



RoosterVial™-hDF-XF

XENO-FREE (XF) HUMAN DERMAL FIBROBLASTS



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

RoosterBio hDFs enable robust, reproducible, and standardized results with cells isolated from the neonatal foreskin of normal, healthy donors. and expanded to 1M cells per vial at a PDL of 15-20. Each lot is performance qualified to expand > 20 additional population doublings and supported by industry leading characterization and quality control.

When paired with RoosterNourish™ in a media-exchange free expansion system, RoosterVial-hDF cells can efficiently scale from 2D to 3D utilizing easy-to-follow protocols and reproducibly produce millions to billions of fibroblasts. Together, these optimized platforms save months of development time and costs while outperforming competing systems.

PRODUCT FEATURES

Xeno-Free | cGMP Formats Available

>20 Additional Population Doublings

Industry Leading Characterization

Supported by 2D & 3D Scalable Processes

PRODUCT BENEFITS



De-Risked Cell-Based Manufacturing



Reduction in Total Manufacturing Costs



Increased Confidence in Key Raw Material



Streamlined Path to Clinical Production

Billions of Cells Easily Achieved in ≤ 10 Days

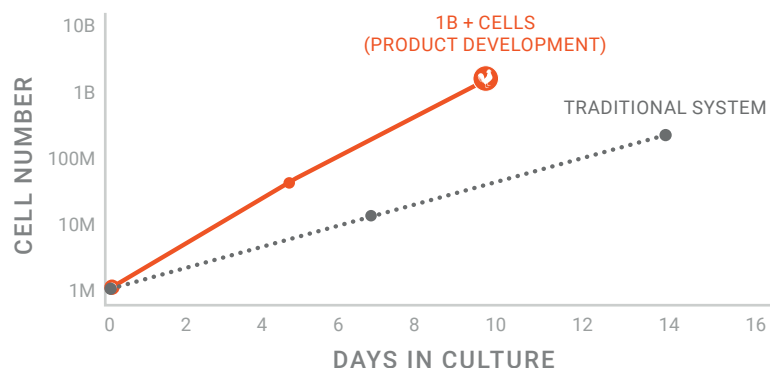


Fig 1

Fibroblast Identity and Morphology Characterization

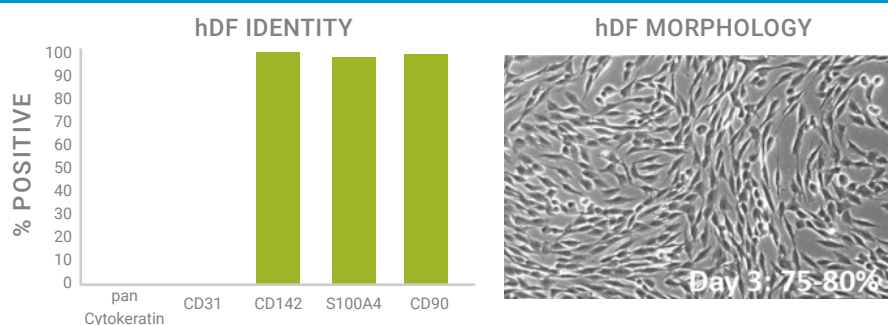


Fig 2

GAIN CONTROL OF YOUR CLINICAL PIPELINE FROM DISCOVERY THROUGH TRANSLATION.



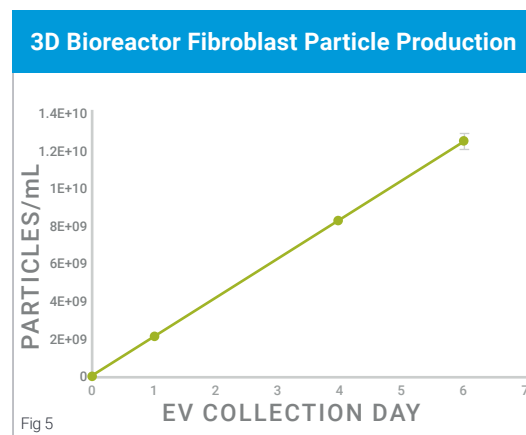
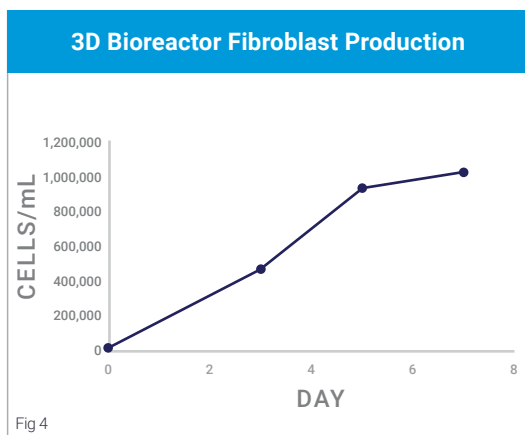
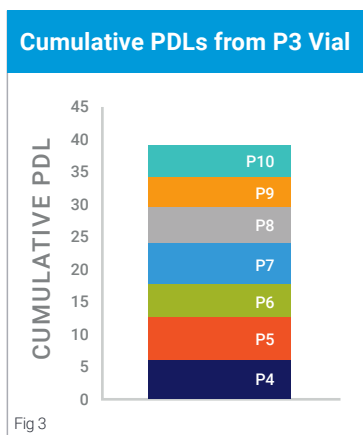
Fig 1. RoosterVial-hDF-XF outperform leading industry products when used alongside RoosterNourish™ media and following expansion protocol recommendations.

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 NEW GREAT IDEAS.

Applications for RoosterVial™-hDF

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



PRODUCT INFORMATION

	ROOSTERVIAL-XF	ROOSTERVIAL-CC*
Manufactured Under GMP		✓
Intended Use	Research and Development Use Only	Further Manufacturing Use Only
Available Tissue Source	Neonatal Foreskin	Neonatal Foreskin
Available Vial Size	1M	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	✓	✓

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-MSX-XF.

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

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

*CliniControl (CC) RoosterBio products are manufactured under GMP and tissue donor met all eligibility and testing requirements per FDA 21CFR Part 1271.

**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 1 Million cryopreserved human dermal foreskin fibroblasts	For Research Use Only
cGMP & Xeno-free CliniControl hDFs			
RoosterVial-hDF-20M-CC	Contact Us	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. Please inquire for more information about access to clinically relevant hDFs for use in development.			



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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.