

UNLOCK YOUR STEM CELLS WITH CliniControl™ (CC)

RoosterNourish™-MSC-CC | Bioprocess Media

Gain control of your clinical pipeline from discovery, to translation, through commercialization.

WWW.ROOSTERBIO.COM



RoosterBio™



RoosterBio CliniControl™ bioprocess media are xeno-free (XF), manufactured under cGMP, and backed by Quality documentation to facilitate your regulatory process.

Engineered for clinical research process and product developers, these highly productive bioprocess media enable scalable hMSC culture for allogeneic and autologous therapeutic manufacturing, delivering robust, reproducible and standardized results.

RoosterNourish™-MSC-CC contains two components: RoosterBasal™-MSC-CC (500 mL) and RoosterBooster™-MSC-CC (10 mL). The use of RoosterNourish-MSC-CC yields superior

cell expansion, over 8-12 hMSC Population Doublings, compared to conventional hMSC culture media. Implement clinically-relevant ancillary materials to generate unprecedented media efficiencies in adult stem cell manufacturing, and accelerating your process and product development workflow.

PERFORMANCE & QUALITY CONTROL

CliniControl™ products radically simplify every step in product development and clinical translation, improving your likelihood of commercial success. RoosterNourish™-MSC-CC bioprocess media set the new standard of industry-leading performance. These highly-engineered media formulations, manufactured to the highest QC standards, yield reproducible results that scale with your process, affording even greater economies of scale.

Performance

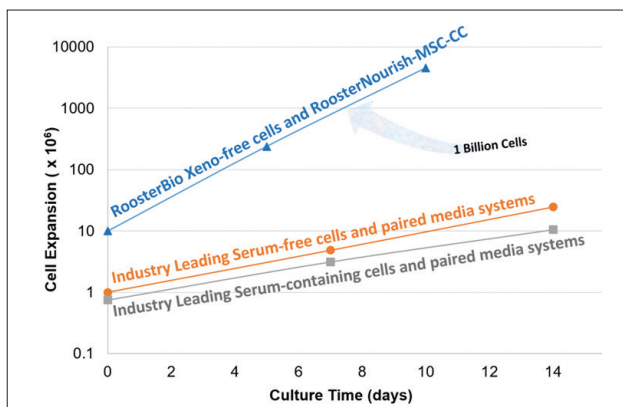


Fig 1: RoosterBio XF hBM-MSCs cultured in our RoosterNourish™-MSC-CC (KT-021) increase media productivity and outperform the leading industry products to significantly decrease time and cost associated with stem cell manufacturing.

CliniControl™ products are ready for each process step as you move from research to clinical translation. RoosterBio products are engineered to scale with your growth.

Characterization of XF hBM-MSCs

TRI-LINEAGE DIFFERENTIATION POTENTIAL

(A) Adipogenesis

(B) Osteogenesis

(C) Chondrogenesis

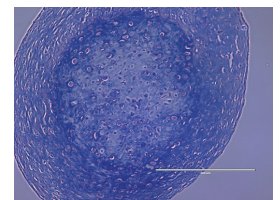
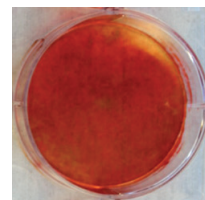
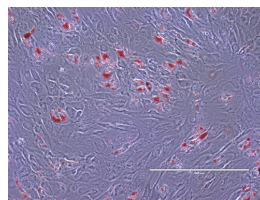


Fig 2: Tri-lineage differentiation. XF hBM-MSCs expanded in RoosterNourish™-MSC-CC bioprocess media maintained their morphology, phenotype and functionality.

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

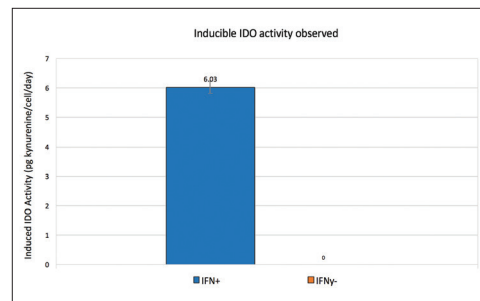
Quickly reach full potential to deliver life-changing treatments.



- > CliniControl™ Applications
 - Cellular therapies
 - Cell-based gene therapies
 - hMSC-derived exosomes (extracellular vesicles)
 - Engineered tissues (e.g., bone, cartilage, muscle, tendon, nerve – among other tissue types)
 - Bioprinted engineered tissues (i.e., cellular component of bioink to print tissue constructs)
 - Drug discovery & screening
- > Manufactured with methods and controls that conform with current good manufacturing practices (cGMP). Our manufacturing facilities are also ISO certified.
- > We provide documentation- and knowledge-based regulatory support to simplify IND/BLA filings.
- > In addition to our CliniControl™ products, we have an extensive companion (translation-friendly) portfolio of analogous, high-quality Research Use Only (RUO) products.

Characterization of XF hBM-MSCs

I. IDO ACTIVITY



II. CYTOKINE SECRETION

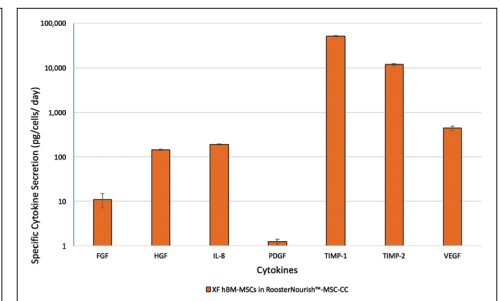


Fig 3: XF hBM-MSCs expanded in RoosterNourish™-MSC-CC bioprocess media maintained their functionality: (I) Immunomodulatory function, (II) Angiogenic cytokine secretion, and (III) Surface marker expression (not shown).

CliniControl™ BENEFITS

- > Engineered for robust 2D (adherent – on flasks and stacked vessels) and 3D (suspension – in spinner flasks and bioreactor systems) hMSC culture for further manufacturing.
- > Obviates the need for attachment solutions and coating procedures.
- > Yields unprecedented media productivity (millions of cells produced per Liter of media consumed) by the removal of a media exchange between passages. Thus, qualifying a large-scale batch process.
- > Streamlines culture processes, increases consistency, and reduces processing time and labor.
- > Radically shortens development timelines for hMSC-based processes and products.
- > Preserves key hMSC Critical Quality Attributes essential to your product
 - Tri-lineage differentiation potential
 - Key functionality: Cytokine secretion, immunomodulatory activity, and cell surface marker expression – biology is consistent with MSC standards.

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

REDESIGN YOUR hMSC WORKFLOW AND SPEED YOUR PATH TO CLINICAL TRANSLATION. IMPLEMENT CliniControl™.