Cyagen Biosciences Inc.
www.cyagen.jp

Certificate of Analysis

Human Umbicical Cord MSC

Catalog No. HUXUC-01001
Lot Number: 100923F01

Cryopreservation Date: 2010-9-23
Passage Number: 2

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 ≤ 10EU/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, CD105, CD44, CD45 and CD34.
Specification: Cells must show ≥ 70% positivity for expression of cell surface antigens CD29, CD44 and CD105. Cells must show ≤ 5% positivity for expression of cell surface antigens CD34 and CD45.

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.

Results:
Meet all specifications

Jane Chen
QA Manager
Nov 5, 2010