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SAMPLE PREPARATION PROCEDURE

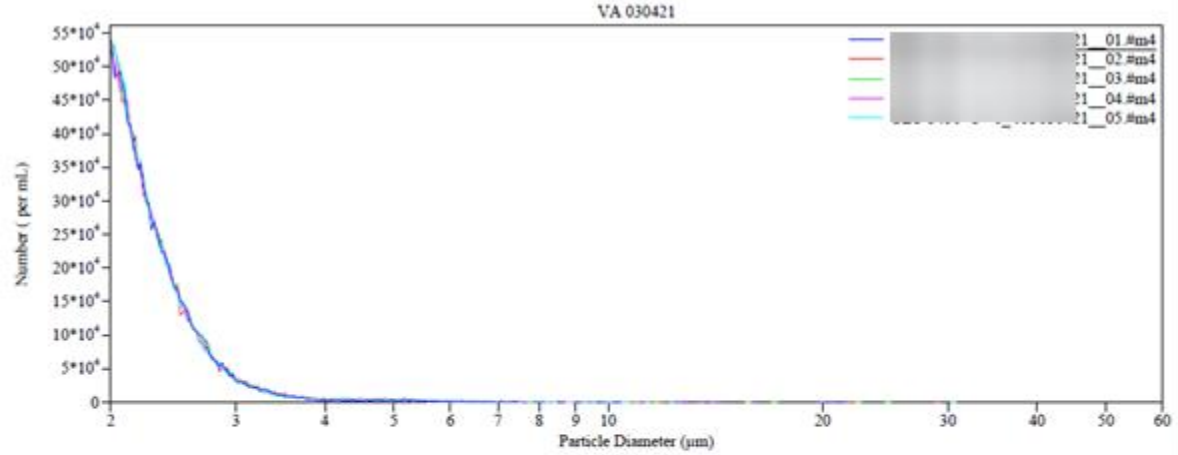
The sample was characterized utilizing sterile Saline as the electrolyte with triple filtered Isoton as the system fluid. After thawing the samples, an aliquot of neat sample was added to 100 mL of Sterile Saline and analyzed in Volumetric Control Mode of 2000 µL with the blank subtracted to remove counts from the electrolyte. The samples were reanalyzed using the same methodology 4 hours minutes after the initial analysis.

SUMMARY OF PARTICLE ANALYSIS STATISTICAL DATA

Item No.	VA Sample ID (S-VAXXXX)		Averaged Number Statistics				
		UNIQUE ID (i.e. lot no.)	Concentration [counts /mL]	Mean	D10	d50	d90
1	VAxxxxxx-1	Sample 1 - 030121	11.00e6	2.354	2.037	2.229	2.759
2	VAxxxxxx -2	Sample 2 - 030121	13.62e6	2.363	2.039	2.243	2.774
3	VAxxxxxx -3	Sample 3 - 030121	5.824e6	2.369	2.037	2.232	2.801
4	VAxxxxxx -4	Sample 4 - 030121	7.113e6	2.382	2.039	2.244	2.817
5	VAxxxxxx -5	Sample 5 - 030121	5.411e6	2.369	2.034	2.218	2.800
6	VAxxxxxx -6	Sample 6 - 030121	6.261e6	2.376	2.035	2.222	2.811
7	VAxxxxxx -7	Sample 7 - 030121	60.47e6	2.902	2.132	2.726	3.906
8	VAxxxxxx -8	Sample 8 - 030121	53.53e6	2.999	2.148	2.816	4.099

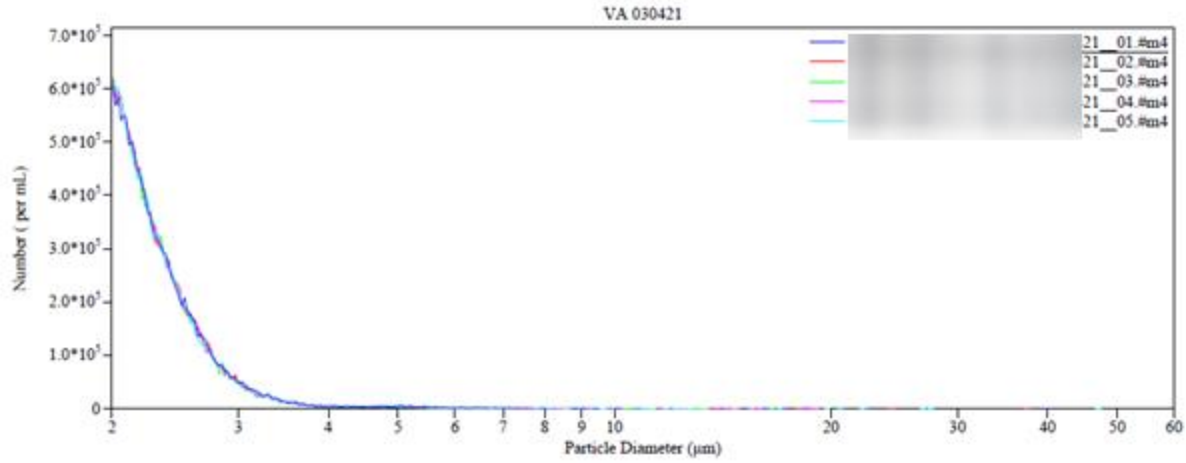
BACKGROUND ON MULTISIZER™4 COULTER COUNTER TECHNOLOGY

Using the Coulter Principle, also known as Electrical Sensing Zone (EZS) the Multisizer™ Coulter Counter provides size distribution in number, volume, and surface area in one measurement, with an overall sizing range of 0.4 µm to 1600 µm. Its response is unaffected by particle color, shape, composition, or refractive index. The Coulter Principle is the leading technology in high resolution and accuracy, and it is enhanced even further in the Multisizer™ 4 by using Digital Pulse processor (DPP). DPP provides ultra-high resolution, multiple channel analysis, and accuracy that is unattainable by other technologies.



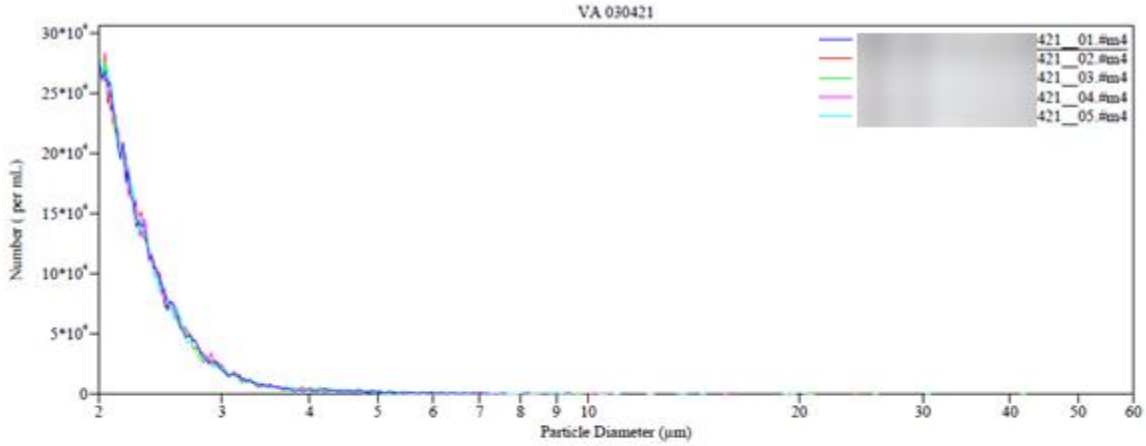
Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
[redacted]_01.#m4	11.02e6	2.360	2.231	2.037	2.231	2.763
[redacted]_02.#m4	10.91e6	2.358	2.230	2.037	2.230	2.764
[redacted]_03.#m4	11.07e6	2.352	2.228	2.036	2.228	2.758
[redacted]_04.#m4	10.97e6	2.350	2.230	2.037	2.230	2.753
[redacted]_05.#m4	11.05e6	2.349	2.226	2.036	2.226	2.755
(Average)	11.00e6	2.354	2.229	2.037	2.229	2.759
(C.V.)	0.6%	0.2%	0.1%	0.1%	0.1%	0.2%



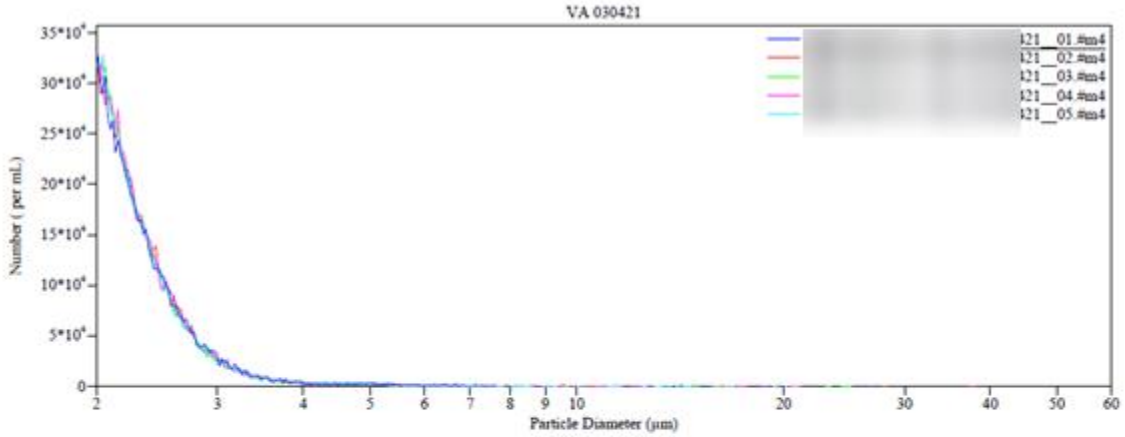
Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
[redacted]_01.#m4	13.63e6	2.367	2.246	2.040	2.246	2.783
[redacted]_02.#m4	13.63e6	2.365	2.244	2.040	2.244	2.772
[redacted]_03.#m4	13.65e6	2.363	2.243	2.038	2.243	2.771
[redacted]_04.#m4	13.68e6	2.361	2.242	2.039	2.242	2.770
[redacted]_05.#m4	13.49e6	2.360	2.241	2.038	2.241	2.772
(Average)	13.62e6	2.363	2.243	2.039	2.243	2.774
(C.V.)	0.5%	0.1%	0.1%	0.0%	0.1%	0.2%



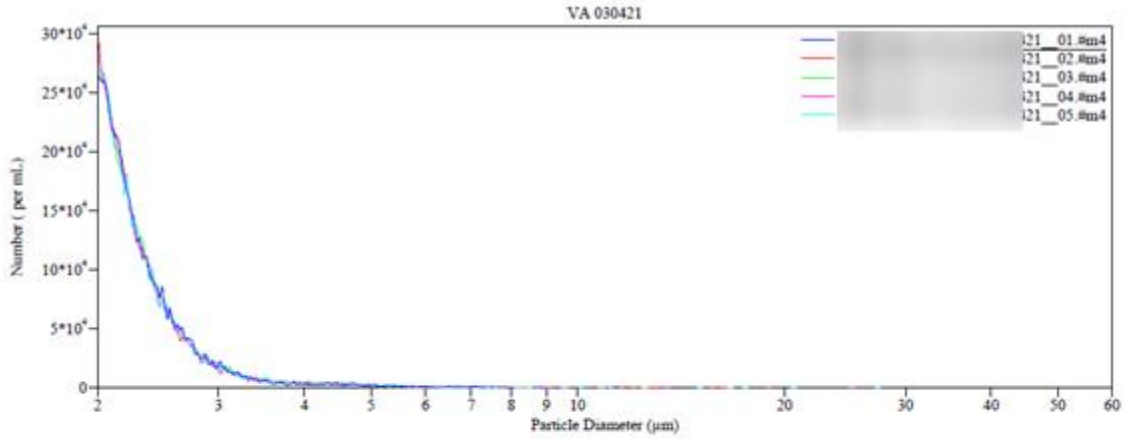
Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
[redacted]421__01.#m4	5.825e6	2.373	2.233	2.037	2.233	2.808
[redacted]421__02.#m4	5.833e6	2.368	2.232	2.037	2.232	2.800
[redacted]421__03.#m4	5.772e6	2.371	2.232	2.037	2.232	2.801
[redacted]421__04.#m4	5.828e6	2.369	2.235	2.038	2.235	2.806
[redacted]421__05.#m4	5.863e6	2.367	2.227	2.037	2.227	2.791
(Average)	5.824e6	2.369	2.232	2.037	2.232	2.801
(C.V.)	0.6%	0.1%	0.1%	0.0%	0.1%	0.2%



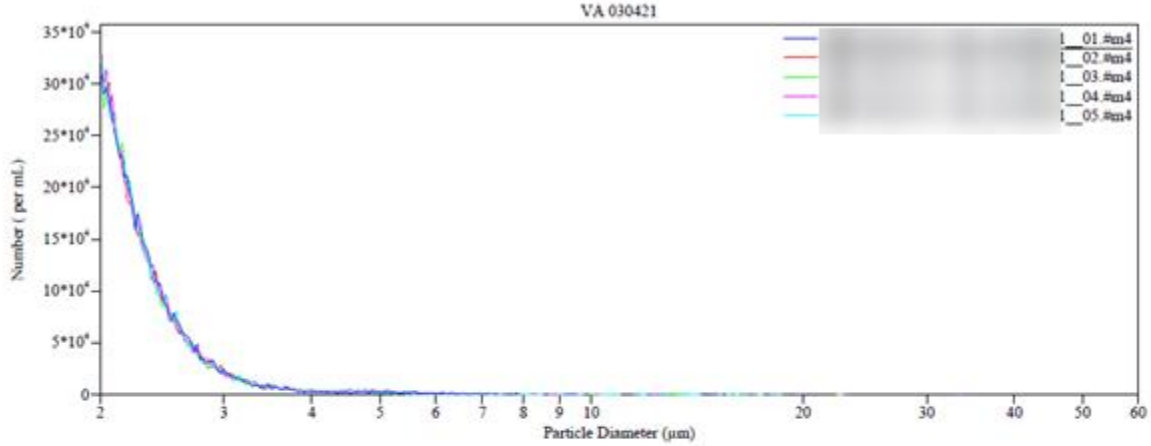
Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
[redacted]21__01.#m4	7.039e6	2.390	2.250	2.039	2.250	2.842
[redacted]21__02.#m4	7.115e6	2.383	2.249	2.040	2.249	2.812
[redacted]21__03.#m4	7.141e6	2.380	2.240	2.039	2.240	2.813
[redacted]21__04.#m4	7.214e6	2.378	2.242	2.039	2.242	2.812
[redacted]21__05.#m4	7.055e6	2.377	2.241	2.038	2.241	2.807
(Average)	7.113e6	2.382	2.244	2.039	2.244	2.817
(C.V.)	1.0%	0.2%	0.2%	0.1%	0.2%	0.5%



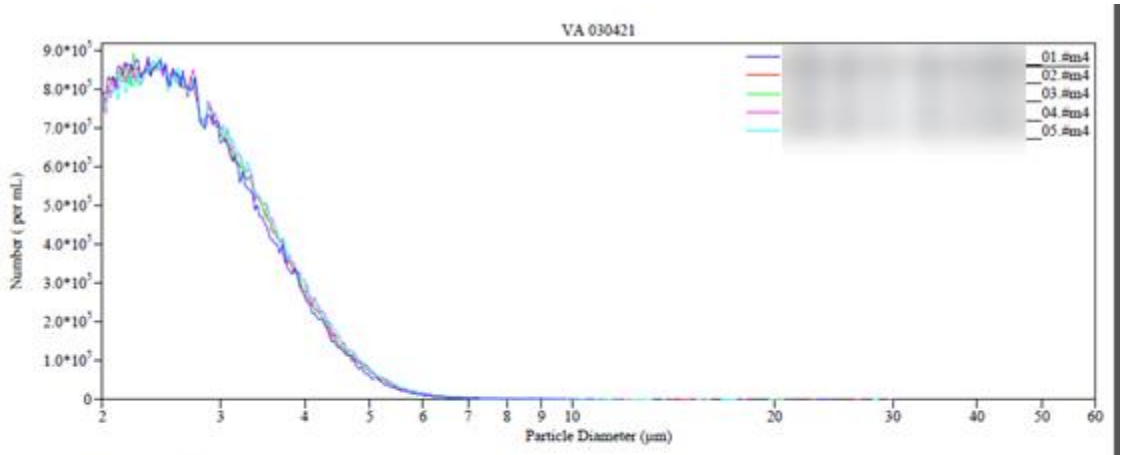
Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
[redacted]21__01.#m4	5.417e6	2.372	2.220	2.036	2.220	2.800
21__02.#m4	5.430e6	2.372	2.216	2.033	2.216	2.798
21__03.#m4	5.435e6	2.372	2.223	2.034	2.223	2.815
21__04.#m4	5.419e6	2.363	2.215	2.034	2.215	2.795
21__05.#m4	5.357e6	2.368	2.217	2.035	2.217	2.793
(Average)	5.411e6	2.369	2.218	2.034	2.218	2.800
(C.V.)	0.6%	0.2%	0.2%	0.1%	0.2%	0.3%



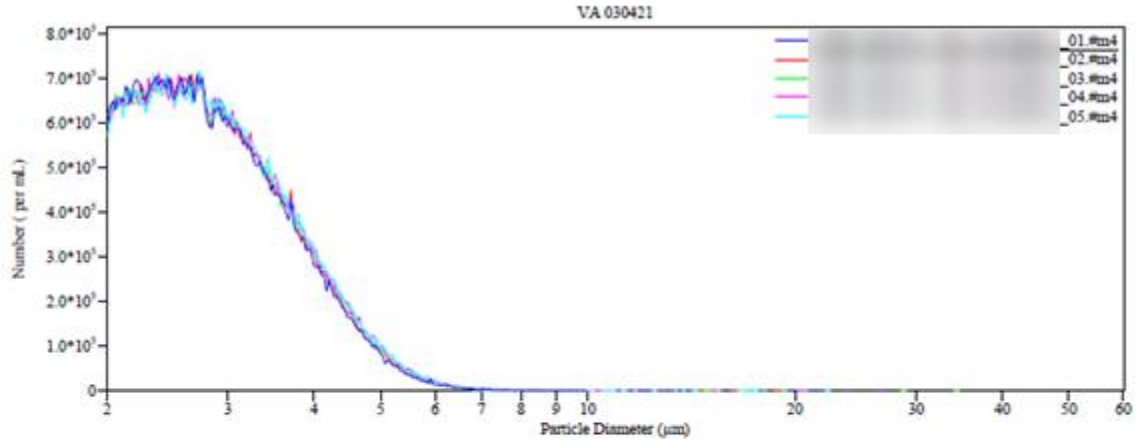
Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
[redacted]__01.#m4	6.306e6	2.382	2.228	2.036	2.228	2.809
__02.#m4	6.272e6	2.378	2.224	2.035	2.224	2.819
__03.#m4	6.243e6	2.378	2.221	2.036	2.221	2.814
__04.#m4	6.234e6	2.373	2.220	2.034	2.220	2.816
__05.#m4	6.251e6	2.369	2.219	2.034	2.219	2.797
(Average)	6.261e6	2.376	2.222	2.035	2.222	2.811
(C.V.)	0.5%	0.2%	0.2%	0.1%	0.2%	0.3%



Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
_01.#m4	59.48e6	2.875	2.701	2.127	2.701	3.859
_02.#m4	60.20e6	2.897	2.721	2.131	2.721	3.894
_03.#m4	60.57e6	2.905	2.728	2.132	2.728	3.913
_04.#m4	61.11e6	2.913	2.736	2.135	2.736	3.928
_05.#m4	60.98e6	2.919	2.743	2.137	2.743	3.936
(Average)	60.47e6	2.902	2.726	2.132	2.726	3.906
(C.V.)	1.1%	0.6%	0.6%	0.2%	0.6%	0.8%



Number Statistics (Arithmetic)
Calculations from 2 µm to 60 µm

	Amount per mL	Mean µm	Median µm	d10 µm	d50 µm	d90 µm
_01.#m4	52.94e6	2.977	2.793	2.144	2.793	4.053
_02.#m4	53.37e6	2.992	2.807	2.147	2.807	4.082
_03.#m4	53.60e6	3.003	2.820	2.148	2.820	4.108
_04.#m4	53.75e6	3.009	2.824	2.149	2.824	4.124
_05.#m4	54.00e6	3.016	2.836	2.151	2.836	4.130
(Average)	53.53e6	2.999	2.816	2.148	2.816	4.099
(C.V.)	0.7%	0.5%	0.6%	0.1%	0.6%	0.8%
(S.D.)	399.2e3	0.015	0.017	0.0026	0.017	0.032