

Certificate of Analysis

Human Mesenchymal Stem Cells

Catalog No. HUXMA-01001

Lot Number: 171228I31

Cryopreservation Date: 2017-12-28

Passage Number: 2

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 $\leq 10\text{EU/ml}$.

Exogenous Virus: Samples using ELISA assay to detect HIV, HBV, HCV and Syphilis.

Specification: Results must be negative.

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, CD73, CD105, CD11b/c, CD44, CD45 and CD34.

Specification: Cells must show $\geq 70\%$ positivity for expression of cell surface antigens CD29, CD73, CD44 and CD105. Cells must show $\leq 5\%$ positivity for expression of cell surface antigens CD34, CD11b/c and CD45.

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.

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.



Jane Chen
QA Manager
Feb 12, 2018