



RoosterVial™ MSCs

XENO-FREE (XF) HUMAN MESENCHYMAL STEM/STROMAL CELLS



An off-the-shelf hMSC working cell bank (WCB), RoosterVial hMSCs are available in XF formats for research and product development, as well as cGMP CliniControl™ (CC) formats for allogeneic clinical manufacturing.

From tissue to final cell-bank, MSC manufacturing is a lengthy, resource intensive journey with multiple opportunities for failure. RoosterBio has reduced this burden for hundreds of customers with off-the-shelf hMSCs sourced from healthy donors screened according to final use criteria. Once tissue is procured, the hMSCs are isolated and expanded using a validated and proprietary manufacturing process. The resulting cells are banked as RoosterVials and rigorously characterized for safety, MSC identity, and functional attributes prior to release. This commitment to manufacturing robustness and quality ensures consistent and reproducible experimental starting points – giving you confidence in your key starting cellular raw material. Additionally, cGMP CliniControl RoosterVial hMSCs are manufactured under current Good Manufacturing Practices (cGMP) and supported by US FDA Type II Master Files for use as a raw material for advanced cell and extracellular vesicle (EV) therapeutics.

When used alongside our exchange-free RoosterNourish™ expansion media, RoosterVial is designed to facilitate rapid scale-up in 2D and 3D MSC expansion, producing 100s of millions to billions of high-quality hMSCs at a fraction of the cost and time of traditional systems – so you can concentrate on your next big idea.

PRODUCT FEATURES

Xeno-Free | cGMP Formats Available

Multiple Tissues | Multiple Donors

cGMP Format Supported by Type II Drug Master File

Supported by 2D & 3D Scalable Processes

PRODUCT BENEFITS



De-Risked Cell-Based Manufacturing



Hand-Delivered Key MSC Characterization



Increased Confidence in Key Raw Material



Streamlined CMC & Regulatory Submission

Billions of Cells Easily Achieved in ≤ 10 Days

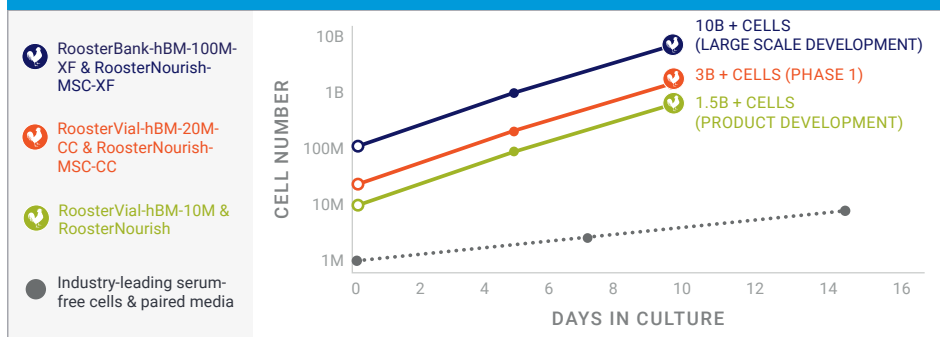


Fig 1

hMSC Identity and Morphology Characterization

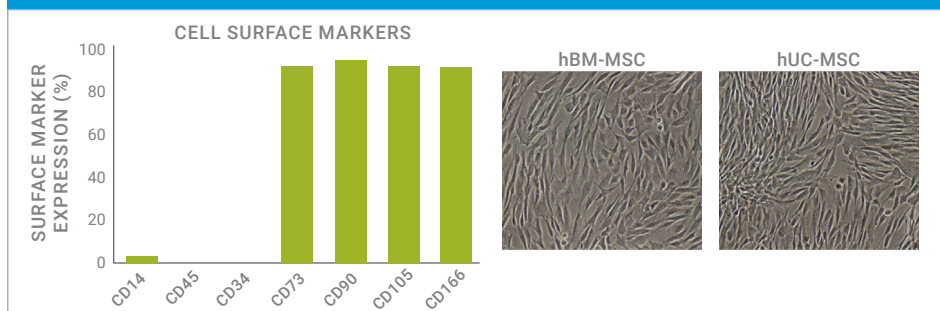


Fig 2

GAIN CONTROL OF YOUR CLINICAL PIPELINE FROM DISCOVERY THROUGH TRANSLATION.



RoosterBio®

"The robust MSC characterization practices followed by RoosterBio are important for my lab's research, and thus RoosterBio MSCs are our first choice in commercial cell procurement."

- Rebekah Samsonraj
Assistant Professor, University of Arkansas

Fig 1. RoosterVial outperforms leading industry systems when used alongside RoosterNourish media and following recommended expansion protocols.

Fig 2. (a) RoosterVial hMSCs vials meet ISCT guidelines for hMSC surface protein expression, as well as (b) exhibit healthy hMSC morphology from seeding through expansion.

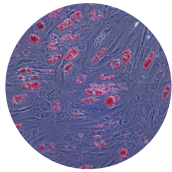
CONSISTENT YIELDS. ROBUST RESULTS.
SCALABLE TO BILLIONS OF hMSCS TO POWER YOUR NEXT GREAT IDEA.

Applications for RoosterVial™-hBM

CELL & GENE THERAPY | EXOSOME / EXTRACELLULAR VESICLE PRODUCTION | TISSUE ENGINEERING

Trilineage Differentiation Potential

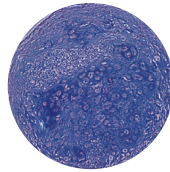
ADIPOGENESIS



OSTEOGENESIS



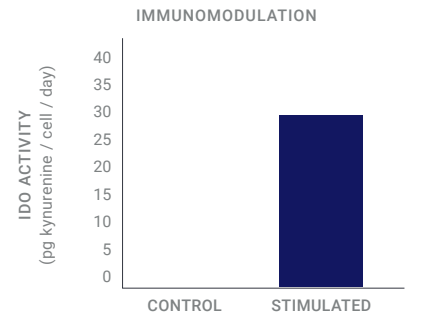
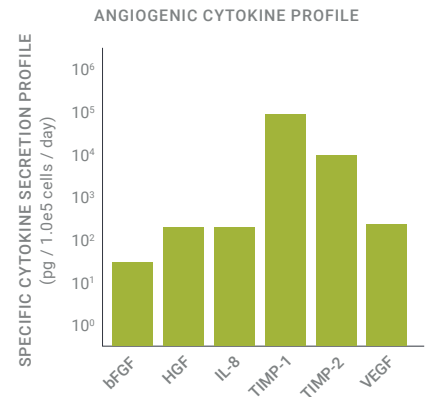
CHONDROGENESIS



PRODUCT INFORMATION

| | ROOSTERVIAL-XF | ROOSTERVIAL-CC* |
|---------------------------------------|--------------------------------------|--------------------------------|
| Manufactured Under GMP | | ✓ |
| FDA Type II MasterFile | | ✓ |
| Intended Use | Research and Development Use Only | Further Manufacturing Use Only |
| Available Tissue Source(s) | Bone Marrow, Umbilical Cord, Adipose | Bone Marrow, Umbilical Cord |
| Available Vial Size | 1M or 10M | 20M |
| Donor Profile [Age / Sex / Ethnicity] | ✓ | ✓ |
| Sterility Endotoxin Mycoplasma | ✓ | ✓ |
| in vitro Adventitious Agents | | ✓ |
| Species Identification | | ✓ |
| Viral Testing** | | ✓ |
| Cell Count & Viability | ✓ | ✓ |
| hMSC Surface Marker Expression | ✓ | ✓ |
| Cell Expansion Potential | ✓ | ✓ |
| Angiogenic Cytokine Secretion Profile | ✓ | ✓ |
| Immunomodulatory Potential | ✓ | ✓ |
| Tri-Lineage Differentiation Potential | ✓ | ✓ |

Industry Leading hBM-MSC Characterization



*CliniControl (CC) RoosterBio products are manufactured under GMP and tissue donor met all eligibility and testing requirement per FDA 21CFR Part 1271 and supported by Type II Drug MasterFile

**Master Cell Banks (MCBs) tested negative for industry standard viral testing panel.

| PRODUCT | SKU / CATALOG # | UNIT SIZE | INTENDED USE |
|--------------------------------------|------------------------|---|------------------------------------|
| Xeno-free Development Grade hMSCs | | | |
| RoosterVial-hBM-XF | MSC-031 MSC-030 | 1 vial of 1 million cryopreserved bone-marrow derived hMSCs 1 vial of 10 million cryopreserved bone-marrow derived hMSCs | For Research Use Only |
| RoosterVial-hUC-XF | C43001UC C43002UC | 1 vial of 1 million cryopreserved umbilical-cord derived hMSCs 1 vial of 10 million cryopreserved umbilical-cord derived hMSCs | For Research Use Only |
| RoosterVial-hAD-XF | C460001AD C460010AD | 1 vial of 1 million cryopreserved adipose derived hMSCs 1 vial of 10 million cryopreserved adipose derived hMSCs | For Research Use Only |
| cGMP & Xeno-free CliniControl hMSC | | | |
| RoosterVial-hBM-20M-CC | MSC-CC040 | 1 vial of 20 million XF cryopreserved cells – manufactured under cGMP | For Further Manufacturing Use Only |
| RoosterVial-hUC-20M-CC | C04020UC | 1 vial of 20 million XF cryopreserved cells – manufactured under cGMP | For Further Manufacturing Use Only |

Available in starter, donor screening, and tissue screening kit formats paired with RoosterNourish™ expansion media. Please inquire for more information about access to clinically relevant MSCs for use in development.



ROOSTERBIO.COM • 301.200.5366 • INFO@ROOSTERBIO.COM

RoosterBio, Inc is a privately held manufacturing platform technology company based in Frederick, MD focused on accelerating the development of a sustainable regenerative medicine industry, one customer at a time.