

Certificate of Analysis

**Sprague-Dawley Rat Mesenchymal Stem Cells
With RFP**Catalog No. RASMX-01101
Lot Number: 091218B01Cryopreservation Date: 2009-12-18
Passage Number: 5

Viability

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

Sterility

Bacterial and Fungal Contamination: Samples are inoculated and cultured on 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 $\leq 25\text{EU/ml}$.

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 CD90
Specification: Cells must show $\geq 70\%$ positivity for expression of cell surface antigens CD90.

Proliferation Ability

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

RFP Expression

Expression of constitutive RFP is assayed by visual inspection of RFP fluorescence signal.
Specification: The results must indicate $\geq 80\%$ of cells are visually inspected for RFP fluorescence signal during extensive subcultivation.

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.

Results:

All specifications have been met.



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