Certificate of Analysis

Sprague-Dawley Rat Mesenchymal Stem Cells

Catalog No. RASMX-01001
Lot Number: 130628B31

Cryopreservation Date: 2013-06-28
Passage Number: 9

Viability

Cells are assayed for viability post-thaw using vital staining assay with trypan blue.
Specification: Cells should exhibit ≥ 80% viability.

Sterility

Bacterial and Fungal Contamination: Samples are inoculated and cultured in blood agar plate, thioglycolate broth, tryptocase soy broth and sabouraud dextrose agar.
Specification: No growth must be observed.

Mycoplasma: Samples are tested for mycoplasma contamination using a PCR-based assay and direct culture.
Specification: Results must be negative.

Endotoxin: Samples are tested for endotoxin contamination with LAL test.
Specification: Results must show a concentration of ≤ 25EU/ml.

Purity

Cells are assayed for purity using flow cytometric analysis of cell surface antigen expression after cryopreservation. Cells are immunofluorescently stained with fluorochrome−conjugated antibodies specific to cell surface antigens CD29, CD34, CD44, CD45, CD90 and CD11b.

Specification: Cells must show ≥ 70% positivity for expression of cell surface antigens CD29, CD44 and CD90. Cells must show ≤ 5% positivity for expression of cell surface antigens CD34, CD45 and CD11b.

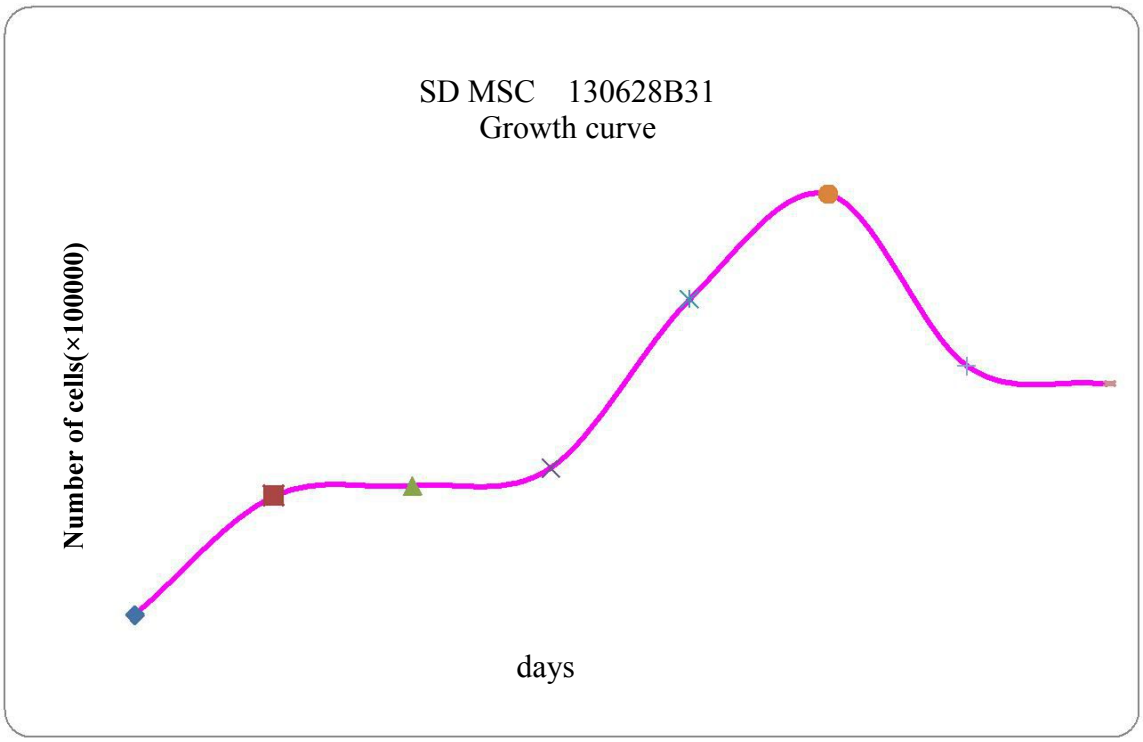
Proliferation Ability

Cells are characterized by their ability to proliferate in culture with an attached well-spread morphology for ≥ 5 passages, and ≤ 5% cells exhibit spontaneous differentiation in each passage.

Differentiation Ability

Cells are assayed after cryopreservation for their ability of tri-lineage differentiation. Cells must be able to differentiate to osteocytes, adipocytes and chondrocytes when cultured in the appropriate differentiation media.

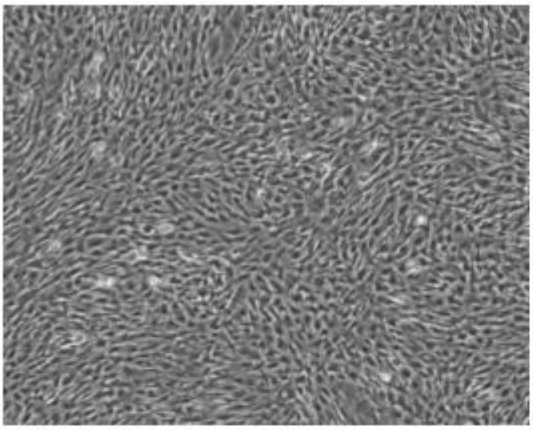
- **Proliferation Ability**



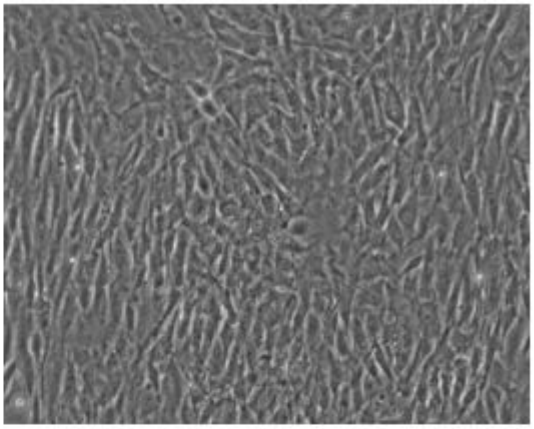
Cell population doubling time was 35.55h

- **Passage ability**

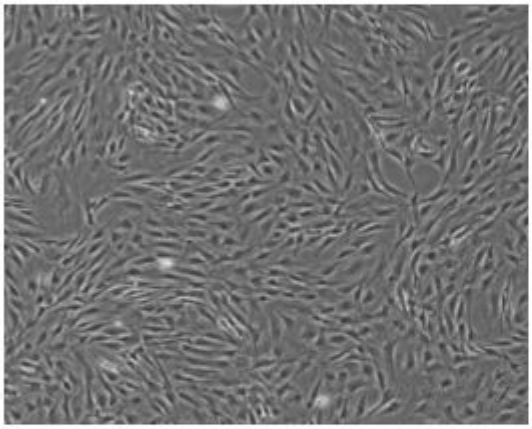
  After passaging for 6 times,cells remain active and can be covered within 72 hours.



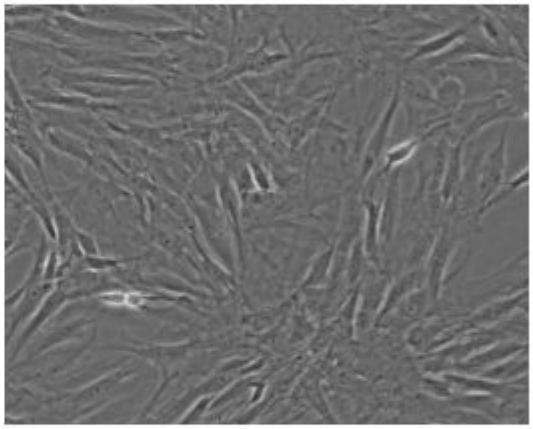
P3-2d-40x



P3-2d-100x



P7-2d-40x



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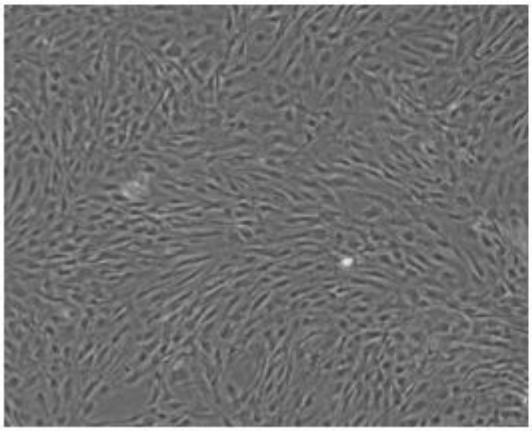
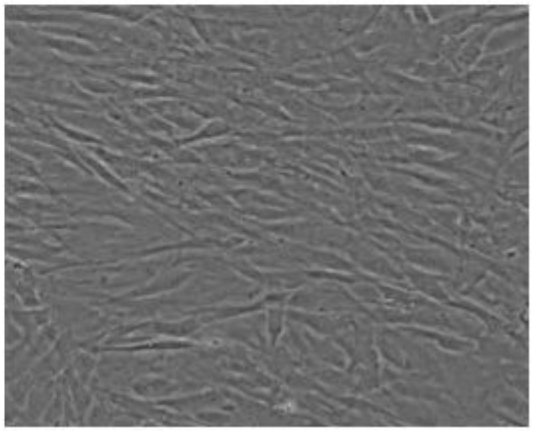
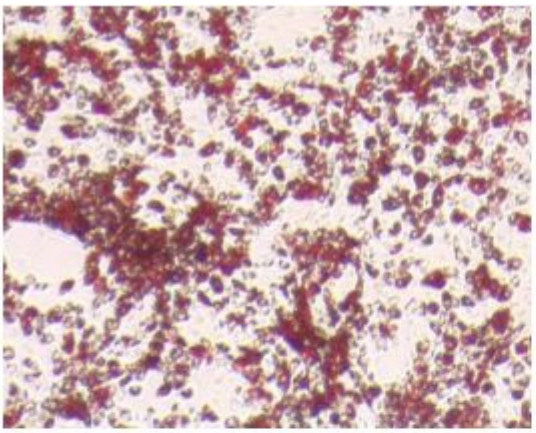


P10-3d-40x

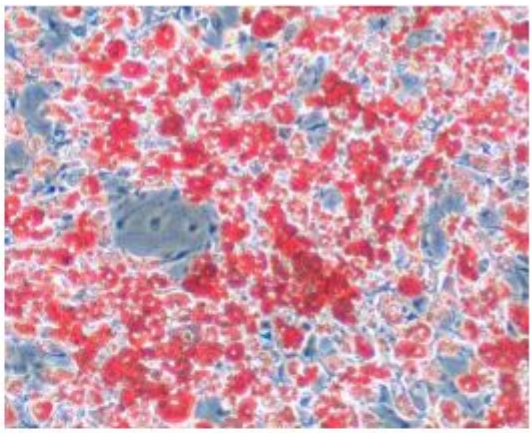


P13-3d-100x

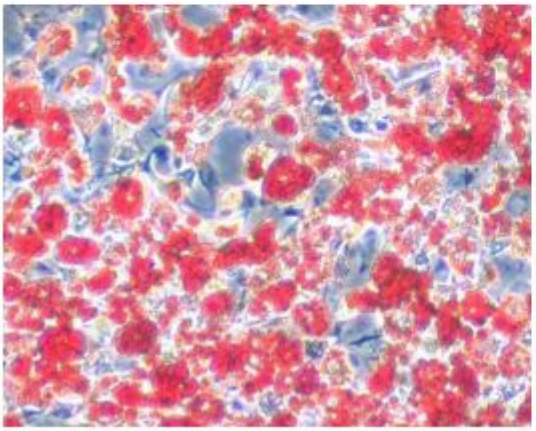
- **Differentiation Ability**



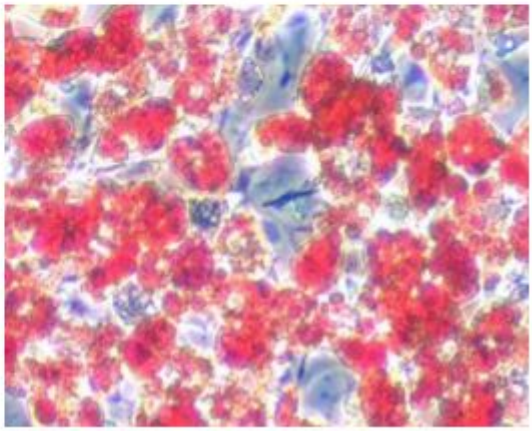
P7-17d-40x



P7-17d-100x



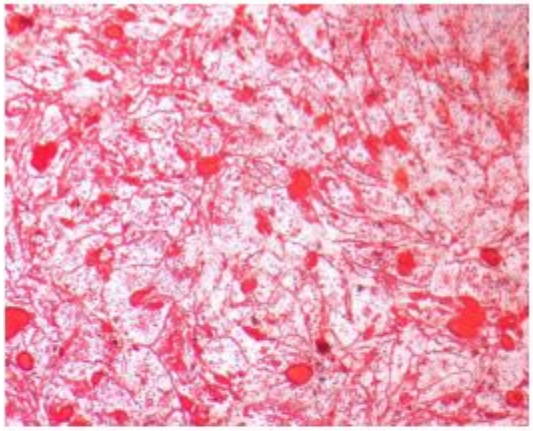
P7-17d-200x



P7-17d-400x

Differentiate to adipocytes when cultured in MSC adipogenic differentiation medium.

- **Differentiation Ability**



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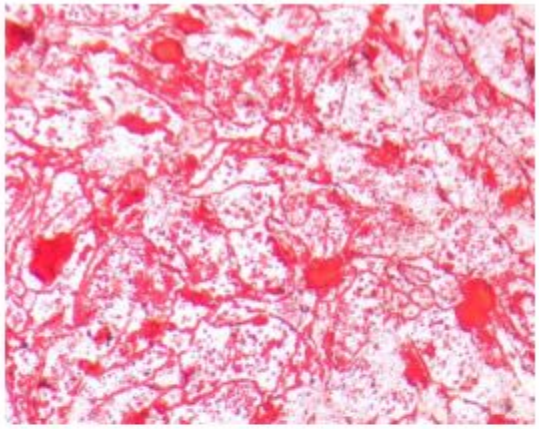

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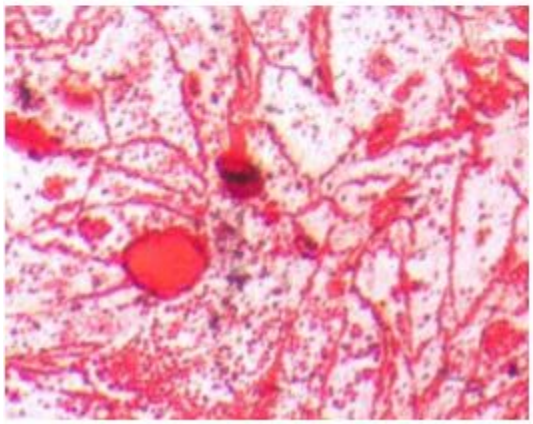
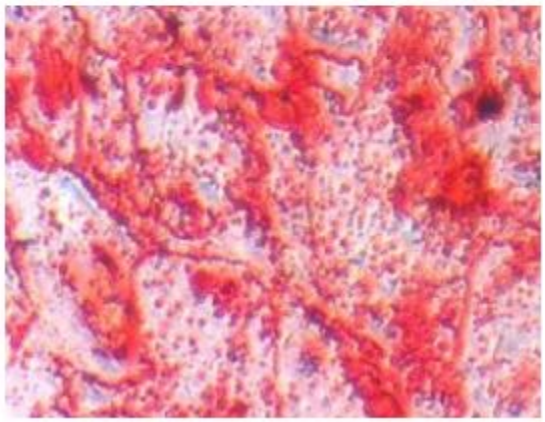


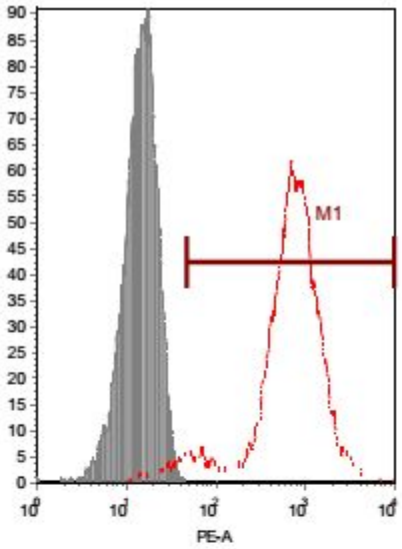
P7-17d-200x



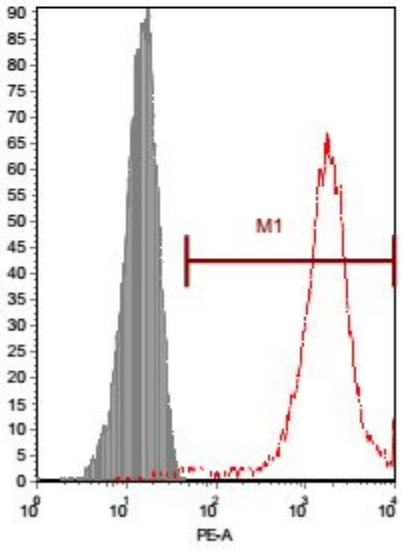
P7-17d-400x

Differentiate to osteocytes when cultured in MSC osteogenic differentiation medium.

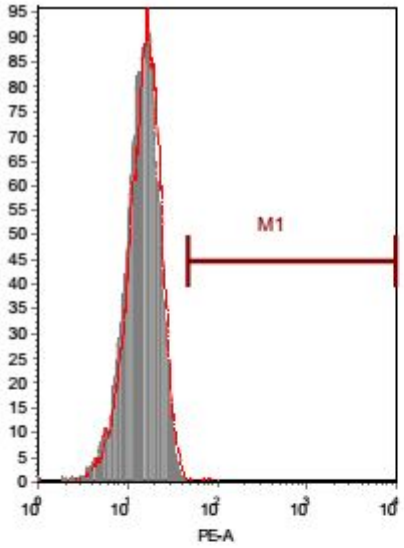
- **Purity** -cell surface antigens



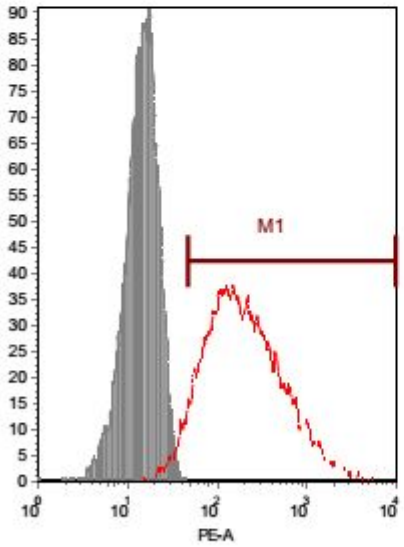
Histogram #	Filename	Parameter	Low bound	High bound	# Events	% of gated cells
1	130816_3 PE-IgG1.fcs	PE-A	48	10000	12	0.12
2	130816_4 PE-CD44.fcs	PE-A	48	10000	9618	95.68



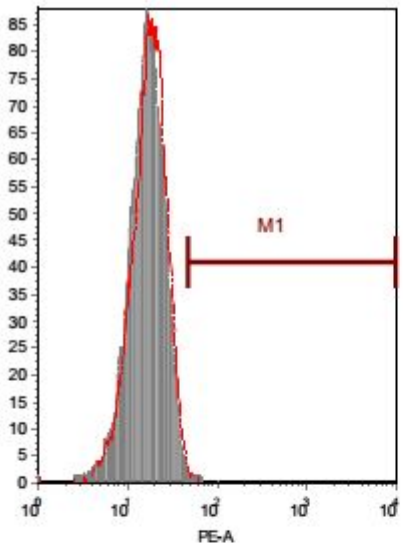
Histogram #	Filename	Parameter	Low bound	High bound	# Events	% of gated cells
1	130816_3 PE-IgG1.fcs	PE-A	48	10000	12	0.12
2	130816_5 PE-CD90.fcs	PE-A	48	10000	9771	97.4



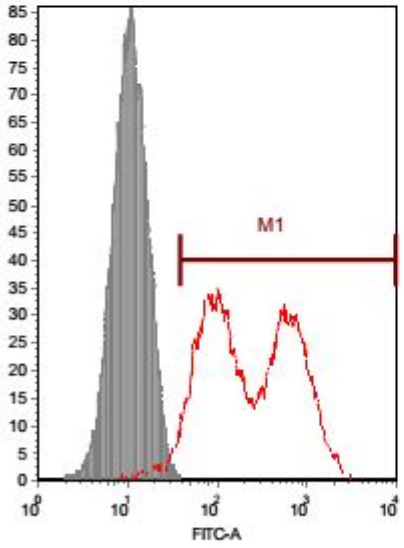
Histogram #	Filename	Parameter	Low bound	High bound	# Events	% of gated cells
1	130816_3 PE-IgG1.fcs	PE-A	48	10000	12	0.12
2	130816_6 PE-CD45.fcs	PE-A	48	10000	38	0.38



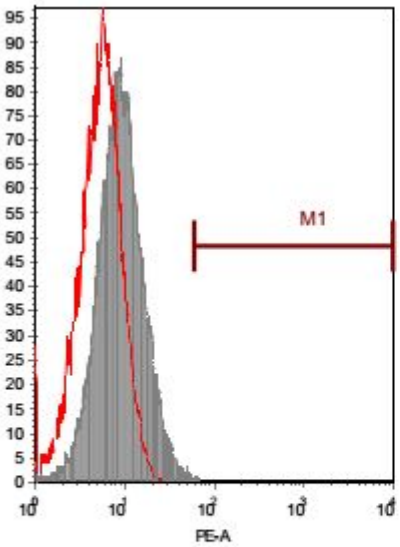
Histogram #	Filename	Parameter	Low bound	High bound	# Events	% of gated cells
1	130816_3 PE-IgG1.fcs	PE-A	48	10000	12	0.12
2	130816_7 PE-CD73.fcs	PE-A	48	10000	9426	93.71



Histogram #	Filename	Parameter	Low bound	High bound	# Events	% of gated cells
1	130816_9 PE-IgG2a.fcs	PE-A	48	10000	36	0.36
2	130816_10 PE-CD11bc.fcs	PE-A	48	10000	58	0.58



Histogram #	Filename	Parameter	Low bound	High bound	# Events	% of gated cells
1	130816_11 FITC-IgG.fcs	FITC-A	39	10000	13	0.13
2	130816_12 FITC-CD29.fcs	FITC-A	39	10000	9654	95.64



Histogram #	Filename	Parameter	Low bound	High bound	# Events	% of gated cells
1	130821_30 PE IgG1.fcs	PE-A	59	10000	25	0.2
2	130821_31 PE CD34.fcs	PE-A	59	10000	14	0.11

- **Results:**

All specifications have been met.

Jane Chen
QA Manager
Aug 18, 2013