

CERTIFICATE OF ANALYSIS

LOT #: 060515

LOT COMPOSITION:

▶ Number of donor(s) in lot	1
▶ Gender	Male
▶ Race	Caucasian
▶ Gestation	26
▶ Passage	2

Cryopreserved human bone marrow derived mesenchymal stem/stromal cells are shipped on dry ice and should be stored in liquid nitrogen immediately upon arrival. There are 1,000,000 cells/vial minimum.

QUALITY CONTROL:

Test	Specification	Result
Cell Appearance	Healthy	Healthy
Cell Count	$\geq 1 \times 10^6$	2.07×10^6
Population Doublings	< 10	7.70
Viability	$\geq 90\%$	98%
Biomarker CD44	$\geq 95\%$	100%
Biomarker CD73	$\geq 95\%$	97%
Biomarker CD90	$\geq 95\%$	100%
Biomarker CD105	$\geq 95\%$	100%
Biomarker CD166	$\geq 95\%$	99%
Biomarker CD14/34/45/HLA-DR	$\leq 5\%$	< 1%
Adipogenesis	Positive	Positive
Chondrogenesis	Positive	Positive
Osteogenesis	Positive	Positive
Clonogenicity	For info only	58%
Endotoxin	$\leq 3\text{EU/mL}$	< 1 EU/mL
Mycoplasma	Negative	Negative
Sterility	USP <71>	Positive

All tissue donors are screened and found to be negative for HIV1/2, Hepatitis B, and Hepatitis C. Samples frozen at P2 are screened and found to be negative for HIV1/2, Hepatitis A, Hepatitis B, Hepatitis C, and HTLV1/2. However, no known test can offer complete assurance that the viruses that these infectious diseases are not present. Since we cannot test all the pathogens, please treat the culture as a potential infectious reagent at Biosafety Level 2 or higher.

Precautionary Notes:

This product is for research only. It is not intended for human, veterinary or in vitro diagnostic use. Limited Product Warranty
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