

# **Certificate of Analysis**

#### Strain Balb/c Mouse Mesenchymal Stem Cells

Catalog No. MUCMX-01001 Lot Number: 120112F01

Cryopreservation Date: 2012-1-12

Passage Number: 6

## **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 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  $\leq 25EU/ml$ .

#### **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, CD117 and Sca 1.

Specification: Cells must show  $\geq$  70% positivity for expression of cell surface antigens CD29, CD44, CD34 and Sca-1. Cells must show  $\leq$  5% positivity for expression of cell surface antigens CD117.

## **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.

#### **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:** 

Meet all specifications

Jane Chen QA Manager Feb 28, 2012