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

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HUACHEN 华辰生物

Partner for End-to-End CGT Solutions

- Suitable for Primary Cell Isolation and Subculture
- Compatible with a variety of mesenchymal stem cells, such as umbilical cord-, adipose-, bone marrow-, amniotic membrane-, hair follicle-, and dental pulp-derived mesenchymal stem cells
- Serum-free, free of any animal-derived components, antibiotic-free, stable in performance, and minimal batch-to-batch variation
- High cell expansion rate, with a single passage expansion fold of over 20x
- Cell yield per T175 flask: >2×10^7 cells;
  Cell yield per 10-layer cell factory: $8–10\times10^8$ cells
- Cell diameter: 14–15 μm, smaller than that of similar products on the market
- GMP level, prepared with water for injection (WFI), endotoxin < 0.1 EU/ml
- Independent R&D and production system, stable supply, and high cost-effectiveness

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novastem-MSC®

间充质干细胞无血清培养基

Serum-Free Medium For Mesenchymal Stem Cell

COMPANY PROFILE

Suzhou Huachen Biotechnology Co., Ltd.
Founded by technical experts with years of in-depth experience in the Cell and Gene Therapy (CGT) field, Suzhou Huachen Biotechnology Co., Ltd. is a one-stop provider of full-process solutions for cell and gene therapy. It focuses on the R&D and sales of high-end reagents in the CGT sector, offering customers high-end reagents that can meet the needs of domestic substitution, as well as integrated process development solutions for cell therapy.

The company has obtained ISO 9001 Quality Management System certification, and some of its products have received Drug Master File (DMF) filing numbers from the U.S. Food and Drug Administration (FDA). It is recognized as a Leading Talent Enterprise in Suzhou Industrial Park and serves as a governing unit of the China Association for Medical Biotechnology.

It has now developed a series of product systems, including:

Hyper Series:

hyperClone NK Activation/Expansion Kit, hyperCryo Cell Cryopreservation Medium;

Nova Series:

novaStem-MSC Mesenchymal Stem Cell (MSC) Medium, novaNK-20 NK Cell Medium, novaT-15 T Cell Medium;

Star Series:

3D StarPore Microcarriers, StarPore Microcarrier-Specific Lysis Buffer, starMedium Chemically Defined Medium

PRODUCT INTRODUCTION

novastem-MSC Serum-Free Medium For Mesenchymal Stem Cell

It can be used for the primary cell isolation and subculture of mesenchymal stem cells (MSCs) from multiple sources, such as umbilical cord (UCMSCs), adipose tissue (ADSCs), bone marrow (BMSCs), amniotic membrane (AMSCs), hair follicles (HFSCs), dental pulp (DPSCs), etc., while maintaining the cells' pluripotent differentiation potential.

It is serum-free, free of any animal-derived components, and antibiotic-free, with stable performance and minimal batch-to-batch variation.

It features a high cell expansion rate, with the cell count at the same passage being significantly higher than that of similar products on the market.

It has an independent R&D and production system, ensuring stable supply and high cost-effectiveness.

It supports clinical-grade / pharmaceutical-grade cell culture.

USAGE INSTRUCTIONS

01 02 03

- **It is recommended that the supplement be thawed at 37°C.**
- **Add it to the medium and mix thoroughly until uniform.**
- **Prepare a complete medium**

Tips: Pay attention to the thawing time; it is optimal to leave a few small ice crystals when thawing is nearly complete. For small-volume use, aliquot and store the supplement in frozen state.

It is recommended that the complete medium be prepared right before use and used up within one month.

If the culture system is small, it is advisable to aliquot the supplement into smaller portions for frozen storage based on actual usage. Prepare the complete medium in proportion when needed to avoid repeated freeze-thaw cycles.

Seeding Density

P1 P7	P8 P10	P11 P13	P14 and above
6000-7000 PCS/cm²	7000-8000 PCS/cm²	8000-9000 PCS/cm²	9000-10000 PCS/cm²

Cell Passage Time

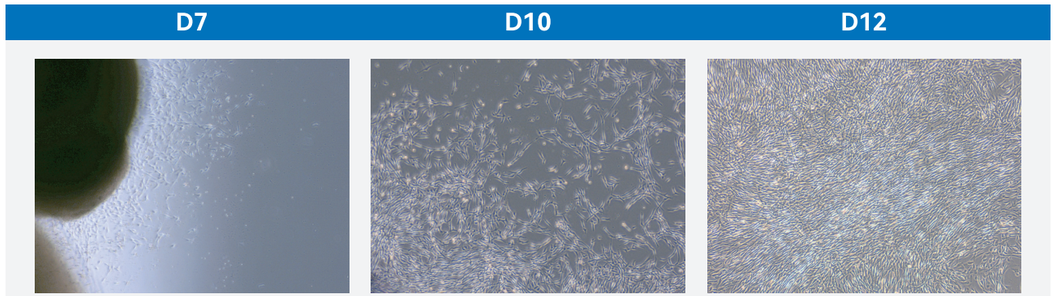
It is generally around 3 days (72 hours). The proliferation rate of different human Mesenchymal Stem Cells (hMSCs) varies. It is recommended to determine the exact passage time based on cell confluency; passage is advised when cell confluency reaches approximately 80-90%. Excessive cell confluency (>95%) will affect subsequent cell growth.

Cell Morphology

The cells are spindle-shaped and exhibit a swirling (or vortex-like) growth pattern.

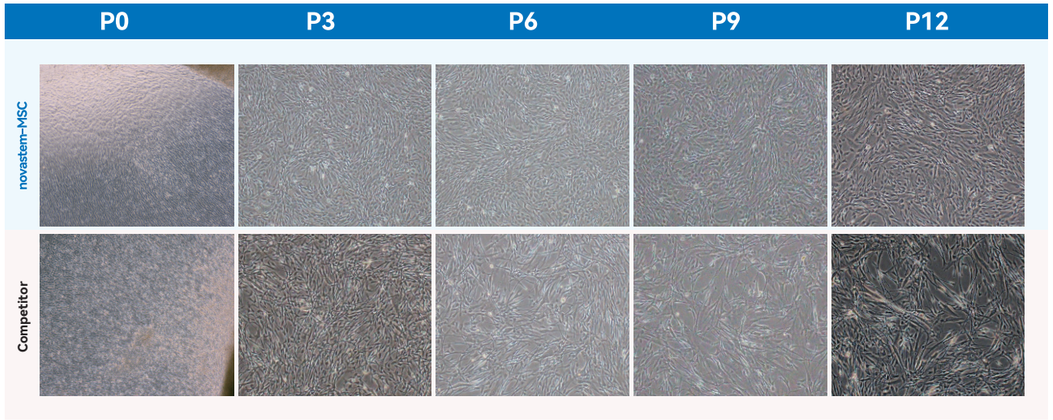
CULTURE OF MESENCHYMAL STEM CELLS

Primary Culture



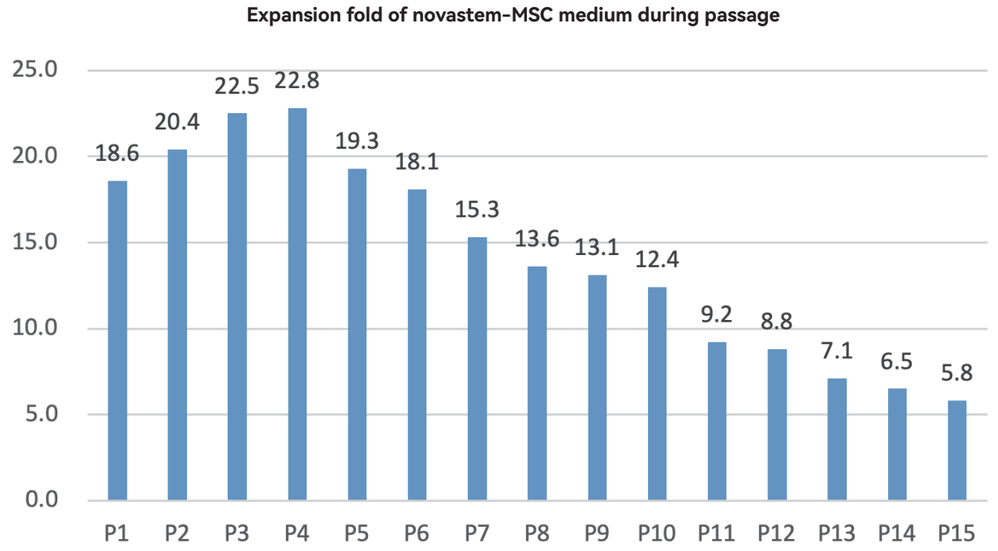
- Isolate the Wharton's jelly tissue from the umbilical cord and perform primary culture using the tissue block adherence method. Inoculate 0.5g of Wharton's jelly into each T75 culture flask. After culturing in a 37°C cell incubator for 1-2 hours, add 6-8ml of cell culture medium. Supplement with 5ml of medium on days 2-3. Change the medium on days 7-10 by discarding the supernatant and adding 10-15ml of fresh medium. Observe the cell expansion on days 12-14 and proceed with digestion and passage.
- The earliest time for cells to migrate out of the tissue blocks is 5-7 days, and a small number of scattered cells can be observed under the microscope.
- The tissue block adherence efficiency is high, with a large number of tissue blocks adhering to the culture surface.
- A greater number of cells can be harvested.

Subculture



- Compared with similar products on the market, it has higher expansion efficiency. The cells at high passages age more slowly and can support culture for more than 20 passages.

Culture Performance



Passage	Seeding Density (cells/cm²)	Time	Culture Vessels	Harvested Cell Count (cells/flask)	Expansion Fold	Total Cell Number	Total Expansion Fold
P0	–	10–14天	T75	1.00E+06	–	2.00E+07	–
P1	7000	72h	T175	2.28E+07	18.6	3.72E+08	18.6
P2	7000	72h	T175	2.50E+07	20.4	7.59E+09	379.44
P3	7000	72h	T175	2.76E+07	22.5	1.71E+11	8537.4
P4	7000	72h	T175	2.79E+07	22.8	3.89E+12	194652.72
P5	7000	72h	T175	2.36E+07	19.3	7.51E+13	3756797.496
P6	7000	72h	T175	2.28E+07	18.1	1.36E+15	67998034.68
P7	7000	72h	T175	2.00E+07	16.3	2.22E+16	1108367965
P8	8000	72h	T175	2.10E+07	15.0	3.33E+17	16625519479
P9	8000	72h	T175	1.93E+07	13.8	4.59E+18	2.29432E+11
P10	8000	72h	T175	1.74E+07	12.4	5.69E+19	2.84496E+12
P11	9000	72h	T175	1.61E+07	10.2	5.80E+20	2.90186E+13
P12	9000	72h	T175	1.54E+07	9.8	5.69E+21	2.84382E+14
P13	9000	72h	T175	1.28E+07	8.1	4.61E+22	2.30349E+15
P14	10000	72h	T175	1.14E+07	6.5	2.99E+23	1.49727E+16
P15	10000	72h	T175	1.02E+07	5.8	1.74E+24	8.68418E+16

- The average expansion fold of the Novastem-MSC system from P1 to P5 is 20.7.
- Counted on average from 10 umbilical cords: for example, if approximately 10g of Wharton's jelly tissue is isolated, 2.0×10^7 cells can be obtained at Passage 0 (P0), and theoretically 1.71×10^{11} cells can be obtained at Passage 3 (P3).
- When prepared into products at the conventional dosage of 5×10^7 cells per unit, it can yield 3,420 units in total.

SUMMARY

Cell Passage Time

It is generally around 3 days (72 hours). Different hMSCs vary in their growth rates. It is recommended to determine the exact passage timing based on cell confluency; passage is advised when cell confluency reaches approximately 80%-90%. Excessively high cell confluency (>95%) will affect subsequent cell growth.

The medium volume is 0.2 mL/cm². No coating is required, and no medium change is needed for 3 consecutive days of culture.

When switching from other culture systems to novastem-MSC, the initial cell expansion fold may be relatively low. It is recommended to resuscitate and seed cells with a 1:1 mixture of the original medium and novastem-MSC. After 1 generation of culture, the system can be completely switched to novastem-MSC.

Cell Digestion

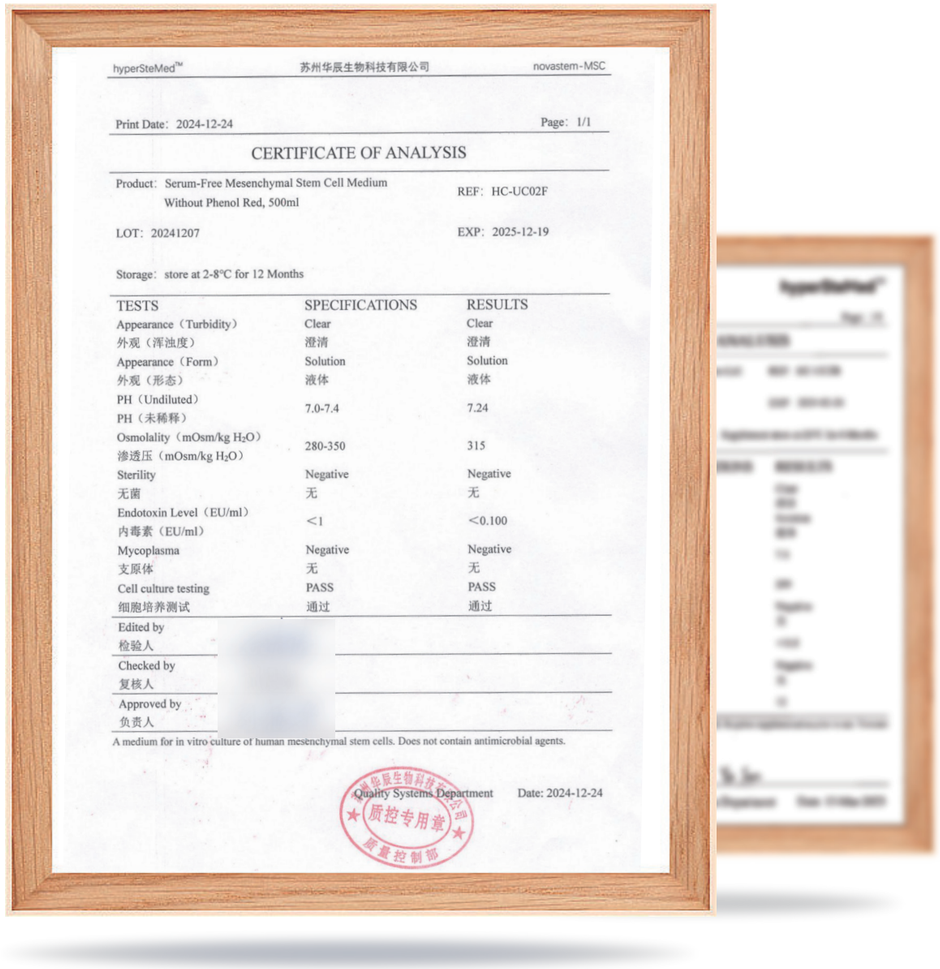
It is recommended to use a relatively gentle trypsin, such as Gibco TrypLE™ Express Enzyme (recombinant, 1X). Dilute it with PBS at a 1:1 ratio to prepare a working solution of trypsin before use. The digestion time is 3–5 minutes. After 1–2 minutes of digestion, gently tap the culture vessel; when most cells are observed to detach, terminate the digestion with medium.

Cell Cryopreservation

It is recommended that the final concentration of DMSO be 5%. Before cell digestion, you can first prepare a cryopreservation solution with a volume ratio of DMSO to complete medium of 1:9, and store it pre-cooled at 2-8℃. After the cells to be cryopreserved are mixed with complete medium, slowly add an equal volume of the pre-prepared cryopreservation solution, mix well, and then aliquot for cryopreservation.

QUALITY CONTROL ANALYSIS

Product Certificate of Analysis



hyperSteMed™ 苏州华辰生物科技有限公司 novastem-MSC

Print Date: 2024-12-24 Page: 1/1

CERTIFICATE OF ANALYSIS

Product: Serum-Free Mesenchymal Stem Cell Medium Without Phenol Red, 500ml REF: HC-UC02F

LOT: 20241207 EXP: 2025-12-19

Storage: store at 2-8℃ for 12 Months

TESTS	SPECIFICATIONS	RESULTS
Appearance（Turbidity） 外观（浑浊度）	Clear 澄清	Clear 澄清
Appearance（Form） 外观（形态）	Solution 液体	Solution 液体
PH（Undiluted） PH（未稀释）	7.0-7.4	7.24
Osmolality（mOsm/kg H_2O） 渗透压（mOsm/kg H_2O）	280-350	315
Sterility 无菌	Negative 无	Negative 无
Endotoxin Level（EU/ml） 内毒素（EU/ml）	<1	<0.100
Mycoplasma 支原体	Negative 无	Negative 无
Cell culture testing 细胞培养测试	PASS 通过	PASS 通过

Edited by 检验人

Checked by 复核人

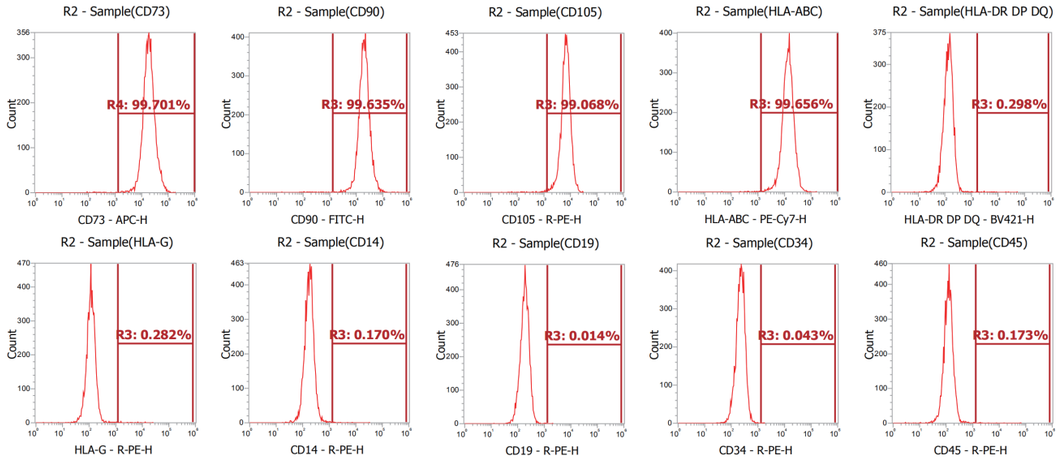
Approved by 负责人

A medium for in vitro culture of human mesenchymal stem cells. Does not contain antimicrobial agents.

Quality Systems Department Date: 2024-12-24

After passing the release inspection, a corresponding Certificate of Analysis (COA) shall be issued. The main test items include characteristics, physical and chemical properties, safety indicators, and functional indicators.

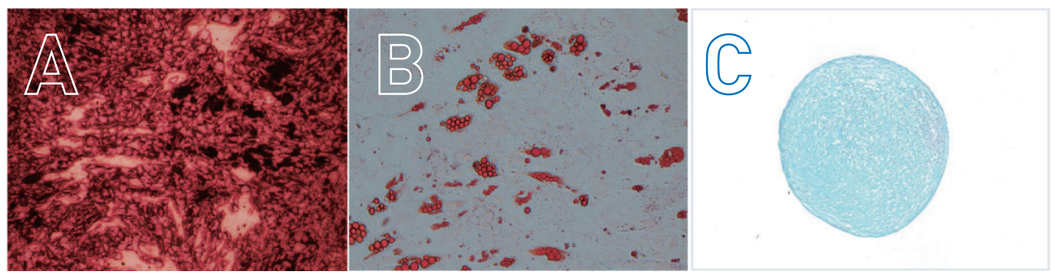
Detection of Cell Surface Markers



Detection of Surface Markers in Cultured hMSCs

The positive rates of CD73, CD90, CD105, and HLA-ABC are >95.0%;
The positive rates of CD14, CD19, CD34, CD45, and HLA-DRDPDQ are ≤2.0%.

Cellular Multilineage Differentiation Potential



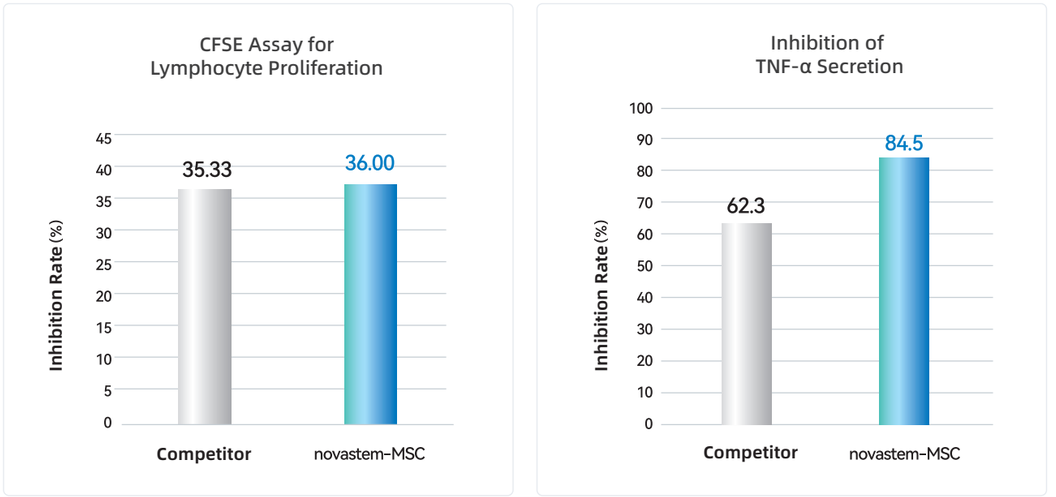
Three-Lineage Differentiation Assays:

A
Osteogenic differentiation
(Alizarin Red staining)

B
Adipogenic differentiation
(Oil Red O staining)

C
Chondrogenic differentiation
(Alcian Blue staining)

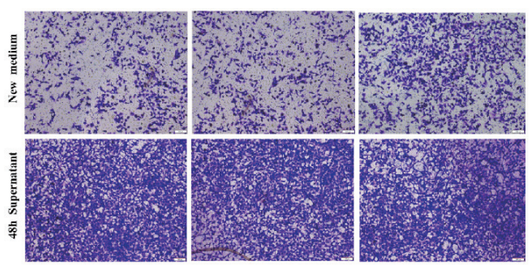
Detection of Cellular Immunomodulatory Capacity

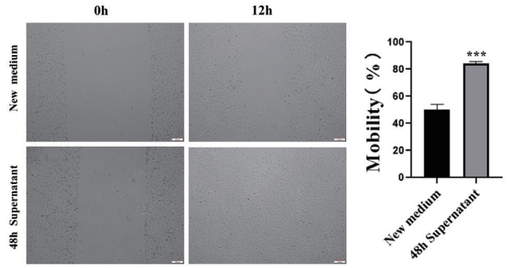


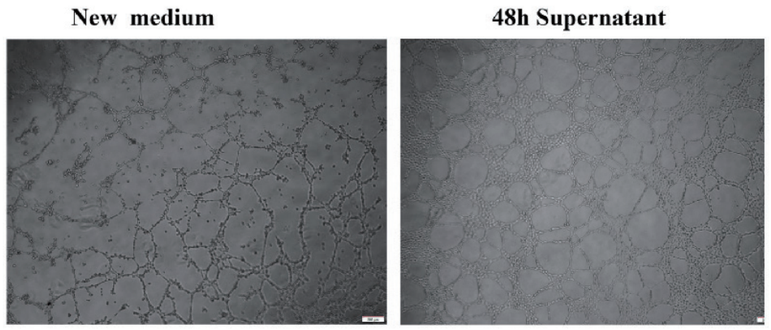
The cultured human Mesenchymal Stem Cells (hMSCs) exhibit the following immuno-modulatory capabilities:

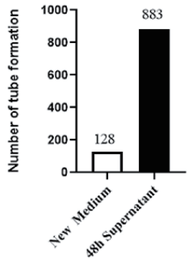
- Inhibiting lymphocyte proliferation;
- Promoting the upregulation of Regulatory T cells (Treg);
- Promoting the downregulation of T helper cell type 1 (Th1) and T helper cell type 17 (Th17);
- Inhibiting the expression of Tumor Necrosis Factor-α (TNF-α).

Detection of Cell Migration Ability
Detection of Angiogenic Ability

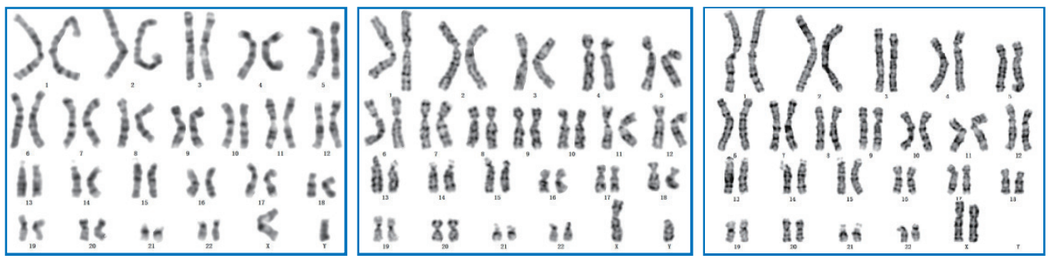








Karyotype Analysis of Cell Chromosomes

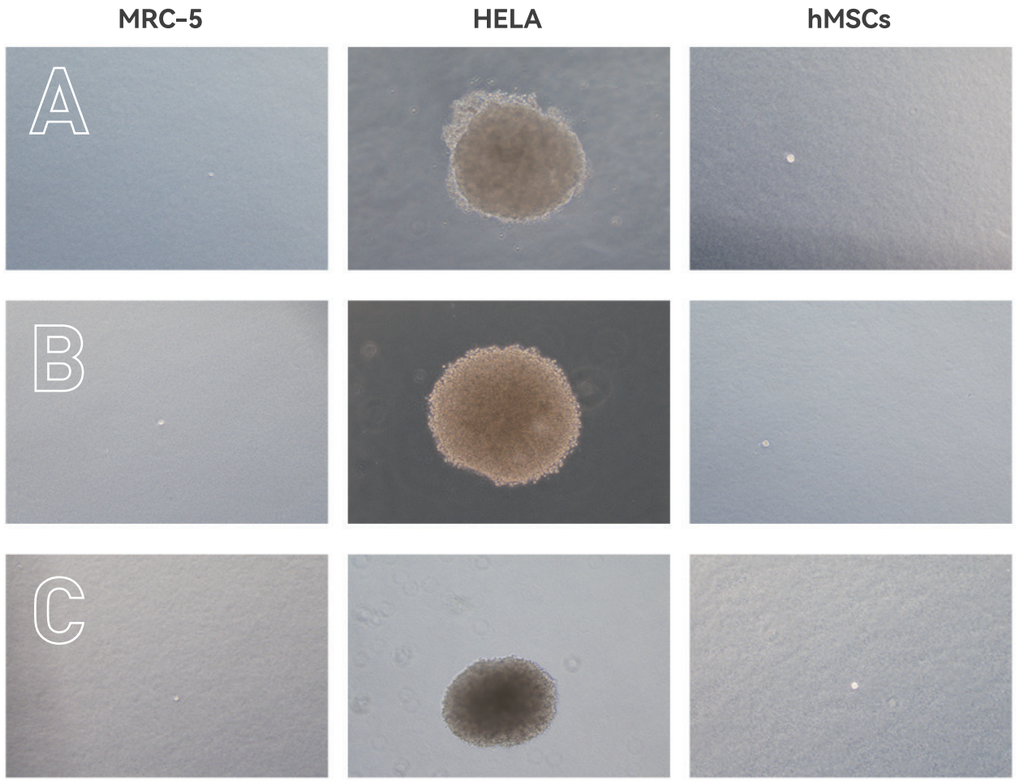


A.P3 B.P8 C.P13

Karyotype Analysis Results of Continuously Cultured hMSCs:

No numerical or structural abnormalities of chromosomes were observed.

In Vitro Tumorigenicity Assay of Cells



A.P3 B.P8 C.P13

Results of In Vitro Tumorigenicity Assay for Continuously Cultured hMSCs:

Human Mesenchymal Stem Cells (hMSCs) failed to form colonies in the soft agar colony formation assay, indicating that they do not possess tumorigenic potential in vitro.

Ordering Information

Kit Name	Kit Cat#	Product Components	Product Cat#	Specs	Qty
Serum-Free Medium For Mesenchymal Stem Cell Kit	HC-UC02RS-kit	novaStem-MSC Serum-Free Medium For Mesenchymal Stem Cell(with Phenol Red)	HC-UC02R	500ml/bottle	1
		novaStem-MSC Basal Medium supplement	HC-UC02S	25ml/bottle	1
	HC-UC02FS-kit	novaStem-MSC Serum-Free Medium For Mesenchymal Stem Cell(without Phenol Red)	HC-UC02F	500ml/bottle	1
		novaStem-MSC Basal Medium supplement	HC-UC02S	25ml/bottle	1