



Regenerative Medicine Solutions - miniTC
cell viability validation study

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Acceptance criteria for the study

	Parameter	Criteria
1	Fat graft volume	35% of the initial total decanted lipoaspirate
2	Stromal cell viability	>85% if processed/tested on the same day >75% if processed/tested on the next day
3	Oil/Lipid layer presence	<10% of of the final volume
4	Endothelial precursors (CD34+)*	>25% in the stromal vascular layer
5	Mesenchymal stem cells (MSC)	>10% in the stromal vascular layer

(*) is reported as responsible for fat graft viability

Testing results for the study

ID	Test #3.1			Test #3.2		Test #3.3		Test #3.4		Test #3.5	
	Volume in ml	Volume out ml (%)	Result	Oil ml (%)	Result	Viability (%)	Results	CD34+ (%)	Result	MSC (%)	Result
1.1	70	18 (26)	Pass	0.5 (2.7)	Pass	89	Pass	54	Pass	44	Pass
2.1	60	16 (27)	Pass	0.5 (3.1)	Pass	83.3	Pass	48	Pass	40	Pass
3.2	30	7 (23)	Pass	0.4 (5.7)	Pass	83.9	Pass	44	Pass	37	Pass
4.1	100	32 (32)	Pass	1.1 (3.4)	Pass	86.9	Pass	57	Pass	45	Pass
5.1	120	35 (29)	Pass	1.0 (2.8)	Pass	91	Pass	48	Pass	41	Pass
6.1	120	30 (25)	Pass	1.2 (4.0)	Pass	94	Pass	50	Pass	41	Pass
7.1	120	32 (27)	Pass	1.2 (3.7)	Pass	87	Pass	49	Pass	43	Pass
8.2	55	14 (25)	Pass	1.2 (8.5)	Pass	81	Pass	46	Pass	36	Pass
9.2	100	27 (27)	Pass	1.5 (5.5)	Pass	84	Pass	51	Pass	41	Pass
10.2	120	31 (26)	Pass	2.0 (6.4)	Pass	83.4	Pass	45	Pass	38	Pass

Viability validation results

STEM CELL EXTRACTION and VIABILITY

Sample analysis Date : 03-OCT-2018

Sample ID : Sample_C MINISTEM

Viable Cells / mL : $1.54E+06$

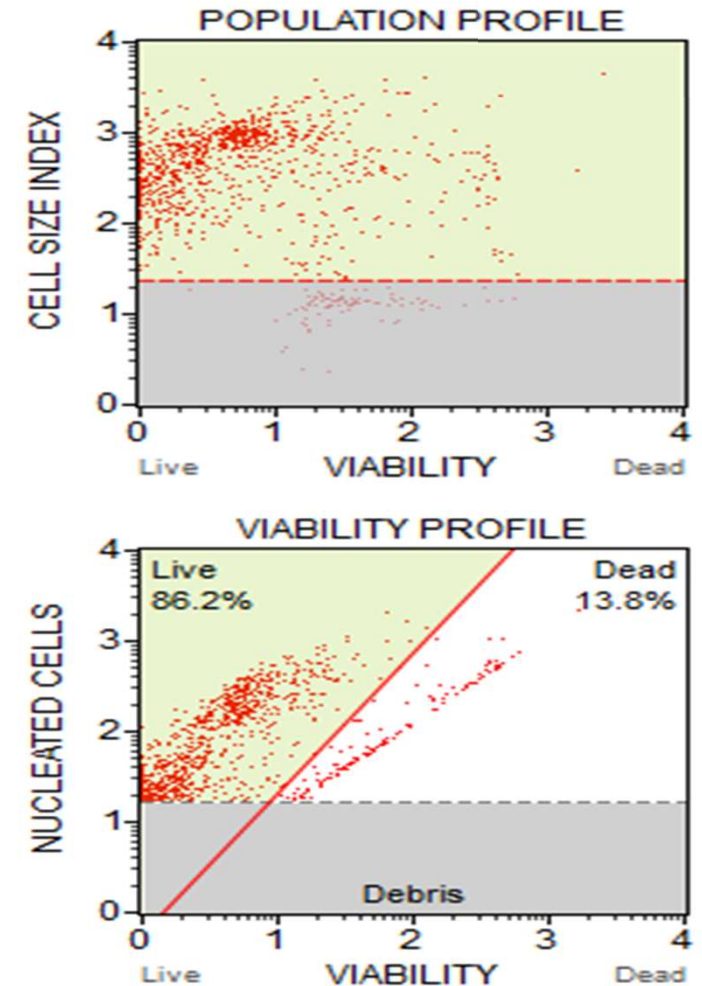
Viability % : 86.20 %

Total Cells / mL : $1.79E+06$

Events Acquired : 1091

Dilution Factor : 10.00

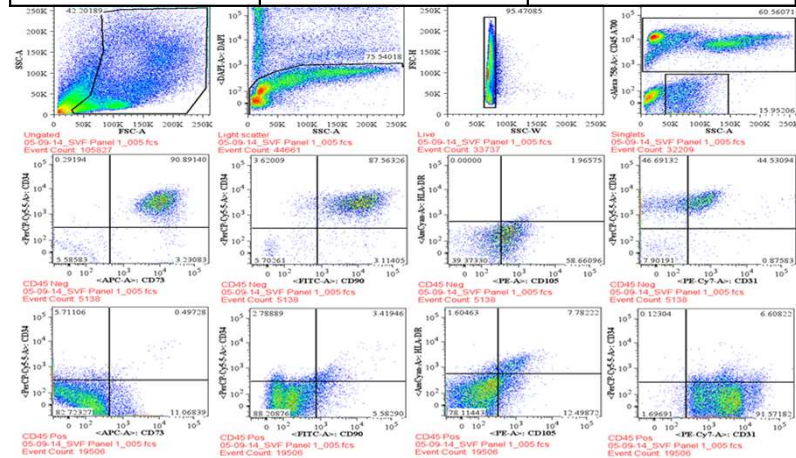
Original Volume : 10.00 mL



MINI-STEM SYSTEM™: KNOW YOUR CELLS

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Fluorophore	Panel 1	Panel 2
PB/V450	DAPI	DAPI
KO/PO/V500	HLA-DR	HLA-DR
FITC	CD90	NG2 (Chondroitin Sulfate)
PerCP	CD34	CD14
PE	CD105	ICAM-1 (CD54)
ECD	CD3+CD19+CD56	CD3+CD19+CD56
PE-Cy7	CD31	CD31
APC/Alexa 647	CD73	HLA-ABC
Alexa 700	CD45	CD45



	5/9/2014		6/27/14	
Panel 1	Count	% of Total Live	Count	% of Total Live
Total Live cells	25045	100.00	26672	100.00
CD45 Pos cells	19488	77.81	22304	83.62
CD45 Neg Cells	5456	21.78	4154	15.57
CD45-CD34+CD73+ Mesenchymal	4988	19.92	3398	12.74
CD45-CD34+CD90+ Mesenchymal	4794	19.14	3479	13.04
CD45-CD34+CD90+CD31+CD105+	3464	13.83	759	2.85
CD45+CD34+CD105+	490	1.96	962	3.61
Panel 2				
Total Live Cells	34585	100.00	56144	100.00
CD45 Pos Cells	26511	76.65	41170	73.33
CD45 Neg Cells	7935	22.94	10712	19.08
CD45-HLA-ABC+HLA-DR- CD54+N	6933	20.05	8808	15.69
CD45+HLA-ABC+HLA-DR+	2427	7.02	6240	11.11
CD45+HLA-ABC+HLA-DR-CD54+N	6480	18.74	3788	6.75
CD45+HLA-ABC+HLA-DR-CD54+N	15246	44.08	24567	43.76
Lymphocytes CD45+CD3+CD19+C	10624	30.72	15263	27.19
Monocytes CD45+CD14+CD3-CD19	2867	8.29	3918	6.98
Granulocytes CD45+CD14-CD3-CD	10187	29.45	18199	32.41

Conclusions of the study

	<u>Parameter</u>	<u>Benchmark</u>	<u>Result</u>
1	Fat graft volume	35% of the initial total decanted lipoaspirate	✓
2	Stromal cell viability	>85% if processed/tested on the same day	n/a
		>75% if processed/tested on the next day	✓
3	Oil/Lipid layer presence	<10% of of the final volume	✓
4	Endothelial precursors (CD34+)*	>25% in the stromal vascular layer	✓
5	Mesenchymal stem cells (MSC)	>10% in the stromal vascular layer	✓