

# EVOLVE YOUR hMSC SUPPLY CHAIN AND REACH NEW HEIGHTS WITH

## CliniControl™ (CC)

RoosterVial™-hBM-20M-CC | High Volume hMSCs | cGMP  
hMSC-based allogeneic therapeutic cell manufacturing will never be the same.

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## RoosterBio®



RoosterBio® is revolutionizing the Regenerative Medicine (RM) industry, one MSC product at a time. Implement the industry's only high-quality, allogeneic, off-the-shelf working cell bank (WCB) for therapeutic cell manufacturing, and bypass major steps in clinical manufacturing.

Reimagine your cell manufacturing process. Start with high-volume, well-characterized, standardized WCBs for large scale hMSC production and establish a new comprehensive, qualified hMSC supply chain. Utilize CliniControl™ (CC) starting materials to radically shorten your clinical development timelines.

RoosterBio CliniControl high volume hMSCs are xeno-free (XF), manufactured under cGMP and supported for use as a manufacturing starting material by Quality documentation and Regulatory support to facilitate IND filings. Each RoosterVial™-hBM-20M-CC contains at least 20 million human bone marrow-derived MSCs. RoosterBio CliniControl cell banks and bioprocess media are engineered to scale with your culture platform and stage of clinical development.

### PERFORMANCE

- > Achieves clinically-relevant lot sizes of low PDL final product in days, not weeks
- > Sets new standard of industry-leading performance while de-risking your hMSC supply chain
- > Designed to thaw and seed into 10-layer stacked vessels with a single-passage process
- > Backed by process recommendations, CliniControl hMSCs are poised to simply integrate into your process

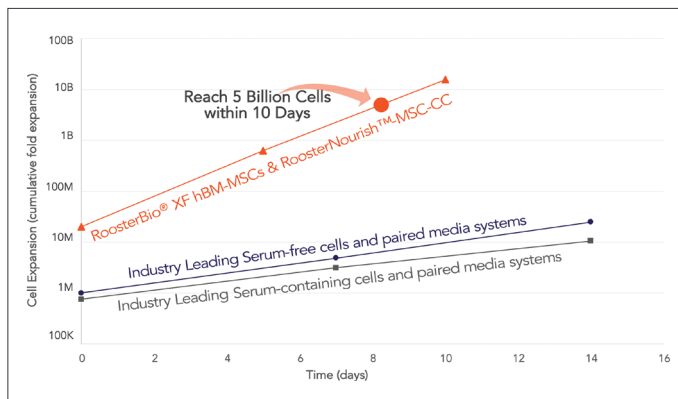


Fig 1: RoosterBio XF hBM-MSCs cultured in RoosterNourish™ MSC-CC (KT-021) yield approximately 5 Billion hMSCs in 10 days. These data represent expected results (lot size yield of 3-5 Billion) using the entire CliniControl™ system (cells, bioprocess medium, and recommended process).

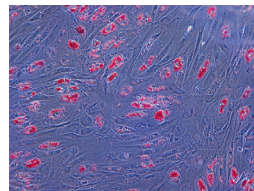
### QUALITY CONTROL

- > CliniControl™ RoosterVial™ cells are expanded under aseptic current Good Manufacturing Practices (cGMP) from master cell banks that have undergone complete viral safety testing. Each lot is tested per current USP or approved test methods and released in accordance with master product specifications. All lot release results are reported on lot-specific CoAs.
- > WCBs are released with a common MSC QC panel to simplify comparability

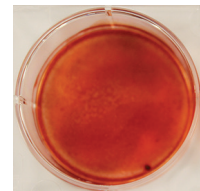
### Characterization of RoosterVial™-hBM-20M-CC

#### TRI-LINEAGE DIFFERENTIATION POTENTIAL

##### (A) Adipogenesis



##### (B) Osteogenesis



##### (C) Chondrogenesis

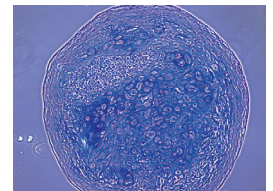


Fig 2: hMSCs expanded from RoosterVial™-hBM-20M-CC (MSC-CC040) express typical MSC surface marker profile (data not shown) and maintain trilineage differentiation potential.

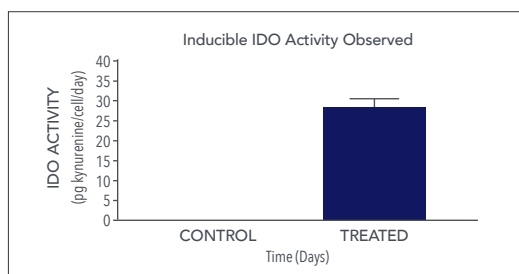
# QUALITY IS OUR PREMIERE COMMITMENT TO DRIVING THE EXPLOSIVE REGENERATIVE MEDICINE INDUSTRY.

Quickly reach full potential to deliver life-changing treatments.



## Characterization of RoosterVial™-hBM-20M-CC

### I. IDO ACTIVITY



### II. CYTOKINE SECRETION

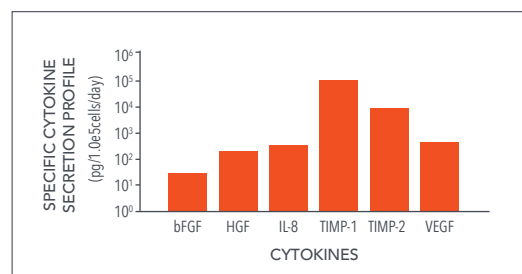


Fig 3: hMSCs expanded from RoosterVial™-hBM-20M-CC (MSC-CC040) maintain MSC functionality: (I) Immunomodulatory activity and (II) Angiogenic cytokine secretion.

- > Manufactured within ISO 9001:2008 certified manufacturing facilities
- > Supported for use as a manufacturing starting material by Quality and Regulatory documentation to simplify IND filings

### > CliniControl™ APPLICATIONS

- Cell-based therapies
- hMSC-derived exosomes
- Engineered tissues and 3D bioprinting
- Drug discovery, screening, and toxicology testing

### PRODUCT FEATURES

- > 20 million XF cells per vial (off-the-shelf WCB)
- > Manufactured under cGMP
- > Cryopreserved using a controlled and fully XF preservation process
- > Tissue of Origin: Healthy human bone marrow
- > Highly-standardized production platform yielding consistent results
- > Well-characterized; supported by detailed functional data

### CliniControl™ ADVANTAGES

- > Radically shortens development timelines for hMSC-based processes and products
- > Obviates the need for establishing a costly and time-intensive hMSC supply chain
- > Scalable platform for ease of transitioning from a robust batch (2D) process to a fed-batch (3D) process
- > Supports your clinical pipeline. Use with CliniControl™ bioprocess medium (RoosterNourish™-MSC-CC) for an anticipated lot size yield of approximately 3-5 Billion hMSCs per our process recommendation.\*
- > De-risks your process by minimizing in-process intervention and driving efficiencies that scale with your manufacturing platform
- > Contributes to a commercially-viable cost of goods

### PROCESS NOTES:

\*Media needs will be dependent on customer's process. Contact us for process recommendations.

\*\*Perform pre-clinical studies using XF hBM-MSc Pre-Clinical Development Kit (KT-023) - a Research Use Only (RUO) kit with comparable materials and similar process recommendations.

Intended Use: For Further Manufacturing Use Only. Not intended for diagnostic use or for direct therapeutic human or veterinary use.

YOU FOCUS ON PRODUCT DEVELOPMENT. WE'VE GOT YOUR SUPPLY CHAIN COVERED.  
LEVERAGE CliniControl™.

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