



# RoosterVial™-hDFs

XENO-FREE (XF) HUMAN NEONATAL DERMAL FIBROBLASTS



**An off-the-shelf hDF working cell bank (WCB), RoosterVial hDFs are available in XF formats for research and product development, DEV+ formats for pre-clinical development, and CGMP CliniControl™ (CC) formats to support allogeneic clinical manufacturing.**

From tissue procurement to final cell bank, hDF manufacturing is a lengthy, resource-intensive process with multiple opportunities for failure. RoosterBio bypasses these challenges with off-the-shelf hDFs sourced from healthy donors and screened to meet the Quality and safety requirements for their intended use. Following tissue procurement, hDFs are isolated and expanded using a standardized process, banked, and rigorously characterized for safety, identity, and functional attributes prior to release to ensure consistent starting material. A single Working Cell Bank vial can manufacture billions of hDFs or trillions of EVs when paired with RoosterBio media and established scalable 2D and 3D processes.

For clinical programs, cGMP CliniControl™ RoosterVial hDFs are manufactured under cGMP from GTP sourced tissues for use as starting materials in advanced cell and extracellular vesicle (EV) therapeutics, cellular reprogramming, aesthetics, tissue engineering, and wound healing. RoosterVial-DEV+ hDFs are a pre-clinical development tool derived from the same cGMP Master Cell Banks as the CliniControl products.

## PRODUCT FEATURES

Xeno-free | cGMP Formats Available

>20 Additional Population Doublings

>10-fold Expansion in Four to Five Days when Cultured with RoosterNourish™

Easy to Follow Expansion Protocols for 2D & 3D Scalable Manufacturing of hDFs and hDF-EVs

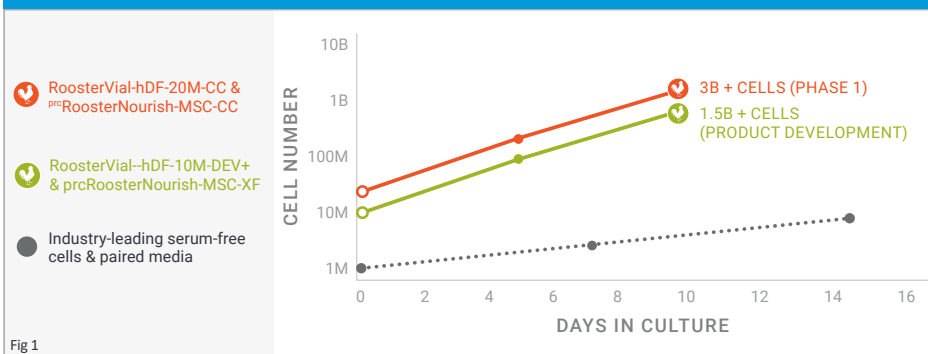
Comprehensive, Lot-Specific Characterization Package

ONE PLATFORM.

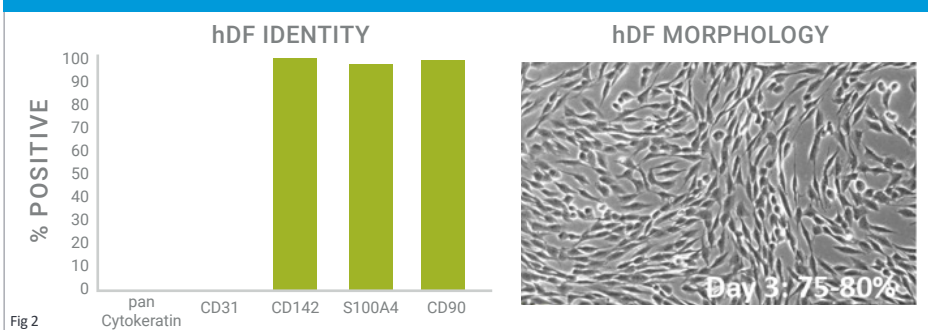
ONE PARTNER.

FROM DISCOVERY THROUGH THE CLINIC.

## Billions of Cells Easily Achieved in ≤ 10 Days



## Fibroblast Identity and Morphology Characterization



RoosterBio®

Fig 1. RoosterVial-hDF-XF outperform leading industry products when used alongside RoosterNourish media and following expansion protocol recommendations.

Fig 2. RoosterVial hDF vials characterized for hDF surface protein expression and demonstrate healthy fibroblast morphology from seeding through expansion.

CONSISTENT YIELDS. ROBUST RESULTS.

SCALABLE TO BILLIONS OF hDFs TO POWER NEXT ADVANCED THERAPEUTIC CANDIDATES

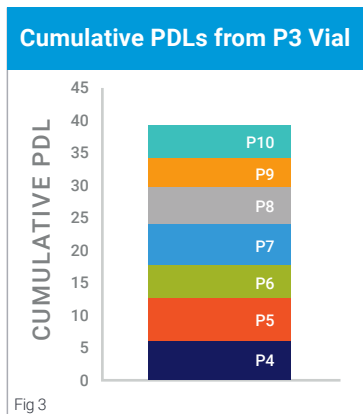


Fig 3

Fig 3. Cumulative population doublings from P3 RoosterVial™-hDF (C55001DF) working cell bank over 7 passages when cultured in a media exchange free process with RoosterNourish™-MSC-XF.

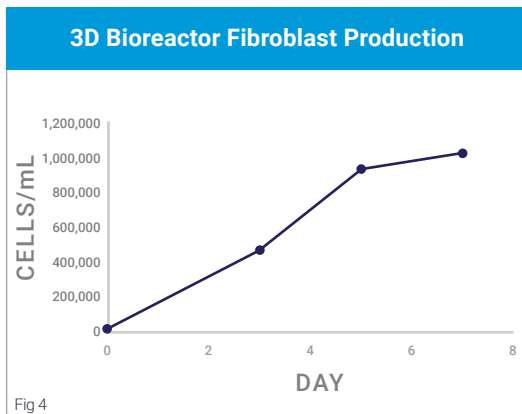


Fig 4

Fig 4. RoosterVial-hDF reaches 1e6 cells/ml in 6 days when cultured in RoosterNourish™-MSC-XF with RoosterReplensish.

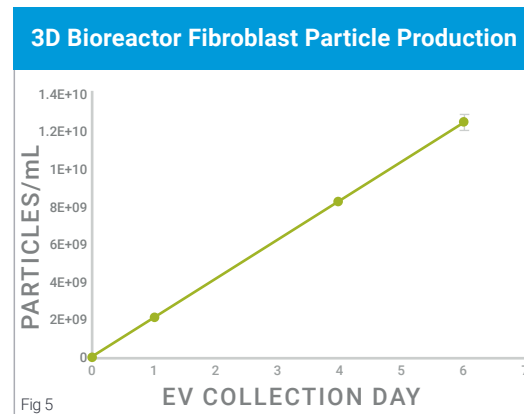


Fig 5

Fig 5. RoosterVial-hDF generates >1E10 particles/ml post 3D cell expansion and switch to RoosterCollect™ exosome collection media.

PRODUCT INFORMATION

	ROOSTERVIAL-XF	ROOSTERVIAL-DEV+	ROOSTERVIAL-CC*
Application	Research and Development	Pre-Clinical Development	Clinical Manufacturing
Derived From cGMP Master Cell Bank		✓	✓
Manufactured Under cGMP			✓
Intended Use	Research and Development Use Only	Research and Development Use Only	Further Manufacturing Use Only
Available Tissue Source	Neonatal Foreskin	Neonatal Foreskin	Neonatal Foreskin
Available Vial Size	1M or 10M	10M	20M
Donor Profile [Age / Sex / Ethnicity]	✓	✓	✓
Sterility   Endotoxin   Mycoplasma	✓	✓	✓
in vitro Adventitious Agents			✓
Species Identification			✓
Viral Testing**		✓	✓
Cell Count & Viability	✓	✓	✓
hDF Surface Marker Expression	✓	✓	✓
Cell Expansion Potential	✓	✓	✓

\*CliniControl (CC) RoosterBio products are manufactured under cGMP and tissue donor met all eligibility and testing requirements per FDA 21 CFR Part 1271 Subparts A-C and applicable sections of Subpart D under Section 1271.150.

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

PRODUCT	SKU / CATALOG #	UNIT SIZE	INTENDED USE
Xeno-free   Development Grade hDFs			
RoosterVial-hDF-1M-XF	C55001DF	1 vial of 1M cryopreserved human dermal foreskin fibroblasts	For Research Use Only
Xeno-Free   DEV+ Pre-clinical hDFs			
RoosterVial-hDF-DEV+	C53010DF	1 vial of 10M cryopreserved human dermal foreskin fibroblasts from GTP donor tissue	For Research Use Only
cGMP & Xeno-free   CliniControl hDFs			
RoosterVial-hDF-20M-CC	C06020DF	1 vial of 20 Million XF cryopreserved cells – manufactured under cGMP	For Further Manufacturing Use Only
Available in starter kit formats paired with RoosterNourish™ expansion media.			

