RoosterBio®

RADICALLY SIMPLIFYING

REGENERATIVE MEDICINE PRODUCT DEVELOPMENT

SARTORIUS

ABOUT ROOSTERBIO

SIMPLIFY YOUR hMSC-BASED THERAPEUTIC PRODUCT DEVELOPMENT

At RoosterBio, we are pioneers in radically simplifying the use of adult human mesenchymal stem/stromal cells (hMSCs) to propel the commercialization of regenerative technologies. By enabling living cells to become more affordable at the lowest cost per million cells with industry leading supporting quality documentation, we make MSCs easier to access and much simpler to incorporate into product development efforts, leading to rapid acceleration in products coming to market that incorporate these technologies.

WHY ROOSTERBIO

We are driving the transition of MSCs from a scarce resource into an abundant resource where billions is the new millions. By increasing their availability, and decreasing complexity required to incorporate into products, we are ushering in a new era of productivity and standardization to the field of regenerative medicine. Our innovative translation-friendly products are high volume, affordable and well characterized hMSCs paired with highly engineered media systems that ease the regulatory pathway and accelerate speed to market.

WHO WE SERVE

RoosterBio products empower researchers and product developers in the cell therapy, gene therapy, extracellular vesicles, tissue engineering and medical devices field. We have served over 300 customers in industry, regenerative medicine accelerators, translational centers, government agencies and academia across 6 continents.

300+ PRODUCT DEVELOPERS, RESEARCHERS, AND SCIENTISTS WORLDWIDE

HAVE USED ROOSTERBIO'S

OFF-THE-SHELF WORKING **CELL BANKS** AND MARKET-DISRUPTING **MSC TECHNOLOGY**

SHORTEN PRODUCT DEVELOPMENT TIMELINES WITH INNOVATIVE PRODUCTS FOR RAPID SCALE-UP

OUR SUPPLY CHAIN	DIY SUPPLY CHAIN
ROOSTERBIO: 3-5 YEARS	TYPICAL TIMELINE: 7-11 YEARS

RESEARCH & OPTIMIZATION → PRODUCT & PROCESS DEVELOPMENT → TECH TRANSFER & MANUFACTURING → FIRST IN-HUMAN TESTING

RUO PRODUCTS
Triple the productivity of R&D

DEVELOPMENT GRADE PRODUCTS
Focus on product development experiments with rapid scale-up

cGMP PRODUCTS
Speed through tech transfer with off-the-shelf fully qualified hMSC WCBs

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Products That Meet Your Application

FEATURES	BENEFITS
High Volume hMSCs	
Available in 1M, 10M and 100M Working Cell Bank Formats	Translation-Friendly hMSC Product Formats Designed for All Stages of Product Development
Bioprocess Media	
Our Rich Bioprocess Media Formulations are the Only Product that Supports Scalable hMSC Platforms	Economical 2D Batch or Bioreactor Fed-Batch Culture Leading to High Productivity and Efficient Cell Expansion
Scalable Process	
Transparent and Traceable Process Development and Scalable Processes	Easily Implementable Protocols and Process Reccomendations for 2D and Scalable Bioreactor Expansion
CliniControl™ Products	
Clinically-Relevant hMSCs with Paired Bioprocess Media	Manufactured Under cGMP and Supported by Type II U.S. FDA Master Files

MSC THERAPY

RADICALLY SIMPLIFYING USE OF hMSCs

ROOSTERVIAL™ AND ROOSTERBANK™

KEY BENEFITS

- Supported by 1st in class hMSC identity and functional characterization
- Multiple formats available in 1M, 10M, 100M vials and bags from bone marrow and umbilical cord
- Manufactured with scalable standardized processes to minimize variability and maximize productivity
- Supplied, easy-to-follow expansion protocols saving you months of process development time
- Generate 10-fold hMSC expansion within 7 days and 100 fold hMSC expansion in 2 weeks or less when cultured with RoosterNourish-MSC-XF
- Reduce your clinical barrier: Use right-sized product formats that accelerate your product development and path to the clinic while saving you time and money
- cGMP version available for rapid translation into clinical manufacturing

ROOSTERNOURISH™ AND ROOSTERREPLENISH™

KEY BENEFITS

- Our rich bioprocess media systems enable economical batch or fed-batch culture meaning you can run your MSC culture without media exchanges
- > 10-fold expansion within 7 days of culture when used with our RoosterVial-hBM-XF and provided processes
- High volumes of cells are quickly realized without any media exchanges, drastically reducing your media consumption by 50% or more
- Achieve unprecedented productivity through efficient media usage and simplified hMSC production, dramatically reducing your costs and labor requirements
- RoosterBio's highly productive media systems are designed for scalability and efficiency to reduce development timelines: Seamlessly move from batch (2D) to fed-batch (3D) culture process
- RoosterReplenish is a bioreactor feed designed to achieve high cell growth in microcarrier-based suspension cultures when paired with our xeno-free (XF) hMSCs in a fed-batch system
- cGMP version available for rapid translation into clinical manufacturing

STANDARDIZED hMSC 2D (FLASK) BIOPROCESS SYSTEMS

2D — Consistent, Scalable Manufacturing

Consistent CMC Across Scales (Tissue > MCB > Standardized WCB)

Scale	Working Cell Banks	P3 Expansion	P4 Expansion	Cellular Yield with Consistent PDL of 16-18
R&D	1M Cells + 50mL media	10-15M cells 1 x T-225	3 x CS2 or 20 x T225 + ~1L RoosterNourish	150-250M
Product Development	10M Cells + 500mL Media	100-150M cells 2 x CS2 or 12 x T225	5-10 x CS10 + 7-15L RoosterNourish	1.5-2.5B
Phase 1 Clinical	20M Cells + 1.5L Media	200-300M cells 1 x CS10	20 x CS10 + 30L RoosterNourish	3-5B
Phase 2 Clinical	2 x 20M Cells + 3L Media	400-600M cells 2 x CS10	40 x CS10 + 60L RoosterNourish	6-10B

CliniControl™ cGMP Products

KEY BENEFITS

- Using standardized cGMP compliant manufacturing process
- High-volume scalable format (20M cell vial) designed to meet the needs of cGMP clinical and commercial manufacturing
- Multiple donors available, tissue collection in compliance with regulation
- Off-the-shelf WCB – bypasses the need of qualifying and releasing a MCB (master cell bank) and WCBs
- US FDA Type II Master file available for reference to support IND filing, reducing your CMC technical writing time and effort
- 2/3 of your hMSC (cellular material) CMC paperwork can be met using our hMSC bioprocess system and Master Files

Which Product Fits Your Requirements?

Catalog #	Product	RUO	RUO-XF	cGMP-XF
KT-001	RoosterNourish™-MSC (SU-005/022 + SU-003)	●		
KT-016	RoosterNourish-MSC-XF (SU-005/022 + SU-016)		●	
KT-021	RoosterNourish-MSC-CC (SU-022 + SU-019)			●
SU-023	RoosterReplenish™-MSC-XF		●	
MSC-001	RoosterVial™-hBM-10M	●		
MSC-003	RoosterVial-hBM-1M	●		
MSC-030	RoosterVial-hBM-10M-XF		●	
MSC-031	RoosterVial-hBM-1M-XF		●	
MSC-035	RoosterBank™-hBM-100M-XF		●	
MSC-040	RoosterVial-hBM-20M-CC			●
C43001UC	RoosterVial-hUC-1M-XF		●	
C43002UC	RoosterVial-hUC-10M-XF		●	

TRANSLATION-FRIENDLY PRODUCTS

THAT STANDARDIZE YOUR

hMSC RESEARCH,

SAVE YOU TIME AND MONEY,

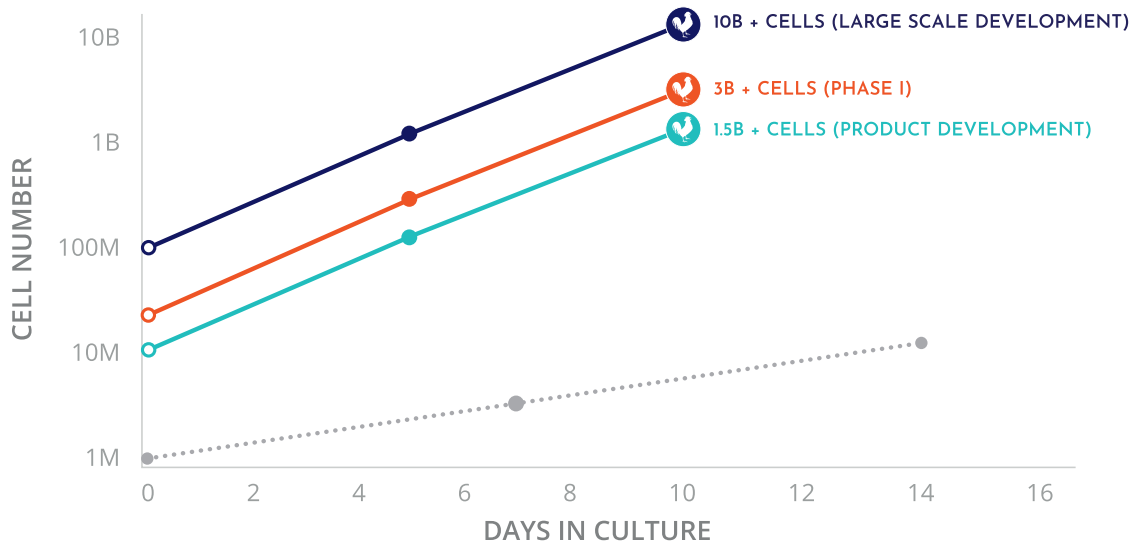
AND

ACCELERATE

YOUR PATH TO THE CLINIC

OUR PRODUCTIVE SYSTEM

BILLIONS OF CELLS EASILY ACHIEVED IN ≤ 10 DAYS



Whether you need 5 million or 5 billion hMSCs, each RoosterVial is guaranteed to expand 10-fold within a week when paired with our highly-engineered bioprocess media and protocol recommendations.

STANDARDIZED hMSC 3D (BIOREACTOR) BIOPROCESS SYSTEMS

3D — Consistent, Scalable Manufacturing

Consistent CMC Across Scales (Tissue > MCB > Standardized WCB)

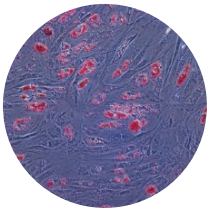
Scale	Working Cell Banks	Seed Train (4 days)	Bioreactor Culture (4-6 days, Day 3 feed)	Cellular Yield with Consistent PDL of 16-18
0.1L R&D	1M Cells + 50mL RoosterNourish	10-15M cells 1 x T-225	2.1M Cells 90mL RoosterNourish + RoosterReplenish	30-50M
3L Product Development	10M Cells + 600mL RoosterNourish	100-150M cells 2 x CS2	70M Cells 3L RoosterNourish + RoosterReplenish	1.2-2B
15L Phase 1 Clinical	2 x 20M Cells + 3L RoosterNourish	400-600M cells 2 x CS10	350M Cells 15L RoosterNourish + RoosterReplenish	6-10B
50L Phase 2 Clinical	100M Cells + 7.5L RoosterNourish	1-1.5B cells 5 x CS10	1.2B Cells 50L RoosterNourish + RoosterReplenish	20-30B

Industry Leading Characterization

RoosterBio hMSCs have the most thorough Certificates of Analysis in the industry. Cells are released on total cell number, growth rate, identity testing (via flow cytometry) and multilineage differentiation. Potency-related markers such as cytokine secretion and immunomodulatory ability are also tested and reported. We provide unparalleled access to multiple donors, multiple tissue types and lot selection guidance.

Characterization of RoosterVial™-hBM-20M-CC

ADIPOGENESIS



OSTEOGENESIS

CHONDROGENESIS

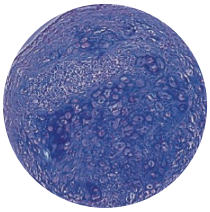
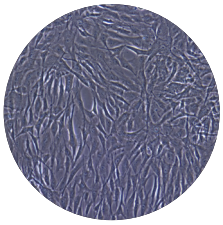


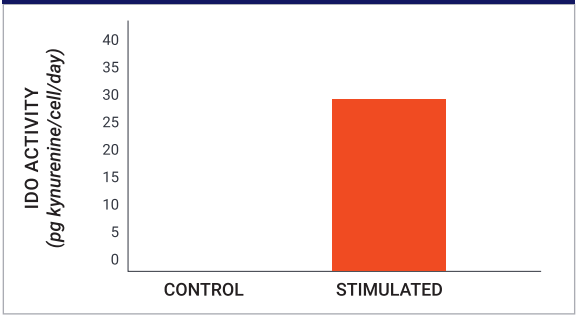
Fig I: hMSCs expanded from RoosterVial-hBM-20M-CC (MSC-CC040) express typical MSC surface marker profile (data not shown) and maintain trilineage differentiation potential



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

Fig 2: hMSCs isolated in XF media mantained their fibroblastic cell morphology

IMMUNOMODULATION



ANGIOGENIC CYTOKINE PROFILE

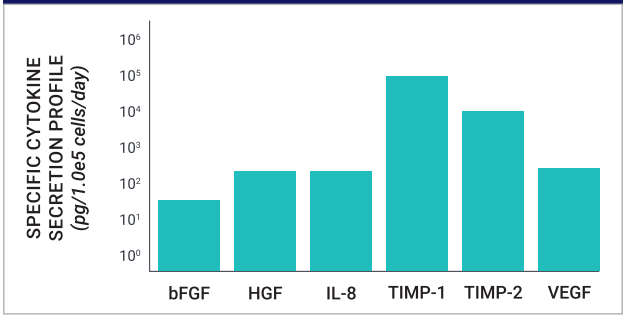


Fig 3 & 4: hMSCs expanded from RoosterVial-hBM-20M-CC (MSC-CC040) maintain MSC functionality (I) Immunomodulation and (II) Angiogenic cytokine profile.

EV COLLECTION

REVOLUTIONIZING EXTRACELLULAR VESICLE PRODUCTION

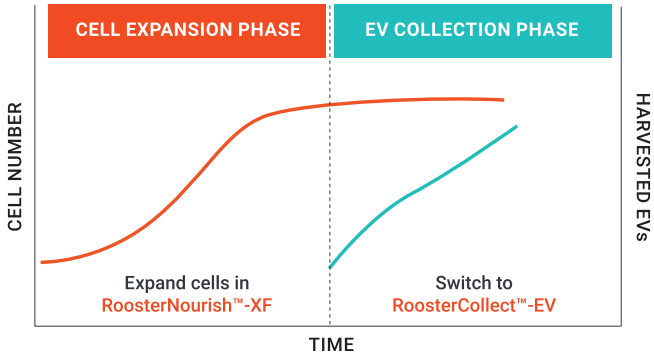
A hMSC-based bioprocess with scalability built in provides a seamless path to bioreactor systems. Generating lots of extracellular vesicles (EVs) starts with a scalable bioprocess system.

hMSC-Based EV Production Systems

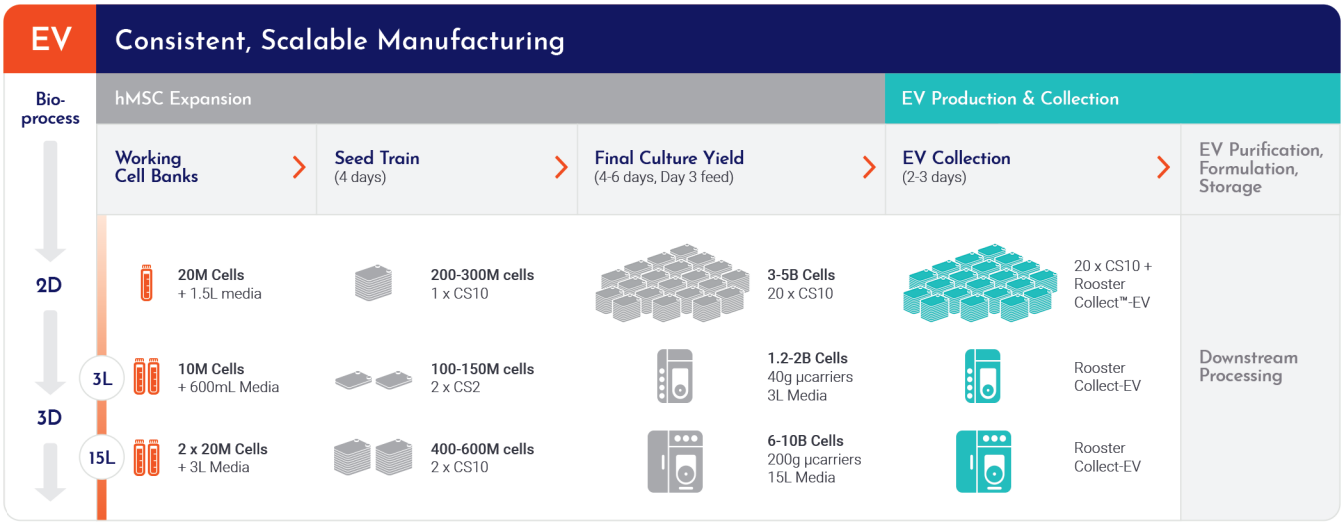
KEY BENEFITS

- Radically shorten the time required to implement extracellular vesicles (EVs) and quickly reach unprecedented production efficiencies
- Easy-to-follow streamlined hMSC expansion and EV collection protocols saves you time and eases workflow implementation
- RoosterBio's hMSC-geared process boosts EV yield and minimizes processing time
- RoosterBio's EV production system seamlessly integrate with 2D or bioreactor culture systems as part of a direct hMSC expansion to EV collection workflow
- EV production supplement for enhancing EV productivity is available
- RoosterBio translation-friendly products and process reduce barrier to clinical translation

Transition From hMSC Expansion to EV Collection



2D and 3D hMSC Expansion to EV Collection



Increased EV Productivity

EV Yields

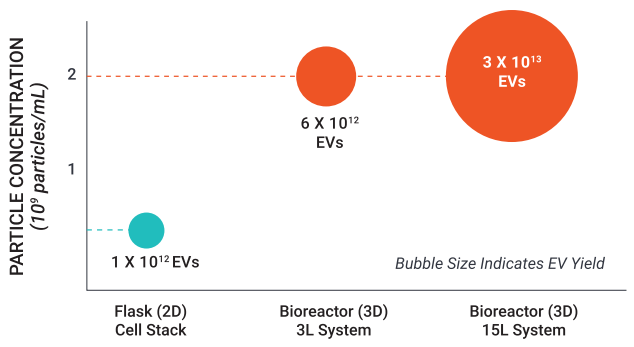


Fig 1: EV productivity and yields increase with our scalable bioprocess system

Scalable EV Collection in Multiple Bioreactor Sizes

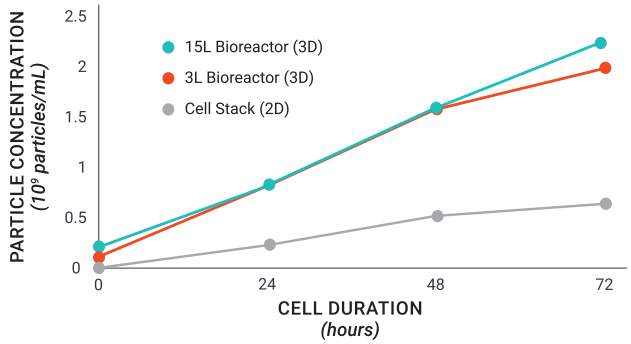


Fig 2: Scalable hMSC expansion and EV collection in 2D and 3D bioreactor

RoosterCollect™-EV Reduced Particle Levels Ensure Confidence

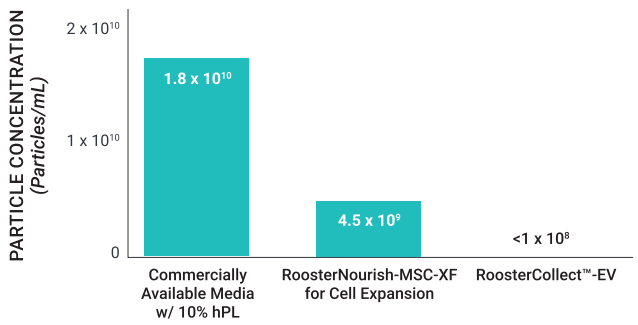


Fig 3: Low particle media, RoosterCollect™-EV, supports a seamless transition from hMSC expansion to EV collection

Particle Collection in EV Size Ranges

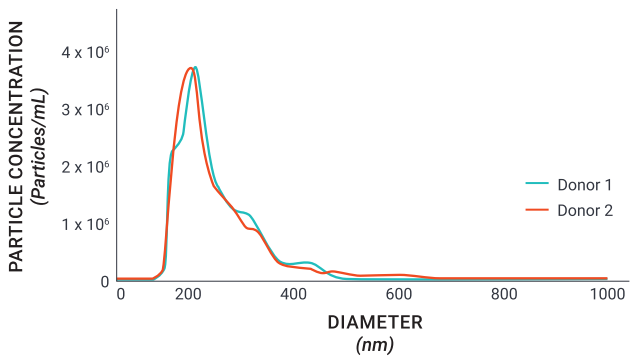


Fig 4: Particles collected from RoosterBio xeno-free hMSCs have diameters in the size range of 50 to 250 nms

Which Media Fits Your Requirements?

Catalog #	Product	RUO	RUO-XF	cGMP-XF
M2001	RoosterCollect-EV		•	
M02001	RoosterCollect-EV-CC			•
S2001	EV Boost™		•	

READY-TO-PRINT AND READY-TO-SEED

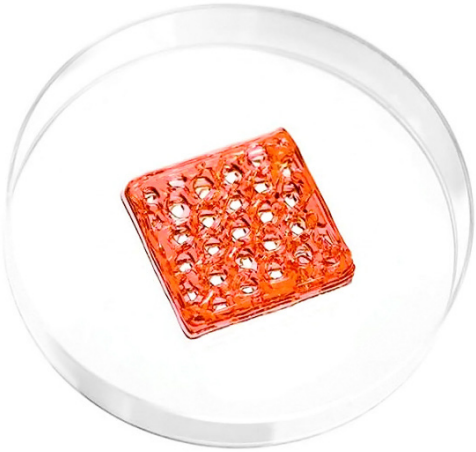
A MSC reagent for same-day experiments, RoosterRTP™ is fully-expanded and ready-to-use in various applications without the need for cell culture.

This 50M viable cell MSC format enables product developers and researchers to remove their cell manufacturing process and get right-to-product development. Save time from repeatedly producing 10M to 100M hMSCs by starting with a standardized cell population (with consistent PDL) that is translation-ready and clinically-relevant.

RoosterRTP-hBM-50M-XF

KEY BENEFITS

- Direct-use hMSC product format: Thaw and use directly to seed or bioprint scaffolds
- Does not require sourcing material for large scale production (and cryopreservation) of hMSCs
- Minimize experimental variability by using a standardized hMSC starting material that is supported by industry-leading functional characterization
- Reduce time between experiments for accelerated discovery, increased data generation and rapid integration
- Cost-effective solution made available at a fraction of typical hMSC cost
- Supports pre-clinical and development work in 3D bioprinting of small and large tissue constructs



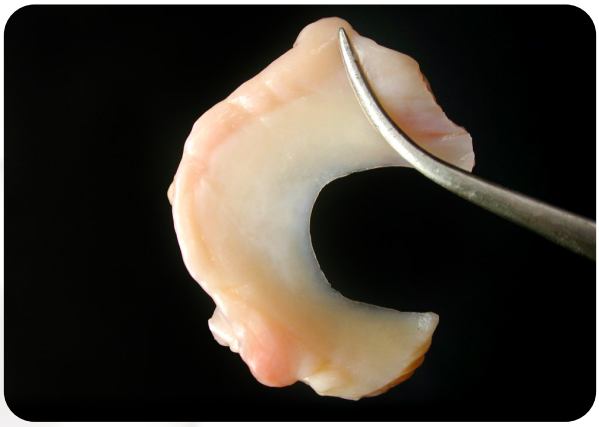
RoosterRTP: A hMSC REAGENT THAT STREAMLINES YOUR BIOPRINTING WORKFLOW

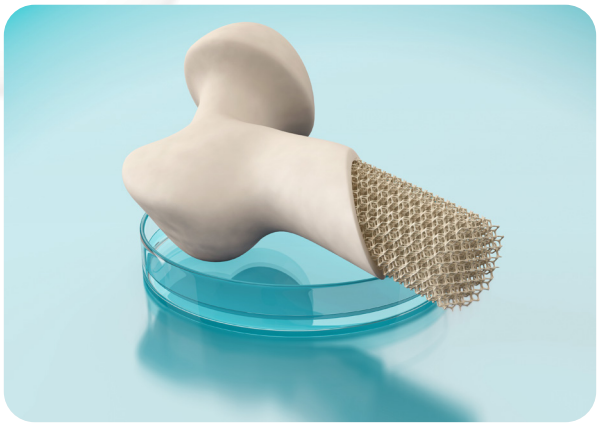
Characterization of RoosterRTP-hBM-50M-XF

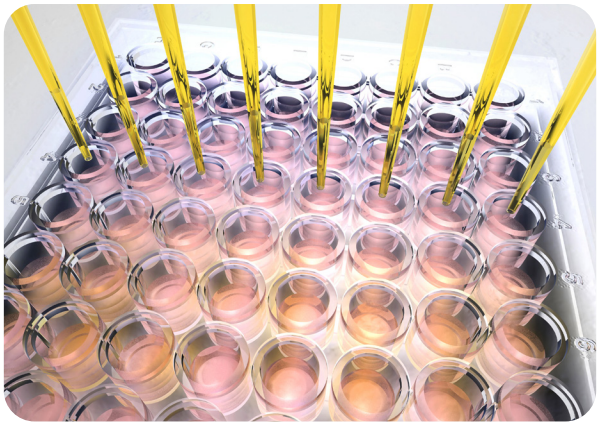
RoosterRTP cells are fully expanded, late-passage (PDL 15-17) hBM-MSCs that maintain the same critical MSC quality attributes of the parental cell lot from earlier passage hBM-MSCs. Each lot is characterized by cell surface marker expression, trilineage differentiation, immunomodulatory potential (IDO assay), and angiogenic cytokine secretion. *QC data available upon request.*

Catalog #	Product	RUO	RUO-XF	cGMP-XF
MSC-034	RoosterRTP-hBM-50M-XF		•	

RoosterRTP™ Applications







TISSUE ENGINEERING

Directly seed into scaffolds or incorporate into biomaterials

BIOPRINTING

Use as a plug & play cellular bioink component

HIGH-THROUGHPUT SCREENING

Mass produce MSC derivatives for drug screening

For any questions, please contact RoosterBio's partner in Korea,

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