

OPTIMIZE YOUR PROCESS

Start with Scalable hMSC
Bioprocess Systems | Xeno-Free

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RoosterBio[®]
Radically Simplifying Use of MSCs



TRANSLATION-FRIENDLY hMSCs THAT ARE READY FOR WHAT'S NEXT



The RoosterVial™-hBM-XF is the Regenerative Medicine (RM) industry's first completely xeno-free (XF) human Mesenchymal Stem/Stromal Cell (hMSC) vial. Building a commercially-viable stem cell biomanufacturing process requires a highly productive, translation-friendly product platform, facilitating rapid clinical translation. Derived from human bone marrow, our XF Working Cell Banks enable robust, reproducible and scalable stem cell biomanufacturing.



Comparable to RoosterBio's flagship hMSC products, our XF hBM-MSCs are isolated from adult human iliac crest and expanded from a variety of normal, healthy donors. Dependent on product format, each cryovial of cells contains 1, 10, 20 or 50 million (M) viable hMSCs at a population doubling level (PDL) 6-10, post-mononuclear cell isolation. Each vial of cells is guaranteed to reach 10 fold expansion in 1 week of culture using our RoosterNourish™-MSC-XF and expansion protocols. E.g., One 10M cell vial will reach 100M within 7 days of culture.



Post-isolation and expansion, XF hBM-MSC cell surface marker profile, tri-lineage differentiation potential, cytokine secretion and immunomodulatory function are not only indicative of normal hMSC function, but also directly comparable to our off-the-shelf RoosterVial™-hBM.

Rapidly and Economically Forge Your Path to Billions of hMSCs

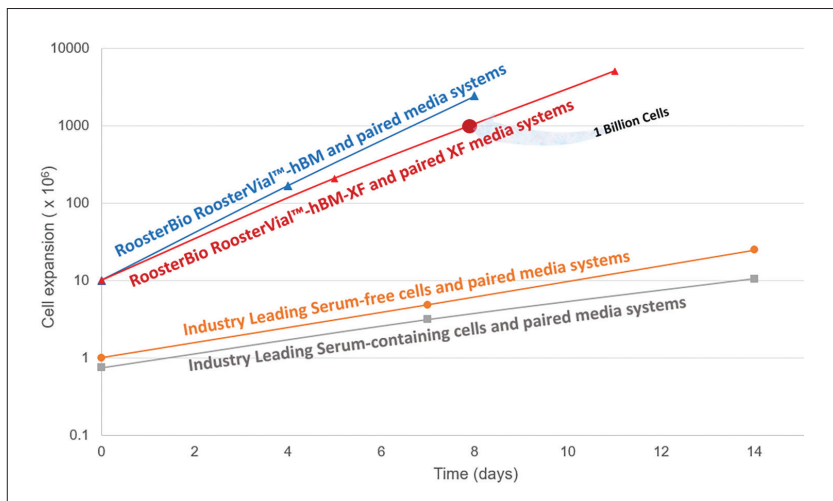


Fig 1: RoosterBio xeno-free (XF) hBM-MSCs cultured in RoosterNourish™-MSC-XF(KT-016) exhibit similar productivity to RoosterBio hBM-MSCs cultured in RoosterNourish-MSC (KT-001). RoosterBio cell and media products outperform the leading industry products and significantly decrease time and cost associated with stem cell manufacturing.

APPLICATIONS

- > Regenerative Medicine & Tissue Engineering R&D
- > Cell Therapy R&D
- > Product and Process Development
- > Pre-clinical data generation with clinically-relevant cellular starting materials

- > **Streamlined culture process:** RoosterBio hMSCs are paired with engineered bioprocess media systems to enable economical batch or fed-batch culture (i.e. cell culture without media exchange).
- > **Reduced barrier to clinical translation:** RoosterBio XF hMSCs provide a Xeno-free cell population. Engineered and produced with the same care as other RoosterBio products, RoosterBio XF hMSCs are manufactured from isolation through to final fill using only animal component-free (excluding human-sourced) raw materials. Thus, RoosterBio XF hMSCs maintain our industry-leading performance metrics.

CHARACTERIZATION OF XF hBM-MSCs

hBM-MSCs Derived in RoosterNourish-MSC-XF Maintain Normal hMSC Morphology

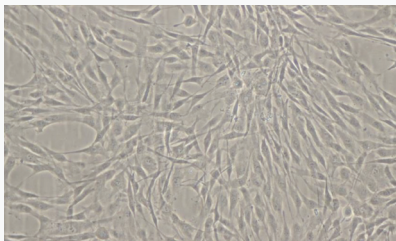


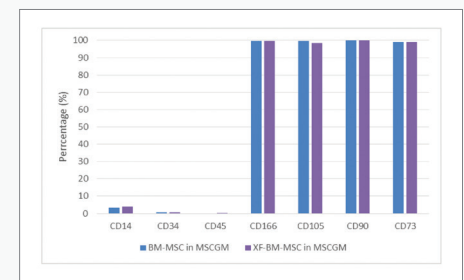
Fig 2: hMSCs isolated in XF media (A) maintained their fibroblastic cell morphology. Cells reached confluency of >85% within 4-5 days of culture.

hMSCs Derived in XF Media Maintained their Potency

I. CYTOKINE SECRETION

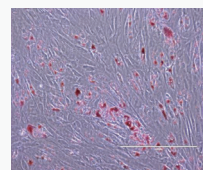


II. SURFACE MARKER EXPRESSION



III. DIFFERENTIATION & IMMUNOMODULATORY POTENTIAL

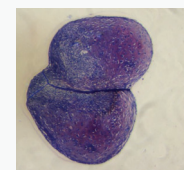
(A) Adipogenesis



(B) Osteogenesis



(C) Chondrogenesis



(D) IDO Activity

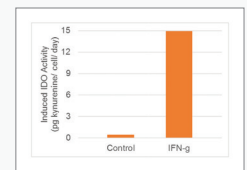


Fig 3: hBM-MSC derived in XF media maintained similar levels of (I) Angiogenic cytokine secretion, (II) Surface marker expression as well as (III) Tri-lineage differentiation and IDO activity.

QUALITY CONTROL

Rigid QC testing is performed on all hMSC and media kit lots. Dependent on product format, cells are assayed for expansion kinetics, viability, identity (via flow cytometry) and multi-lineage differentiation. Cytokine secretion levels and immunomodulatory function are also reported in a Certificate of Analysis.

Intended Use: These products are for Research Use Only.

ORDERING INFORMATION

HIGH VOLUME hMSCs

Catalog No.	Product	Qty	Unit Size & Brief Description
HUMAN BONE MARROW-DERIVED MESENCHYMAL STEM/STROMAL CELLS (hBM-MSCs)			
INDIVIDUAL VIALS			
MSC-030	RoosterVial™-hBM-10M-XF	1 vial	10 million xeno-free (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-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

BIOPROCESS MEDIA

Catalog No.	Product	Qty	Unit Size & Brief Description
MEDIA KITS			
INDIVIDUAL VIALS			
KT-016	RoosterNourish™-MSC-XF	1 unit	500 mL bottle of RoosterBasal™-MSC (SU-005) + 10 mL bottle of RoosterBooster™-MSC-XF (SU-016)
BIOREACTOR FEEDS			
SU-023	RoosterReplenish™-MSC-XF	1 bottle	10 mL XF bioreactor feed

PLUG-AND-PLAY SYSTEMS

Catalog No.	Product	Qty	Unit Size & Brief Description
ROOSTERKITS			
hBM-MSCs			
KT-020	RoosterKit-hBM-1M-XF	1 kit	1 million xeno-free (XF) cryopreserved cells + 1 KT-016 XF media kit
DONOR SCREENING KITS			
hBM-MSCs			
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
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
BIOREACTOR BUNDLES			
hBM-MSCs			
KT-056	XF Bioreactor Starter Bundle	1 bundle	1 RoosterVial™-hBM-1M-XF (1 million hBM-MSCs, MSC-031) + 1 RoosterNourish™-MSC-XF (500 mL, KT-016) + 1 RoosterReplenish™-MSC-XF (10 mL, SU-023) + 1 PBS 0.5 disposable bioreactor vessel (500 mL) + 1 PBS MINI base unit <i>Microcarriers not included - 1 vial required</i>
KT-057	XF Bioreactor Development Bundle	1 bundle	4 RoosterVial™-hBM-1M-XF (1 million hBM-MSCs, MSC-031) + 4 RoosterNourish™-MSC-XF (500 mL, KT-016) + 4 RoosterReplenish™-MSC-XF (10 mL, SU-023) + 4 PBS 0.5 disposable bioreactor vessels (500 mL) <i>Microcarriers not included - 4 vials required</i>
KT-058	XF Bioreactor Scale-Up Bundle	1 bundle	1 RoosterVial™-hBM-10M-XF (10 million hBM-MSCs, MSC-030) + 8 RoosterNourish™-MSC-XF (500 mL, KT-016) + 6 RoosterReplenish™-MSC-XF (10 mL, SU-023) + 1 PBS 3 L disposable bioreactor vessel (3 L) <i>Microcarriers not included - 4 vials required</i>

PERFORM HIGH-IMPACT, TRANSLATIONAL RESEARCH.



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