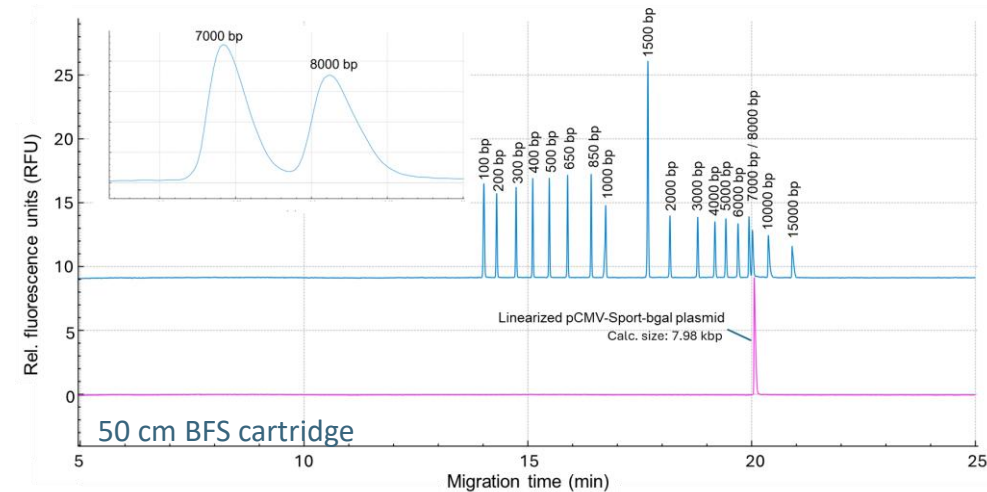
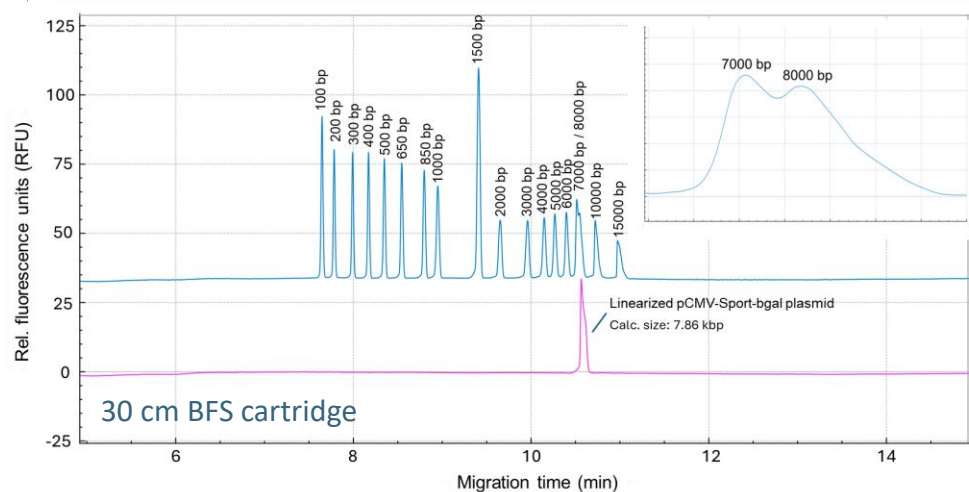
Linear dsDNA analysis

Excellent size-based separation of linear DNA from 0.1–20 kb



Peak ID and size estimation:

- Linearized dsDNA spike-in/ migration time alignment for peak identification in the plasmid sample mixture
- Alignment and comparison with linear dsDNA ladder allow size estimation of the linearized species.



Summary

- High-resolution separation of plasmid topological isoforms and impurities across a wide size range (2.7-18.9 kb), important for manufacturing different-sized mRNAs, saRNA and viral vectors
- Excellent assay repeatability and reproducibility
- Fast time to answer, 2 min per sample, 3.4 hours for a full plate of 96 samples on the BioPhase 8800 system
- Ready-to-use kit together with pre-assembled bare-fused silica (BFS) cartridge for easy and fast topology and linear sizing analysis





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