

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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AMSBIO | www.amsbio.com | info@amsbio.com

 **UK & Rest of the World**
 AMS Biotechnology (Europe) Ltd
 184 Park Drive, Milton Park
 Abingdon, OX14 4SE, UK
 T: +44 (0)1235 828 200
 F: +44 (0)1235 820 482

 **North America**
 amsbio LLC
 1035 Cambridge Street,
 Cambridge, MA 02141
 T: +1 (617) 945-5033 or
 T: +1 (800) 987-0985
 F: +1 (617) 945-8218

 **Germany**
 AMS Biotechnology (Europe) Ltd
 Bockenheimer Landstr. 17/19
 60325 Frankfurt/Main
 T: +49 (0) 69 779099
 F: +49 (0) 69 13376880

 **Switzerland**
 AMS Biotechnology (Europe) Ltd
 Centro Nord-Sud 2E
 CH-6934 Bioggio-Lugano
 T: +41(0) 91 604 55 22
 F: +41(0) 91 605 17 85