

Certificate of Analysis

Fischer 344 (F344) Rat Mesenchymal Stem Cells With RFP

Catalog No. RAFMX-01101 Lot Number: 120816L01

Cryopreservation Date: 2012-8-16 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 ≤ 25 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 \geq 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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Jane Chen QA Manager Sep 25, 2012