



Huachenbio -- Your Professional Choice!

苏州华辰生物科技有限公司

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WeChat
Official Account



WeChat Official
Subscription Account



WeChat ID
for Inquiries



Partner for End-to-End CGT Solutions

- ⊕ Serum-Free, Platelet Lysate-Free
- ⊕ Animal-Derived Component-Free
- ⊕ Human-Derived Component-Free, Contains Recombinant Human Serum Albumin (rHSA)
- ⊕ Chemically Defined, High Batch-to-Batch Consistency
- ⊕ High Efficiency, Supporting Primary and Passage Cultures of MSCs
- ⊕ Manufactured in Compliance with GMP Standards, Supporting Pharmaceutical Registration
- ⊕ Higher Quality, Endotoxin < 0.1 EU/mL



StarMedium® MSC

新一代间充质干细胞化学成分限定培养基

Chemically Defined Medium For Mesenchymal Stem cell

StarMedium® MSC

Chemically Defined Medium For Mesenchymal Stem cell

StarMedium® MSC CD Medium is developed and manufactured based on advanced medium formulations and production technologies. Produced in compliance with GMP standards, it enables a seamless transition from your research and development stage to industrialized clinical applications.

Why Choose StarMedium® MSC CD Medium?



Serum-free

Serum-Free, Platelet Lysate-Free, "Genuine Serum-Free"



Animal origin-free

Animal-derived component-free, which minimizes the risk of pathogen infection, reduces immunogenic reactions, and ensures higher safety



Xeno-free

Human-Derived Component-Free, Contains Recombinant Human Serum Albumin (rHSA), with Controllable Raw Material Quality



Chemically Defined

All component sources and purities are known and clear, with chemically defined composition.



High Batch-to-Batch Consistency

Raw materials can be produced in large quantities with standardization, ensuring minimal batch-to-batch variation and reproducible performance from the research stage to large-scale production.



High Performance High Quality High Yield

- ① Excellent cell proliferation performance and cell morphology;
- ② Endotoxin content < 0.1 EU/mL, which can reduce the number of washing steps and improve cell yield;
- ③ Batch yield is not limited by serum substitutes, with stable components enabling large-scale production.

StarMedium® MSC CD Medium

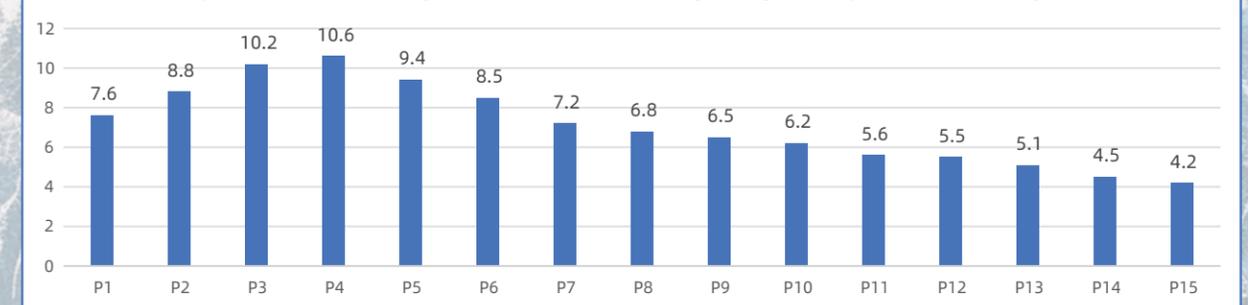
combines advanced formulation technology with GMP-compliant manufacturing, enabling a perfect transfer from R&D to clinical application.

Expansion Fold

StarMedium Continuous Passage of Mesenchymal Stem Cells (MSCs) in Chemically Defined Medium

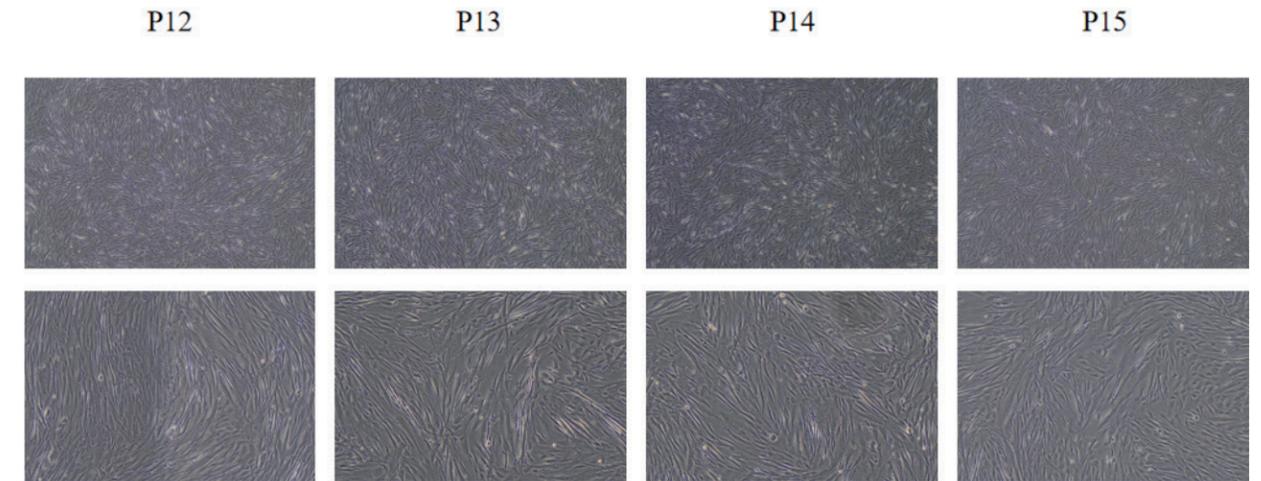
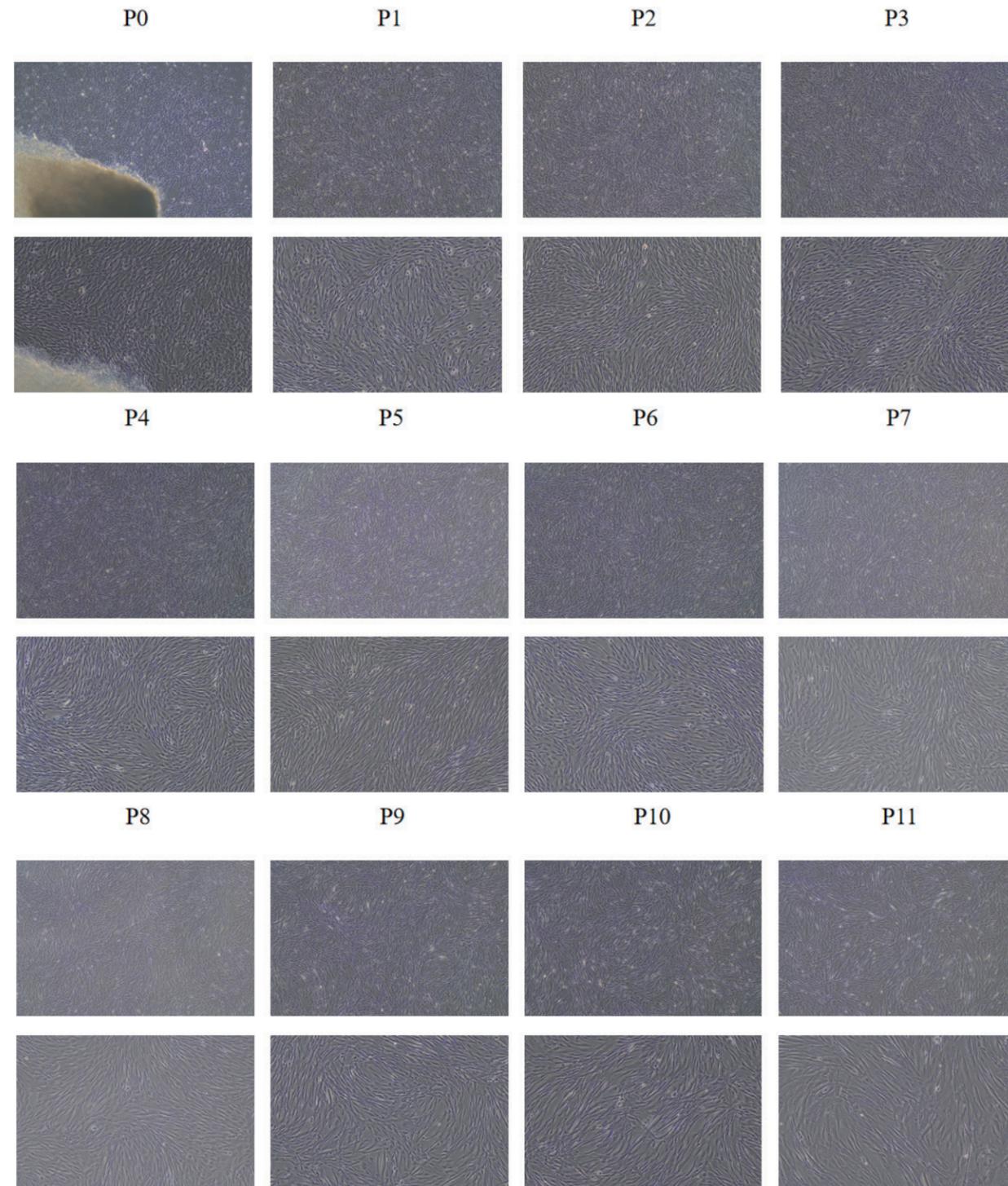
Passage	Seeding Density cells / cm ²	Culture Container	Harvested Cell Number (cells/bottle)	Expansion Fold	Total Expansion Fold
P0	-	T75	5.00E+05	-	-
P1	10000	T175	1.33E+07	7.6	7.6
P2	10000	T175	1.54E+07	8.8	66.88
P3	10000	T175	1.79E+07	10.2	682.176
P4	10000	T175	1.86E+07	10.6	7231.0656
P5	10000	T175	1.65E+07	9.4	67972.01664
P6	11000	T175	1.64E+07	8.5	577762.1414
P7	11000	T175	1.39E+07	7.2	4159887.418
P8	11000	T175	1.31E+07	6.8	28287234.44
P9	12000	T175	1.37E+07	6.5	183867023.9
P10	12000	T175	1.30E+07	6.2	1139975548
P11	12000	T175	1.18E+07	5.6	6383863070
P12	13000	T175	1.25E+07	5.5	35111246882
P13	13000	T175	1.16E+07	5.1	1.79067E+11
P14	13000	T175	1.02E+07	4.5	8.05803E+11
P15	14000	T175	1.03E+07	4.2	3.38437E+12

StarMedium Expansion Fold of Mesenchymal Stem Cells (MSCs) During Passage and Expansion in Chemically Defined Medium

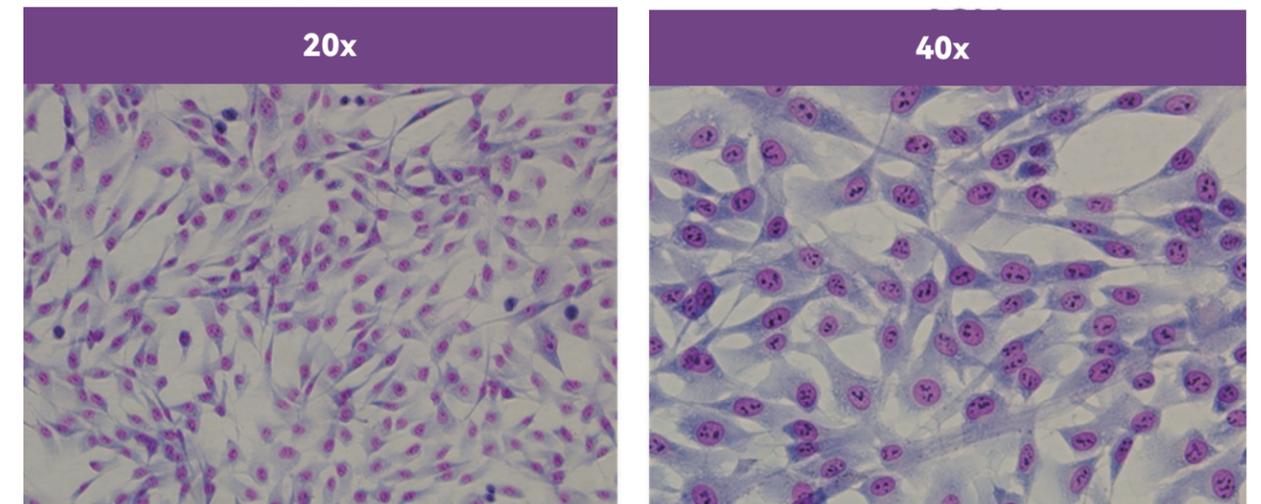


UC-MSC Cell Culture Micrograph

Spiral cell clusters with directionality and good cell morphology



Giemsa Staining for Morphological Identification of UC-MSCs



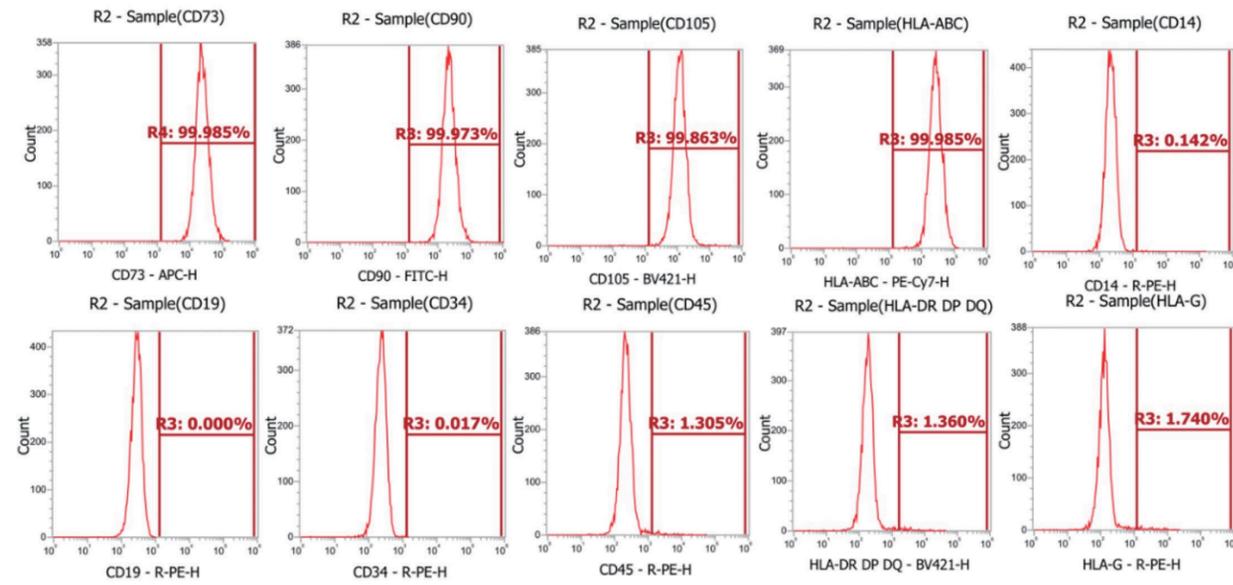
Huachen Bio

3mL
添加物

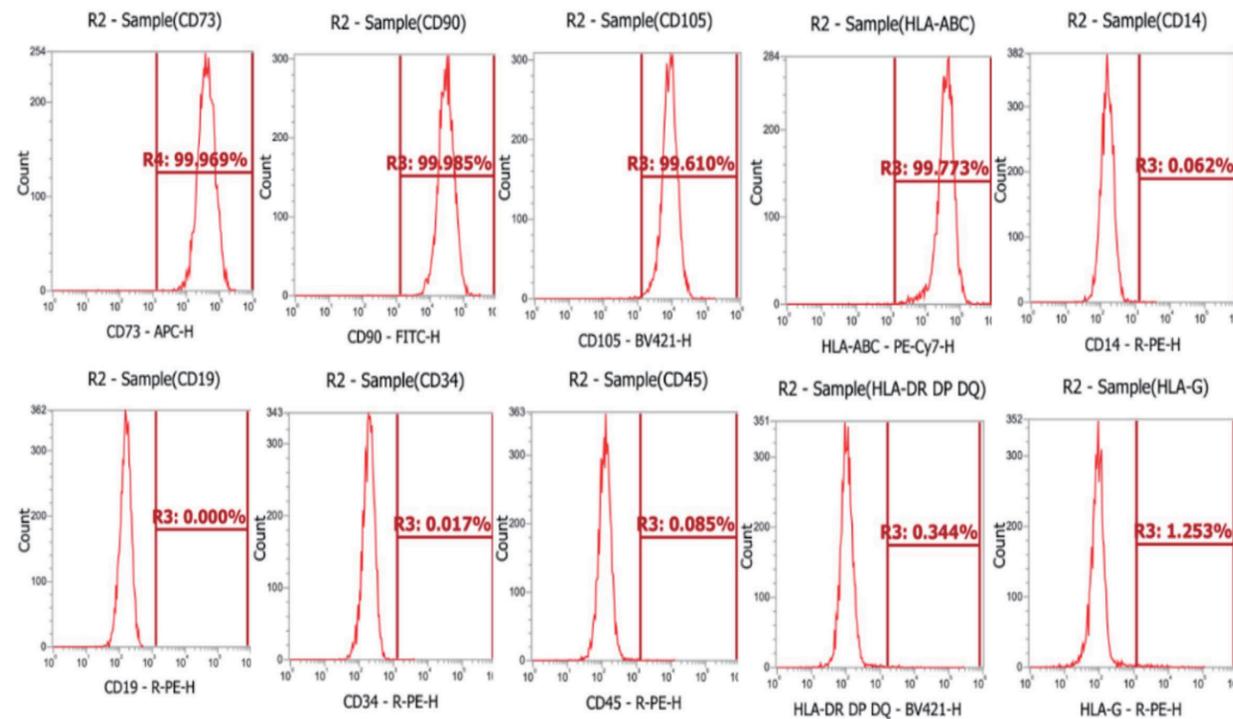


StarMedium® MSC

Chemically Defined Medium for Mesenchymal Stem Cells
Maintains Surface Marker Expression of UC-MSCs Across Multiple Passages

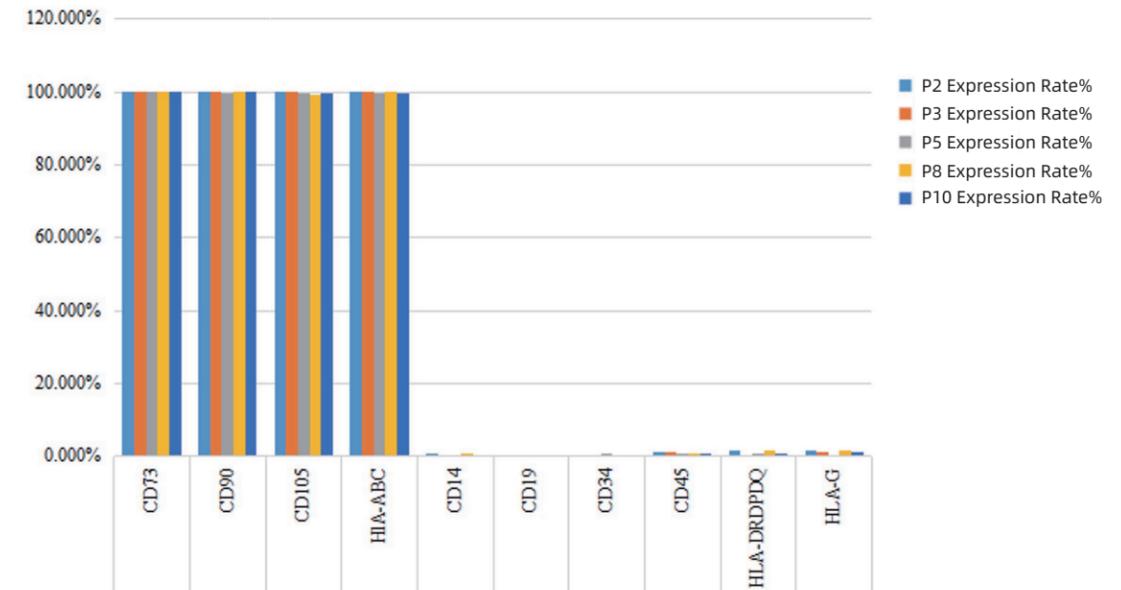


Detection of Characteristic Surface Markers in P2-Generation UC-MSCs



Detection of Characteristic Surface Markers in P10-Generation UC-MSCs

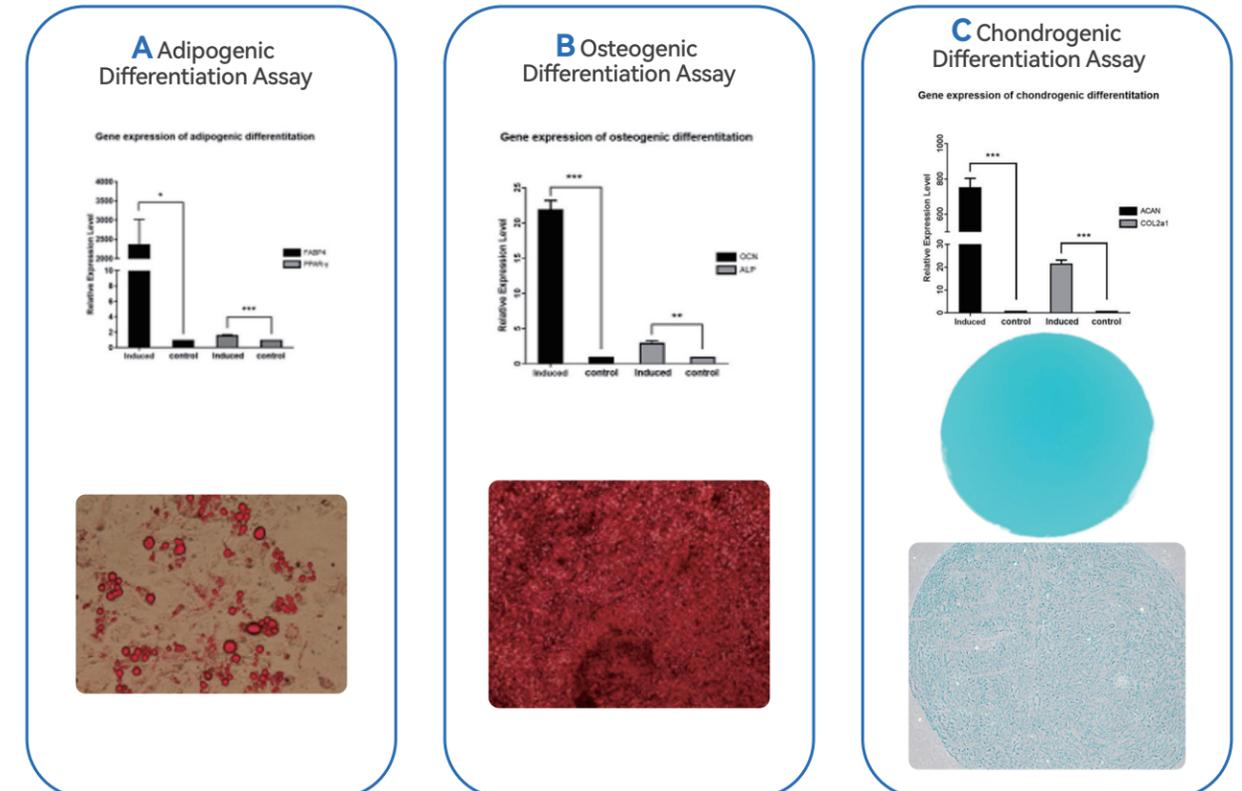
Detection Results of UC-MSC Surface Markers



Detection of Expression Rates of Characteristic Surface Markers in UC-MSCs

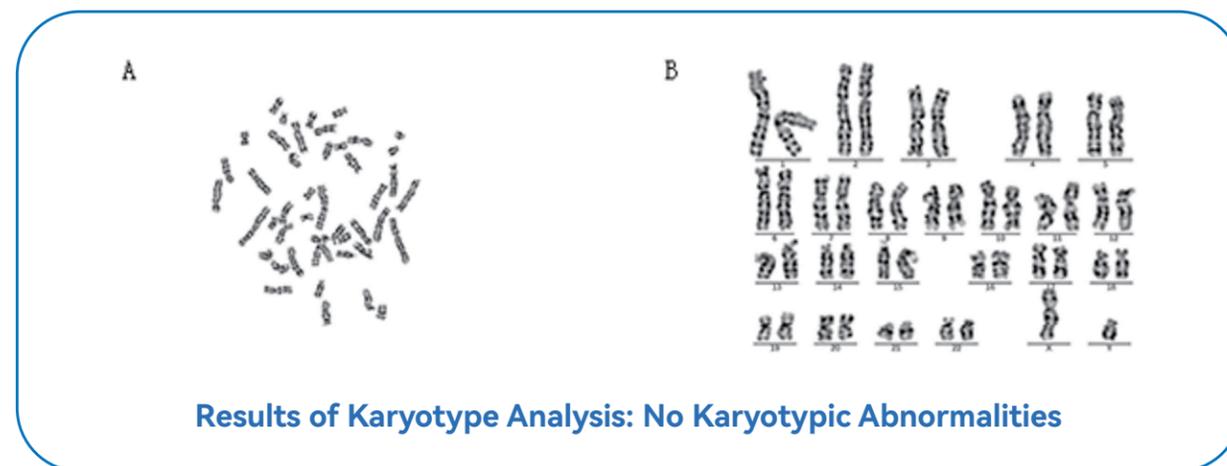
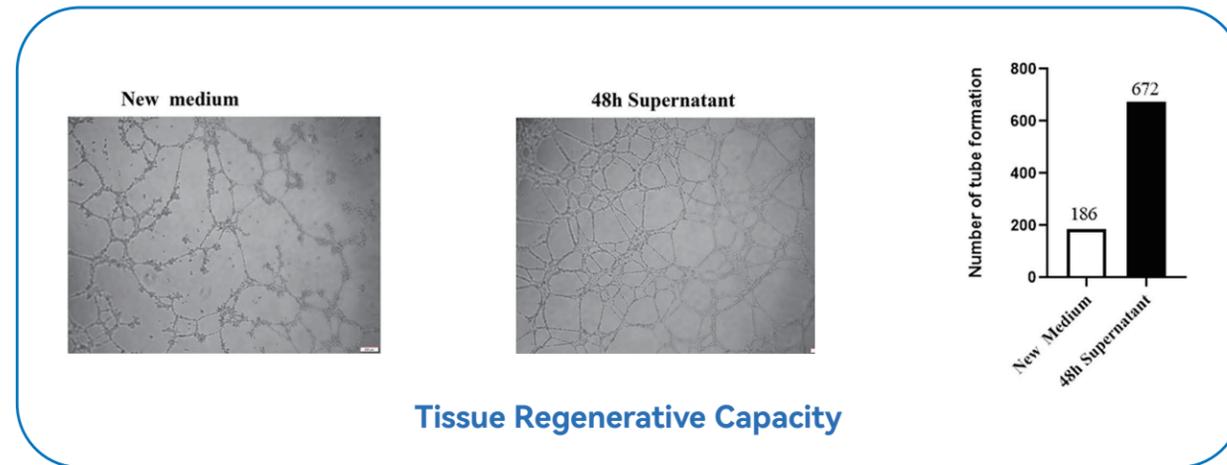
StarMedium® MSC

Mesenchymal Stem Cell Chemically Defined Medium Can Well Maintain the Adipogenic, Osteogenic, and Chondrogenic Differentiation Capabilities of MSCs



StarMedium® MSC

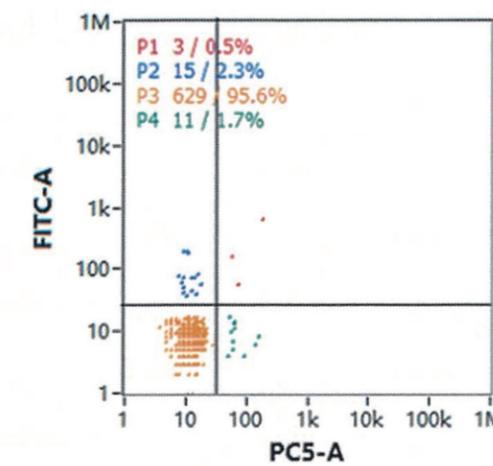
Mesenchymal Stem Cells (MSCs) Cultured in Chemically Defined Medium for MSCs Possess Tissue Regenerative Capacity and High Clinical Safety



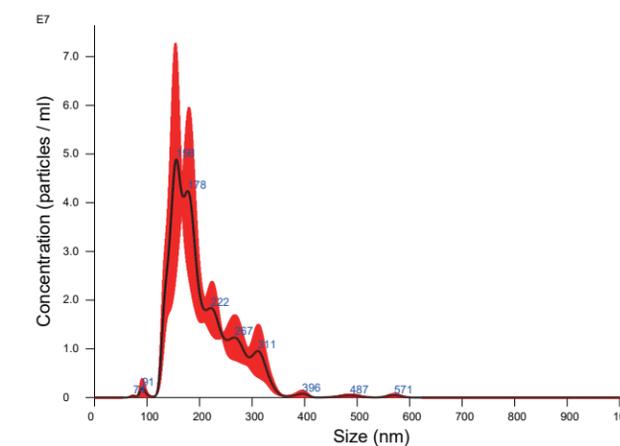
Chemically Defined Medium (Complete Medium) Quality Metrics: Particle Concentration, Size Distribution & Protein Positivity

Sample Name	Lot Number	Conc. particles/ml	Size(nm)	Positivity (%)
Chemically Defined Medium For Mesenchymal Stem cell	20251004 Basal Medium+ 20251105 Supplement	1.33E+08	68.2	0.5

Samples: Chemically Defined Medium For Mesenchymal Stem cell



Determination of Exosome Particle Count in Day 4 Supernatant from 3D Microcarrier Culture



Results

Stats: Merged Data

Mean:	203.1 nm
Mode:	155.8 nm
SD:	62.6 nm
D10:	143.5 nm
D50:	184.4 nm
D90:	291.3 nm

Stats: Mean +/- Standard Error

Mean:	203.1 +/- 2.9 nm
Mode:	168.8 +/- 8.1 nm
SD:	62.0 +/- 3.1 nm
D10:	144.9 +/- 4.1 nm
D50:	180.5 +/- 7.7 nm
D90:	291.0 +/- 12.0 nm
Concentration (Upgrade):	4.40e+09 +/- 2.15e+08 particles/ml
	14.8 +/- 0.5 particles/frame
	15.8 +/- 0.5 centres/frame

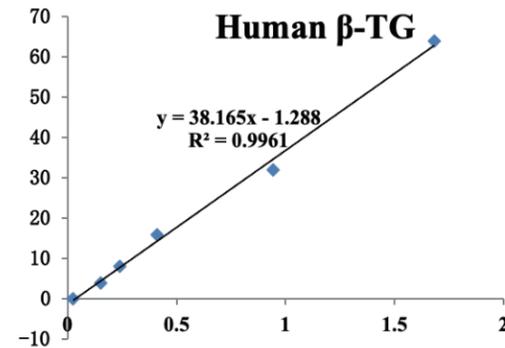
26.1.30 | NTA: 4.4E9 /mL

Precisely Defined, Chemically Defined Serum-Free Culture Media

Selection of Detection Methods for Platelet Lysate Products

Target	Recommendation	Key Points
CD41/CD42b	Flow Cytometry, ELISA	Western Blot: Maintain Conformation Post-Lysis
β-TG/PF4	ELISA	≤3 freeze-thaw cycles; avoid precipitation

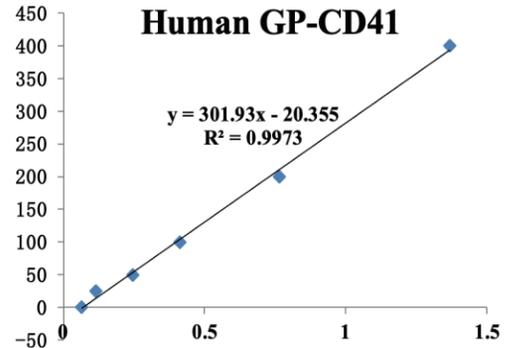
Human β-Thromboglobulin (β-TG) ELISA Kit						
Instrument: Infinite F50 Method: See manual						
Standard Curve						
X	0.0261	0.1528	0.2381	0.411	0.9423	1.6812
Y	0	4	8	16	32	64
	ng/mL					



Sample A: Huachen Bio Chemically Defined Medium (without platelet lysate supplementation) β-TG Concentration: 0 ng/mL

Sample B: Brand X Medium with Platelet Lysate Supplementation β-TG Concentration: 63.14 ng/mL

Human Platelet Membrane Glycoprotein CD41 (GP-CD41) ELISA Kit						
Instrument: Infinite F50 Method: See manual						
Standard Curve						
X	0.0635	0.1157	0.2456	0.412	0.7653	1.3692
Y	0	25	50	100	200	400
	pg/mL					



Sample A: Huachen Bio Chemically Defined Medium (without platelet lysate supplementation) GP-CD41 Concentration: 0 ng/mL

Sample B: Brand X Medium with Platelet Lysate Supplementation GP-CD41 Concentration: 325 ng/mL

Test Report

<p>深圳市明鉴检测技术有限公司 检测报告</p> <p>报告编号: MJ251220-032</p> <table border="1"> <tr> <th>委托编号</th> <td>MJ251220-022</td> <th>样品编号</th> <td>S251220-032</td> </tr> <tr> <th>样品名称</th> <td>人β-血小板糖蛋白(β-TG) 定量</td> <th>样品批号</th> <td>20251205</td> </tr> <tr> <th>送检单位</th> <td colspan="3">苏州华辰生物科技有限公司</td> </tr> <tr> <th>委托单位</th> <td colspan="3">苏州华辰生物科技有限公司</td> </tr> <tr> <th>检测地址</th> <td colspan="3">中国(江苏)自由贸易试验区苏州片区苏州工业园区星湖街328号徐达创新中心A3-504-1</td> </tr> </table> <p>样品情况</p> <table border="1"> <tr> <th>样品类型</th> <th>样品规格</th> <th>样品数量</th> <th>样品状态</th> </tr> <tr> <td>完全培养基</td> <td>5 ml/支</td> <td>1 支</td> <td>液体</td> </tr> <tr> <td>收样日期</td> <td>2025.12.20</td> <td>检测日期</td> <td>2025.12.29 - 2026.01.05</td> </tr> </table> <p>检测方法: 见“检测方法”栏。</p> <table border="1"> <thead> <tr> <th>检测项目</th> <th>检测方法</th> <th>结果</th> </tr> </thead> <tbody> <tr> <td>人β-血小板糖蛋白(β-TG) 定量</td> <td>《中国药典》2025 第三增补册 3429 页 免疫化学法: 酶联免疫吸附法</td> <td><2 ng/mL (定量限)</td> </tr> <tr> <td>人血小板膜蛋白 CD41 (GP-CD41) 定量</td> <td>《中国药典》2025 第三增补册 3429 页 免疫化学法: 酶联免疫吸附法</td> <td><6.25 ng/mL (定量限)</td> </tr> </tbody> </table> <p>检测方法: 见“检测方法”栏。</p> <p>检测日期: 2026.01.05 - 2026.01.05</p>		委托编号	MJ251220-022	样品编号	S251220-032	样品名称	人β-血小板糖蛋白(β-TG) 定量	样品批号	20251205	送检单位	苏州华辰生物科技有限公司			委托单位	苏州华辰生物科技有限公司			检测地址	中国(江苏)自由贸易试验区苏州片区苏州工业园区星湖街328号徐达创新中心A3-504-1			样品类型	样品规格	样品数量	样品状态	完全培养基	5 ml/支	1 支	液体	收样日期	2025.12.20	检测日期	2025.12.29 - 2026.01.05	检测项目	检测方法	结果	人β-血小板糖蛋白(β-TG) 定量	《中国药典》2025 第三增补册 3429 页 免疫化学法: 酶联免疫吸附法	<2 ng/mL (定量限)	人血小板膜蛋白 CD41 (GP-CD41) 定量	《中国药典》2025 第三增补册 3429 页 免疫化学法: 酶联免疫吸附法	<6.25 ng/mL (定量限)	<p>深圳市明鉴检测技术有限公司 检测报告</p> <p>报告编号: MJ251220-032</p> <p>附件:</p> <p>一、蛋白检测</p> <p>人β-血小板糖蛋白(β-TG) 定量 (ELISA)</p> <p>采用双抗体一步夹心法酶联免疫吸附 (ELISA) 试剂盒, 检测样品中 β-血小板糖蛋白(β-TG) 含量, 检测结果见下表:</p> <p>人血小板膜蛋白 CD41 (GP-CD41) 定量 (ELISA)</p> <p>采用双抗体一步夹心法酶联免疫吸附 (ELISA) 试剂盒, 检测样品中 人血小板膜蛋白 CD41 (GP-CD41) 含量, 检测结果见下表:</p> <table border="1"> <tr> <th>样品信息</th> <td colspan="3">20251205 (S251220-032)</td> </tr> <tr> <th>人 GP-CD41 含量 检测结果</th> <td colspan="3"><6.25 ng/mL (定量限)</td> </tr> <tr> <th rowspan="3">标准曲线 拟合参数</th> <th colspan="3">拟合方程: Y=A*X+B</th> </tr> <tr> <th>A</th> <th>B</th> <th>R²</th> </tr> <tr> <td>0.0157</td> <td>0.0792</td> <td>0.992</td> </tr> </table> <p>检测日期: 2026.01.05 - 2026.01.05</p>		样品信息	20251205 (S251220-032)			人 GP-CD41 含量 检测结果	<6.25 ng/mL (定量限)			标准曲线 拟合参数	拟合方程: Y=A*X+B			A	B	R ²	0.0157	0.0792	0.992
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DMF Registration Number: 041792



FDA U.S. FOOD & DRUG ADMINISTRATION

DMF 041792 **DMF ACKNOWLEDGEMENT**

SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.
ATTENTION: ZHENHUA SUN, GENERAL MANAGER
UNIT 504-1, BUILDING A3, CREATIVE INDUSTRY PARK
NO. 328 XINGHU STREET, SUZHOU INDUSTRIAL PARK
SUZHOU CITY, JIANGSU PROVINCE, CHINA

Dear Zhenhua Sun,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER ASSIGNED: 041792
DATE OF SUBMISSION: APRIL 29, 2025
DMF TYPE: II
SUBJECT (TITLE): CHEMICALLY DEFINED MEDIUM FOR MESENCHYMAL STEM CELLS
HOLDER: SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.
SUBMITTED BY: SUZHOU HUACHEN BIOTECHNOLOGY CO., LTD.
AGENT: NONE

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF if it is submitted to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

Huachen Bio: Core Technology Platforms

Overall Solution

10 Billion-Scale Culture Process of Stem Cells Using 3D Microcarriers

100 Billion-Scale Culture Process of NK Cells

Independent Intellectual Property Rights
Core Technology Platforms

Culture Medium Development Platform

- Component Screening Procedure for Chemically Defined (CD) Medium
- Optimization and Simulation Procedure for Stem Cell Culture on 3D Microcarriers
- Integrated Intelligent Manufacturing System Management Platform for Cells

Ordering Information

Kit Name	Product Cat#	Specs	Remarks
StarMedium Chemically Defined Medium For Mesenchymal Stem cell(With Phenol Red)	HC-CD03R	500ml/bottle	①Serum-free, animal-derived component-free, platelet lysate-free, truly serum-free; ②Suitable for primary and passage culture; ③Human-derived component-free, containing recombinant human serum albumin ; ④Chemically defined composition, high batch-to-batch consistency; ⑤High performance, efficiently promoting MSC expansion;
StarMedium Chemically Defined Medium For Mesenchymal Stem cell(Without Phenol Red)	HC-CD03F	500ml/bottle	⑥Manufactured in compliance with GMP standards, supporting clinical-grade/pharmaceutical-grade cell culture; ⑦3ml additive volume, low protein content;
StarMedium Medium Supplement	HC-CD03S	3ml/bottle	⑧Higher quality, endotoxin <0.1 EU/ml.