RoosterBio®

Product Insert

MESENCHYMAL STEM/STROMAL CELL CATALOG – (HIGH VOLUME hMSCs)

Catalog No.	Product	Qty	Unit Size & Components
HUMAN BONE MARROW-DERIVED MESENCHYMAL STEM/STROMAL CELLS (hBM-MSCs)			
INDIVIDUAL VIALS			
MSC-003	RoosterVial™-hBM-1M	1 vial	1 million cryopreserved cells
MSC-001	RoosterVial-hBM-10M	1 vial	10 million cryopreserved cells
MSC-005	RoosterVial-hBM-50M	1 vial	50 million cryopreserved cells
MSC-006	RoosterRTP™-hBM-50M	1 vial	50 million Ready-to-Print cryopreserved cells
MSC-031	RoosterVial-hBM-1M-XF	1 vial	1 million xeno-free (XF) cryopreserved cells
MSC-030	RoosterVial-hBM-10M-XF	1 vial	10 million XF cryopreserved cells
MSC-033	RoosterVial-hBM-20M-XF	1 vial	20 million XF cryopreserved cells
MSC-032	RoosterVial-hBM-50M-XF	1 vial	50 million xeno-free formulation (XFF) cryopreserved cells
MSC-034	RoosterRTP-hBM-50M-XF	1 vial	50 million XFF Ready-to-Print cryopreserved cells
WORKING CELL BANKS			
MSC-004	RoosterBank™-hBM-1M	1 bank	5 or 10 vials of 1 million cryopreserved cells
MSC-002	RoosterBank-hBM-10M	1 bank	5 or 10 vials of 10 million cryopreserved cells
MSC-1M-5XF	RoosterBank-hBM-1M-XF	1 bank	5 vials of 1 million XF cryopreserved cells
MSC-1M-10XF	RoosterBank-hBM-1M-XF	1 bank	10 vials of 1 million XF cryopreserved cells
MSC-10M-5XF	RoosterBank-hBM-10M-XF	1 bank	5 vials of 10 million XF cryopreserved cells
MSC-10M-10XF	RoosterBank-hBM-10M-XF	1 bank	10 vials of 10 million XF cryopreserved cells
HUMAN UMBILICAL CORD-DERIVED MESENCHYMAL STEM/STROMAL CELLS (hUC-MSCs)*			
INDIVIDUAL VIALS			
C43001UC	RoosterVial-hUC-1M-XF	1 vial	1 million XF cryopreserved cells
C43002UC	RoosterVial-hUC-10M-XF	1 vial	10 million XF cryopreserved cells
WORKING CELL BANKS			
K40101	RoosterBank-hUC-1M-XF	1 bank	5 vials of 1 million XF cryopreserved cells
K40102	RoosterBank-hUC-1M-XF	1 bank	10 vials of 1 million XF cryopreserved cells

K40103	RoosterBank-hUC-10M-XF	1 bank	5 vials of 10 million XF cryopreserved cells
K40104	RoosterBank-hUC-10M-XF	1 bank	10 vials of 10 million XF cryopreserved cells
HUMAN ADIPOSE-DERIVED MESENCHYMAL STEM/STROMAL CELLS (hAD-MSCs)			
INDIVIDUAL VIALS			
MSC-021	RoosterVial-hAD-1M	1 vial	1 million cryopreserved cells
MSC-020	RoosterVial-hAD-10M	1 vial	10 million cryopreserved cells
MSC-024	RoosterVial-hAD-50M	1 vial	50 million cryopreserved cells
WORKING CELL BANKS			
MSC-022	RoosterBank™-hAD-1M	1 bank	5 or 10 vials of 1 million cryopreserved cells
MSC-023	RoosterBank-hAD-10M	1 bank	5 or 10 vials of 10 million cryopreserved cells
ROOSTERKITS			
hBM-MSCs			
KT-002	RoosterKit™-hBM-1M	1 kit	1 million cryopreserved cells + 1 KT-001 media kit
KT-020	RoosterKit-hBM-1M-XF	1 kit	1 million xeno-free (XF) cryopreserved cells + 1 KT-016 XF media kit
hUC-MSCs*			
K40105	RoosterKit-hUC-1M-XF	1 kit	1 million xeno-free (XF) cryopreserved cells + 1 KT-016 XF media kit
hAD-MSCs			
KT-005	RoosterKit-hAD-1M	1 kit	1 million cryopreserved cells + 1 KT-001 media kit
DONOR SCREENING KITS			
hBM-MSCs			
KT-014	hBM-MSC Donor Screening Kit	1 kit	3 vials of 1 million cryopreserved cells (1 each from 3 donors) + 1 KT-001 media kit
KT-022	XF hBM-MSC Donor Screening Kit	1 kit	3 vials of 1 million XF cryopreserved cells (1 each from 3 donors) + 1 KT-016 XF media kit
hAD-MSCs			
KT-015	hAD-MSC Donor Screening Kit	1 kit	3 vials of 1 million cryopreserved cells (1 each from 3 donors) + 1 KT-001 media kit
PRE-CLINICAL DEVELOPMENT KITS			
hBM-MSCs			
KT-023	XF hBM-MSC Pre-Clinical Development Kit	1 kit	20 million XF cryopreserved cells + 3 KT-016 XF media kits

TRT

* RoosterVial-hUC-XF manufactured and sold by RoosterBio, INC and supported by licensed technology from Tissue Regeneration Therapeutics Inc. (TRT) core technology and patent family: US 8,790,923; US 8,278,102; US 7,547,546; US 9,611,456; US 9,611,456; US 8,481,311; US 9,611,456.

INTENDED USE: FOR RESEARCH USE ONLY. Not approved for human, or diagnostic use. **WARNING**: These products are of human origin and should be handled as potentially infectious. Follow appropriate safety precautions.

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PRODUCT DESCRIPTION

Human Mesenchymal Stem/Stromal Cells

Human Mesenchymal Stem/Stromal Cells (hMSCs) have the potential for self-renewal and can differentiate to cells from a number of mesenchymal lineages. MSCs also secrete a number of trophic factors and possess the ability to modulate the body's immune response when transplanted alone or with other cells. There are 900+ global clinical trials investigating hMSC use across a host of diseases, and hMSCs have demonstrated excellent safety profiles. Thus, hMSCs will continue to be key components of future cellular therapies, cell-based gene therapies, hMSC-derived exosomes, and bioprinted engineered tissues.

RoosterBio® provides high quality, high volume human bone marrow- (BM), umbilical cord- (UC), and adipose- (AD) derived MSCs, isolated and expanded from iliac crest (BM), perivascular Wharton's jelly (UC), or lipoaspirates (AD), from a variety of healthy adult donors. Cryovials contain 1, 10, 20, or 50 million (M) viable hMSCs at Population Doubling Level (PDL) 8-10 post-mononuclear cell isolation (BM and AD) or 15-18 post isolation (UC) (except for RoosterRTP™ cells). Each vial of cells is guaranteed to expand at least 10x within 1 week when paired with our bioprocess media and batch culture systems (i.e., streamlined batch or fed-batch processing in 2D (adherent culture on single & multi-layer vessels) or 3D (suspension culture in spinning vessels & bioreactors), respectively); using our protocols / processes recommendations.

RoosterRTP hMSCs are Ready-to-Print (RTP), thaw and use cells provided at PDL 15-17. These late passage cells are not intended for further subculturing and banking – and are available in this fully-expanded format as serum-containing as well as in a xeno-free formulation (XFF).

RoosterKits

A hBM-, hUC-, and hAD-MSC RoosterKit™ contains 1M cryopreserved cells and one RoosterNourish™-MSC media kit, each. When expanded using our protocols, RoosterKits allow customers to rapidly and economically test RoosterBio hMSCs in their experimental systems before scaling up.

Donor Screening Kits

hBM- and hAD-MSC Donor Screening Kits contain three vials of 1 million cryopreserved cells, each from 3 different donors, and one RoosterNourish-MSC media kit for cell expansion. These kits enable rapid and economic screening of 3 donors for product & process development prior to scaling up with donor- and lot-matched Working Cell Banks (and 10M and 50M RoosterVials).

Pre-Clinical Development Kits

Pre-Clinical Development Kits contain 1 vial of 20 million xeno-free (XF) cryopreserved cells, from 1 donor, and 3 RoosterNourish-MSC-XF media kits for batch culture and cell expansion in 10-layer vessels. For rapid product & process development, clinically-relevant starting and ancillary materials are designed for IND-enabling pre-clinical data collection. Scale and format readily translates to CliniControl™ Products for further manufacturing use.

Working Cell Banks & RoosterBanks

hBM-, hUC-, and hAD-MSC Working Cell Banks (WCBs) are available as RoosterBanks in both the 1M and 10M RoosterVial™ size. Each RoosterBank™ contains 5 or 10 vials of cryopreserved cells from the same donor and cell lot. Thus, using RoosterBio WCBs minimize experimental variability and standardize experimental workflow. Importantly, when expanded with our bioprocess media systems, WCBs allow for a consistent PDL between experiments. Best practices in primary cell culture recommend tracking and reporting cumulative PDL, rather than passage number, on expanded cells and maintaining consistent PDL between experiments since hMSC function changes with PDL. *For more information on this and for a PDL calculator worksheet, please contact your local RoosterBio sales representative.*

QUALITY CONTROL

Quality Control (QC) testing is performed on hMSCs and bioprocess media kits. Products are tested for sterility and ensured to be free of microbial contaminants. Depending on product format, QC testing also includes cell attachment, expansion, viability, identity (via flow cytometry), differentiation (to bone, fat, and cartilage), angiogenic cytokine secretion, and immunomodulatory function. A Certificate of Analysis (CoA) is provided with

each product lot, and customers can request specific QC data (MSC identification & functional characterization) to facilitate donor selection for experimental design.

STORAGE AND USE

hBM-MSCs, hUC-MSCs, and hAD-MSCs should be thawed and used immediately upon receipt or stored immediately in liquid nitrogen, vapor phase. Storage at -80˚C is not sufficient for long-term cell preservation.

INTENDED USE: FOR RESEARCH USE ONLY. Not approved for human, or diagnostic use. **WARNING**: These products are of human origin and should be handled as potentially infectious. Follow appropriate safety precautions.