

THE 3rd GENERATION OF CULTURE MEDIUM

CellCor™



A New Step for the Industrialization of Advanced Biologics

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From Bench to Clinic



Xcell Therapeutics provides research solutions from the perspective of researchers and serves as a guide in IND filing and drug development.

We were founded with two core visions:

Building industry leadership through advanced cell culture technologies and leading the localization of cell culture media.

Since then, Xcell Therapeutics has focused on advancing its research, development and the production of cell culture media customized for cell and gene therapy (CGT) and exosome applications.

As a result, we have **successfully launched the world's first GMP-grade, chemically defined medium specifically designed for mesenchymal stem cells.**

Xcell Therapeutics is a pioneer in the development of therapies by manufacturing animal origin-free cell culture media.

In this catalog, we aim to present new solutions launched in accordance with current global trends, complemented by Xcell Therapeutics' expertise.

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Considerations for raw materials when selecting cell culture media in the **CGT industry**

Xcell Therapeutics is a specialized manufacturer of cell culture media, providing innovative solutions that align with global trends in the cell and gene therapy (CGT) industry. The CellCor™ MSC CD AOF is a MSC-specific culture medium that is completely animal origin free. This launch enables us to offer top-tier products that align with recent regulatory changes in the rapidly evolving field of cell therapy. Xcell Therapeutics is committed to providing top-tier products to facilitate the work of researchers, from the research stage to clinical application and therapeutic development.

01

Regulations and Key Guidance on Raw Materials

Region	Raw Materials
International	<ul style="list-style-type: none"> - WHO GMP for Biological Products - Various ISO Standards (ISO9001, 13485, 20399 and TC276) - Various ICH Guidelines (ICH Q5A, ICH Q5D, ICH Q, 3 ICH Q2)
USA	<ul style="list-style-type: none"> - USP <1043> Ancillary Materials for Cell, Gene and Tissue-Engineered Products - USP <92> Growth Factors and Cytokines Used in Cell Therapy Manufacturing (limited to rh-IL4) - FDA chemistry, manufacturing, and controls (CMC) Guidance - 21 CFR Part 1271 Section 1271.210-GTPs - 21 CFR Part 211 subpart E-GMPs - Master File process available

Relevant Documents to key materials

Most of the information regarding quality control standards for raw materials can be found in documents provided by various suppliers. In addition to assessing the suitability of raw materials, a variety of information is essential for drug development and approval for clinical trials, regulatory submissions to the Ministry of Food and Drug Safety (MFDS).

Developers need to find suppliers who can provide essential documents with the Regulatory Support File (RSF), and suppliers are obligated to submit such documents to the MFDS and regulatory agencies.

GMP-related Documentation
21 CFR Part &
ISO 13485 Certifications

Certificate of Analysis (CoA) and
Certificate of Origin (CoO)

Regulatory Support File (RSF) or
Drug Master File (DMF)

Sterility, Endotoxin,
Mycoplasma Tests

Adventitious Virus Testing and
Virus Inactivation
(can be omitted for AOF products)

Sterile Product SAL 10

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All Product Lines Supporting Clinical Trials and Regulatory Documents

All Product Lines Supporting Regulatory Documents

Non-clinical and clinical processes for the development of cell therapies require higher levels of quality control and risk management documentation for raw materials. The following documents are available for this process: CellCor™ is manufactured in FDA and ISO 13485 certified facilities under strict quality management systems. We provide a variety of regulatory documents to support cell therapy production across research, clinical approval, and commercialization stages.

	RUO grade	GMP grade
Application	Research & development, Preclinical research	IND, Commercialization
Quality system	ISO9001/ISO13485 Certified	ISO9001/ISO13485 Certified
Production	ISO certified facilities	ISO certified facilities
	Research-grade materials or reagent grade	Vendor audit & Confirmation of supplier certification acquisition
	-	In operation Environment monitoring
Quality control	Chemical testing	Chemical testing
	Sterility testing	Sterility testing
	Mycoplasma testing	Mycoplasma testing
	Endotoxin testing	Endotoxin testing
	Performance testing	Performance testing
	10th Production Identification testing	Identification testing (with acceptance criteria), CoA
	-	Other physical and chemical tests
Validation	Validated key equipment	Validated key equipment
	Validated key analytical instrument	Validated key analytical instrument
	-	Validated key Manufacturing process
	-	Validated key analytical methods
Stability	First production 1 batch Long-Term Stability	Process Validation 3 Batch Long-Term Stability
	-	In-use vertical stability test
Documentation	Certificate of Analysis (CoA)	Certificate of Analysis (CoA) with ISO certification mark
	Safety Data Sheets (SDS)	Safety Data Sheets (SDS)
	-	Certificate of Origin (CoO)
	-	Regulatory Support Files (RSF)
	-	Drug Master File (DMF)

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What Is Animal Origin Free Medium?

Chemically defined medium

- Cell culture media can be classified into serum-contained medium, serum-free medium, xeno-free medium, and chemically defined medium based on the presence or absence of animal or human-derived components.
- A chemically defined medium refers to a cell culture medium in which all ingredients are composed of recombinant proteins and chemical compounds.

Xcell's Definition

- Our chemically defined media are further categorized into ACF and AOF. AOF represents the highest level of media manufacturing in compliance with regulations.

AOF (Animal Origin Free)

No contact with animal derivatives, from manufacturing to finished product

ACF (Animal Component Free)

Animal derivatives may come into contact during the manufacturing process, but are not included in the finished product

	1 st Generation	2 nd Generation		3 rd Generation	
	Serum-contained Medium	Serum-free Medium	Xeno-free Medium	Chemically defined Medium	
				ACF *	AOF **
Animal Derivatives	Contamination by animal-derived serum , such as FBS, and animal-derived exosome	Serum-free		Contains recombinant proteins and chemical compositions; free of animal derivatives	
		Contains animal derivatives May be contaminated by animal-derived exosome	Contains human derivatives May be contaminated by human-derived exosome	No animal derivatives in the finished product	Animal derivatives are excluded in ingredients and all production processes
Safety	Immunogenicity, prion, and viral infection issues may occur	Immunogenicity and viral infection issues may occur	Human-derived viral infection issues may occur	Exclusion of animal-derived materials at the source to ensure safety	
Stability in Supply Chain	Unstable	Unstable	Unstable	Consistent availability of bulk supplies	
Lot-to-Lot Variation	Variation	Variation	Variation	Minimization of variation	

* ACF: Animal component free, ** AOF: Animal origin free

Why Chemically Defined Media?

- Market demand is rapidly increasing due to R&D activities utilizing cells across various industries, including cell and gene therapy products (CGT).
- The demand for safe products is rising due to concerns over safety issues such as virus contamination and immunogenicity associated with the current use of fetal bovine serum (FBS).
- It is recommended to avoid the use of animal-derived reagents worldwide.
- Rigorous management and safety assessment data are required to evaluate the potential risks of contamination by exogenous agents from biological raw materials.

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Products: All in One Medium



Product	CellCor™ MSC CD AOF	CellCor™ EXO CD	CellCor™ Kera CD AOF	CellCor™ DPC CD
Cat.No	YSP018(RUO) YSP023(GMP)	YSP017	YSP019	YSP007
Volume	500 mL	500 mL	500 mL	500 mL
Grade	RUO, GMP	RUO	RUO	RUO
Phenol-red	O	O	O	O
Storage	- 20 °C	2 – 8 °C	- 20 °C	- 20 °C
Shelf Life	12 months	12 months	12 months	12 months
Cell type	Human MSC Animal MSC	Human MSC derived exosome	Human Keratinocyte	Human Dermal Papilla Cell
Supplement	X	X	X	X
Coating	X	X	X	X

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MSC Expansion Medium

CellCor™ MSC CD AOF

Mesenchymal stem cells (MSCs) currently represent a major portion of the cell therapy market, and can be used in a variety of applications. CellCor™ MSC CD AOF is a serum-free, chemically-defined medium that can be used in primary culture for optimal culture conditions.

- **Animal origin-free CD medium:** AOF-grade product, with high regulatory accessibility for cell therapy markets
- **High Performance:** Can be used in any MSCs from a variety of tissue sources and provides stable culture and excellent cell yields, which is optimized for large-scale culture
- **Low immunogenicity:** Slower senescence compared to 1st and 2nd generation media (FBS(+), Xeno(-)), and less expression of immunogenicity and inflammation-related genes in the cells themselves
- **RUO & GMP grade:** Suitable for MSC research and mass production as well as cell therapy drug manufacturing, and can be used for human- and animal-derived stem cells

FIGURE 1

Comparison of human MSC expansion

Compared to 1st and 2nd generation media, MSCs cultured in CellCor™ MSC CD AOF proliferate faster and more stably, and demonstrate a significantly higher cumulative yield of cells.

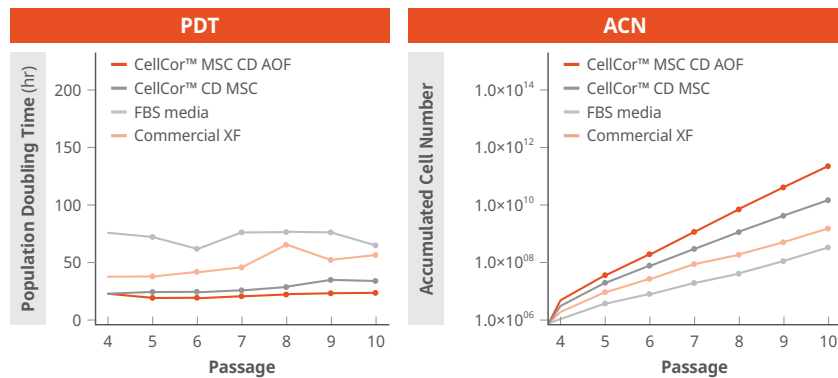
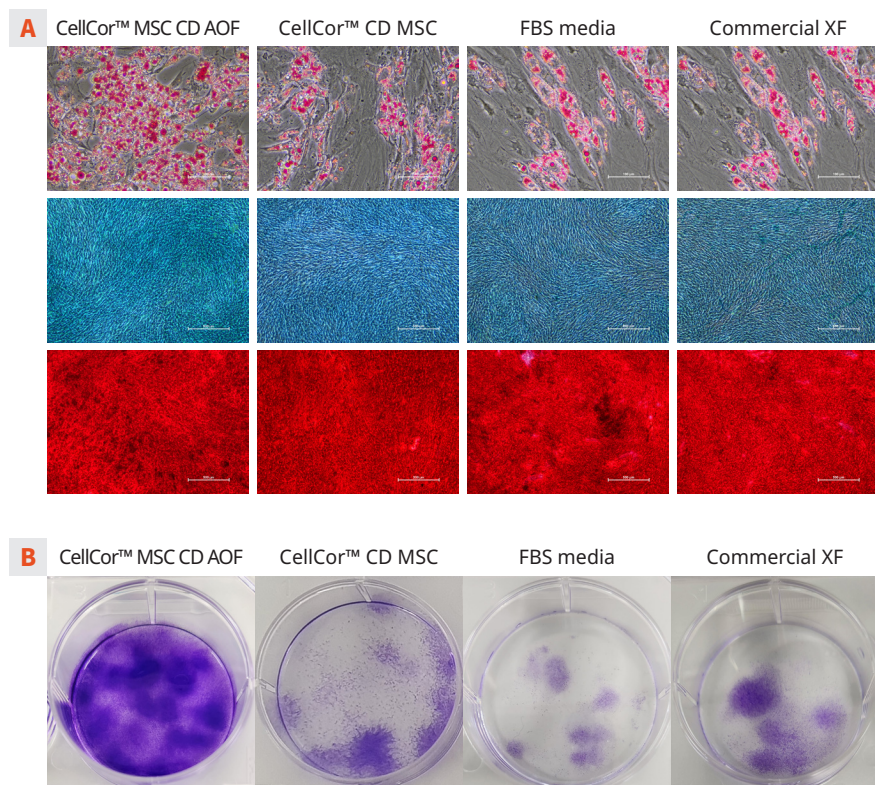


FIGURE 2

Ability of trilineage differentiation and colony forming assay

A | MSCs cultured in CellCor™ MSC CD AOF maintained stable stem cell differentiation ability compared to FBS(+) and commercial media.

B | Colony forming assay was conducted to identify self-renewal ability. Highest self-renewal capacity detected in MSCs cultured in CellCor™ MSC CD AOF



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FIGURE 3
Morphology of MSC cultured with CellCor™ MSC CD AOF

MSCs cultured in CellCor™ MSC CD AOF maintain their morphological characteristics well and enable stable cultivation.

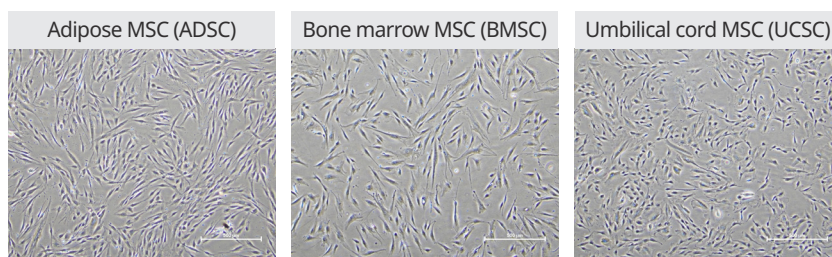
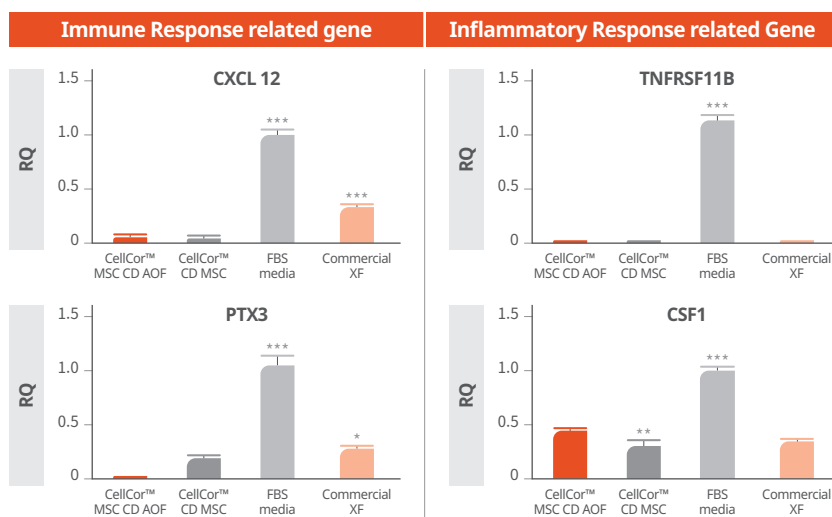


FIGURE 4
Immune and Inflammatory Response related gene expression level

MSCs cultured in CellCor™ MSC CD AOF exhibit lower expression of immune- and inflammation-related genes compared to 1st and 2nd generation media (* $p < 0.02$, *** $p < 0.001$)



Easy-to-culture

CellCor™ MSC CD AOF has been developed as a complete departure from traditional media. It requires no additional supplements and can be used directly, providing convenience for users. It adheres well to most culture vessels, facilitating smooth cell growth regardless of coating. CellCor™ MSC CD AOF reduces the need for medium changes across subsequent cell culture passages, making it more economical in terms of media consumption compared to conventional media.

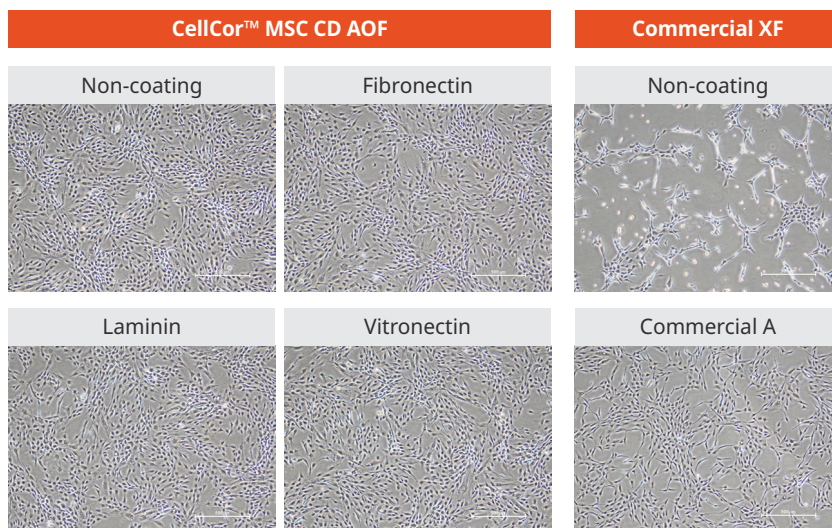
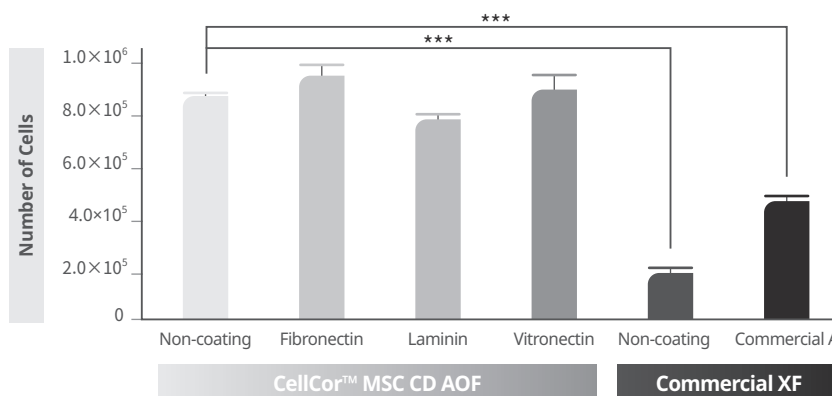


FIGURE 5
Cell Culture Coating Verification Test

MSCs cultured in commercial XF media show variable outcomes depending on the presence of coatings. In contrast, under CellCor™ MSC CD AOF culture conditions, cells demonstrate superior cultivation capabilities across all conditions, independent of coating (*** $p < 0.001$).



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Human MSC-derived Exosome Collection Medium

CellCor™ EXO CD

FBS-containing media are prevalent in the industry for exosome extraction. However, impurities present in exosomes are the major hurdle in the development of therapeutic and cosmetics. CellCor™ EXO CD, a serum-free chemically defined medium, allows for the isolation of pure MSC-derived exosomes. CellCor™ EXO CD was developed to overcome the disadvantages of FBS-containing and XF media, aiming to provide convenience to researchers.

- **Serum-free medium with chemically defined ingredients:** BSA-free, ensuring high purity of exosomes
- **Exosome-free:** Low level of background particles; refrigerated to eliminate impurities arising from thawing
- **Convenient:** No need for media replacement steps prevents contamination risks; reduces time/costs in isolation/purification steps due to the absence of FBS and hPL-derived ingredients during exosome harvesting.
- **High Performance:** As a medium suitable for MSC cultivation, it enables a high yield of exosomes even from a small cell count, facilitating large-scale production of exosomes with high activity and potency.

FIGURE 1

Comparison of human MSC expansion

The co-medium assay showed a low level of background particles, enabling exosome analysis without external contamination (** $p < 0.01$)

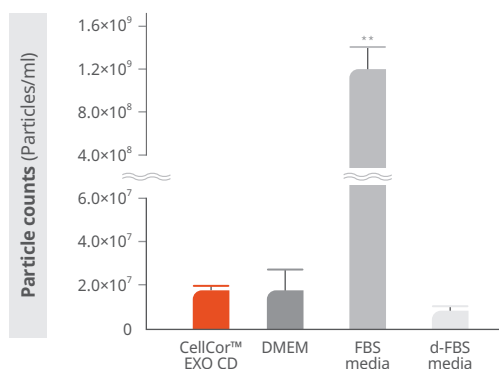


FIGURE 2

Cell count comparison at the time of conditioned media harvest

Stable cell growth allows for stable exosome recovery. (final cell count after starting culture with 1 × 10⁵ cells)

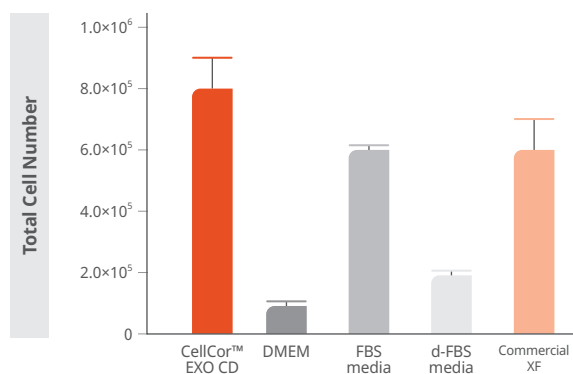
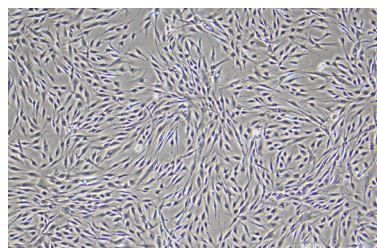


FIGURE 3

Morphology

CellCor™ EXO CD can also be used for MSC culture, maintaining stable cell conditions during exosome collection.

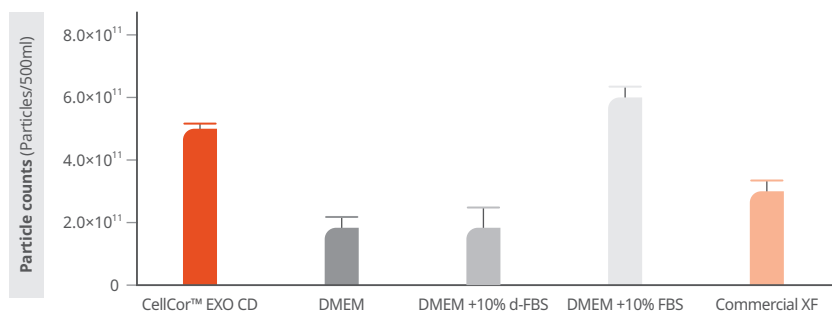


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FIGURE 4
A comparison experiment of exosome yields by cell culture media

In comparison tests with commercial media, CellCor™ EXO CD demonstrated the highest yield of exosomes. (based on protocols for each medium).



Application

As important as the yield of exosomes is their potency. Even when processing the same quantity of exosomes, those with higher purity exhibit better efficacy.

Exosomes harvested using CellCor™ EXO CD demonstrate superior effectiveness.

FIGURE 5
Angiogenesis assay

Demonstrated angiogenic effect is equal to or greater than that of FBS(+) medium and commercial media.

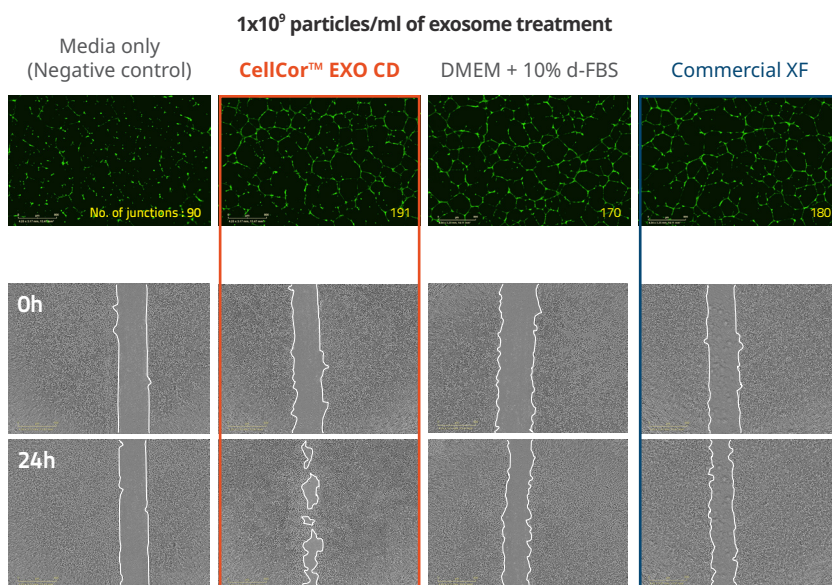
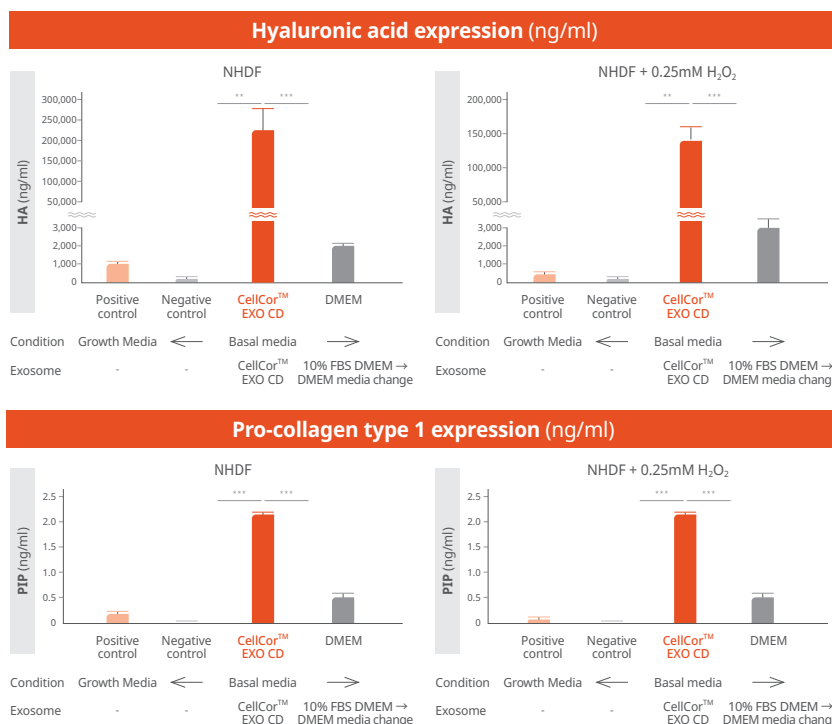


FIGURE 6
Wound healing assay

Demonstrated higher wound healing when compared with FBS(+) and commercial media, indicating higher therapeutic potential

FIGURE 7
Effects testing of dermatologically active ingredients

Higher expression levels of hyaluronic acid and procollagen than those of exosomes extracted from other media when treated with the same amount of exosomes (**p<0.005, ***p<0.001)



XCELL Exosome Solution

Thawing

Expansion

Seeding

Xcell Therapeutics understands the needs of the MSC-exosome industry and provides non-stop solutions, from MSC culture to exosome isolation and purification.

CellCor™ MSC CD AOF | EXO CD

- ❶ CellCor™ MSC CD AOF stabilizes cells after thawing, enabling stable proliferation of MSCs.
- ❷ CellCor™ EXO CD facilitates cell culture across all passages of exosome production.
- ❸ Conditioned media (CM) can be recovered at the appropriate confluency without exchanging media

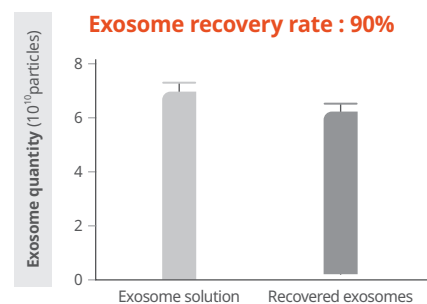
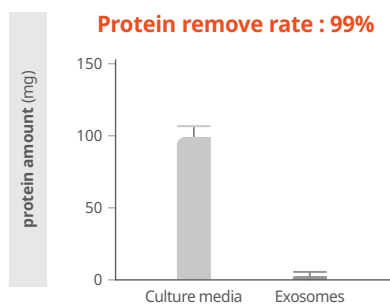
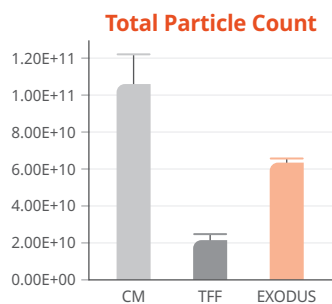


Automatic Exosome Isolation System



Lab-scale EXODUS H-600 (0.01 mL~250 mL)

- **H600** is an advanced device capable of efficiently isolating and purifying high-purity exosomes at a high yield within a short period, leveraging its differentiated technological capabilities.
- It can effectively extract exosomes from small-volume samples.
- Automated separation/purification processes enhance user convenience.
- **Protein removal of over 95%:** It can remove impurities other than exosomes.
- **Exosome recovery of over 90%:** Stable recovery allows for experimentation with small-volume samples.



High Purity and High Yield
 Impurity protein removal rate > 99%,
 Exosomes recovery rate > 90%

Exosome detection via the ultrafast-isolation system : EXODUS, Nature Methods | VOL 18 | February 2021 | 212-218

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Collection

All in one, utilizing CellCor™ products for stem cell cultivation, from exosome production to isolation.

CellCor™ EXO CD

CM recovery available
(Validation required regarding cell confluency)



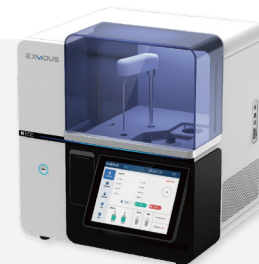
Isolation

Stable and superior MSC cultures, conditioned media (CM) recovery without exchanging media, and complete exosome isolation with EXODUS

EXODUS

Exosome can be isolated and purified from CM (automated)

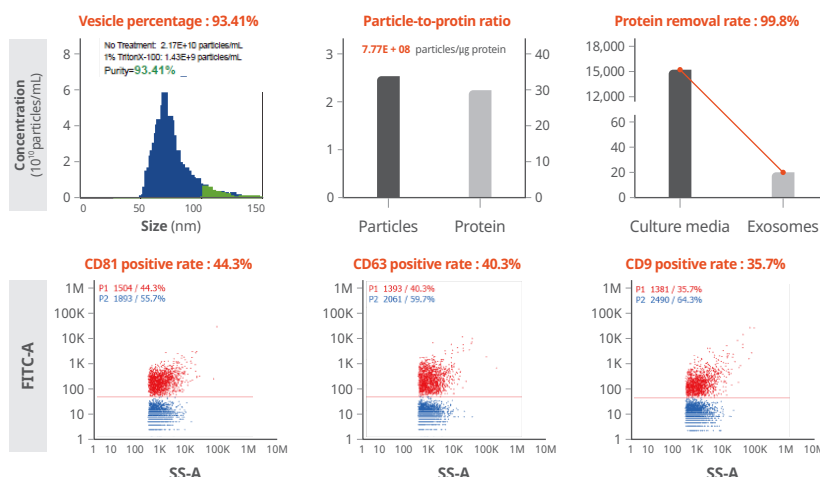
* Sales only in Korea



EXODUS T-2800 (Closed System) Available for Use in GMP

- **T-2800** is large-scale equipment capable of automated isolation of exosomes in a range of 0.5 to 10 L.
- No pretreatment is required, all cell debris is removed without centrifugation, and exosomes can be isolated without the need for filters.
- **BSA removal of over 95%:** Surpasses the limits of TFF
- All processes are automated and closed, reducing batch-to-batch variation and enabling monitoring. All processes satisfy GMP and 21 CFR part 11 requirements.

Performance demonstration of high-purity exosome



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Human Keratinocyte Culture medium

CellCor™ Kera CD AOF

Keratinocytes are cells that make up over 90% of the epidermis and are known to be involved in keratinization and immunity. They are also used to develop skin cell therapies for various conditions including burns, wounds, and foot ulcers. CellCor™ Kera CD AOF is a BPE-free medium, ensuring regulatory safety in the development of pharmaceuticals and medical devices for skin substitutes, as well as in the cosmetics industry.

Complete, animal origin-free CD medium: Safety assured for development of medical devices and treatment for skin conditions

All-in-one medium: No supplements or coatings needed

Maintains stable cell morphology: Stable expression of cytokeratin family, a keratinocyte marker

High proliferative capacity: Superior proliferation compared to commercial media, allowing cells to be cultured up to later passages and enabling large-scale cell culture

Establishment stability: Enables stable establishment from skin tissue; maintains high cell performance and activity

FIGURE 1

Comparison of protein expression & gene expression that represent the character of keratinocyte in cultured with three types of media

Comparison of Cytokeratin 5 and Cytokeratin 14 protein/gene activity in keratinocytes cultured in CellCor™ Kera CD AOF with those in commercial BPE(+) and BPE(-) media

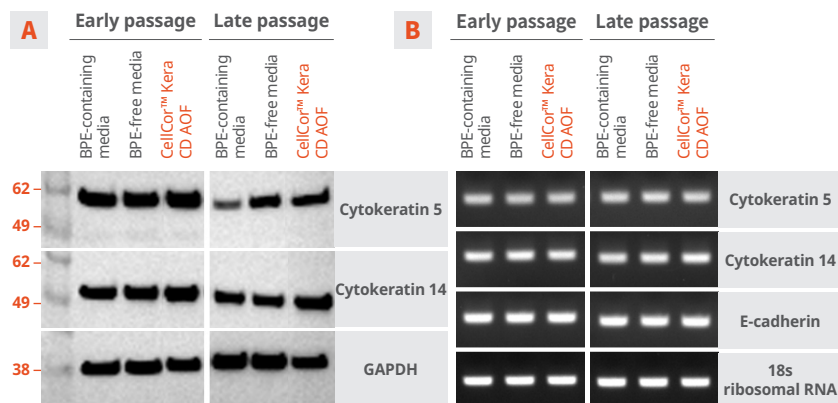


FIGURE 2

Comparison of Growth rate, cell viability and cell size in keratinocyte cultured with two types of media

Comparison of proliferation rate, cell viability, and cell size of keratinocytes cultured in CellCor™ Kera CD AOF with those in commercial BPE(+) and BPE(-) media

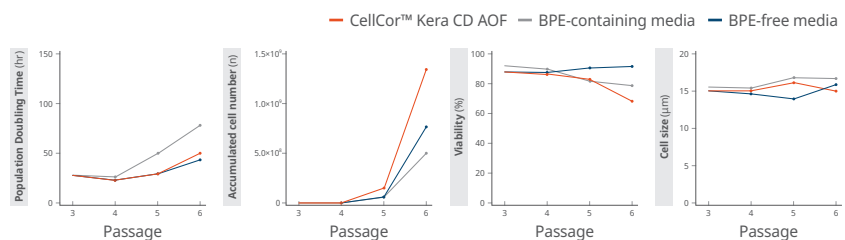
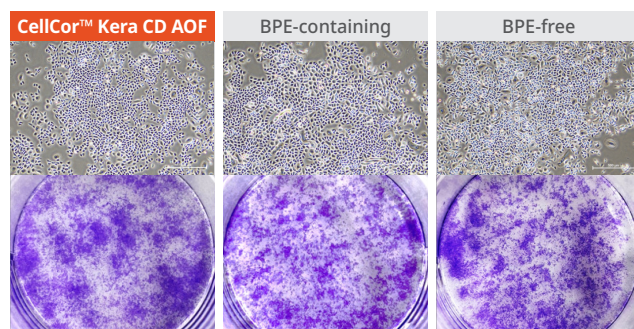


FIGURE 3

Comparison of cellular activity of keratinocyte in cultured with three types of media

Comparison of cell activity of keratinocytes cultured in CellCor™ Kera CD AOF with that of commercial BPE(+) and BPE(-) media



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Human Dermal Papilla Cell Culture medium

CellCor™ DPC CD

Dermal papilla cells (DPCs) are known to be the primary cells that serve an essential role in the production of new hair during the hair growth cycle. DPCs are being used for the purpose of developing hair loss therapeutics in the CGT industry.

CellCor™ DPC CD is a chemically defined medium recognized for its ability to provide stable dermal papilla cell (DPC) growth and hair restructuring.

All-in-one medium: No supplements or coatings needed

Medium optimized for DPC culture: Safe, as it does not contain animal derivatives, and maintains stable cell properties for consistent growth

High growth rate: Higher growth rate and cell viability compared to commercial media

Low cell senescence: Low senescence of cells compared to serum(+) containing media

Hair restructuring ability: High hair restructuring ability compared to serum(+) containing medium

FIGURE 1

Comparison of Growth rate and viability in DPCs cultured with two types of media

Comparison of growth rate and cell viability of DPCs cultured in serum(+) containing medium and CellCor™ DPC CD

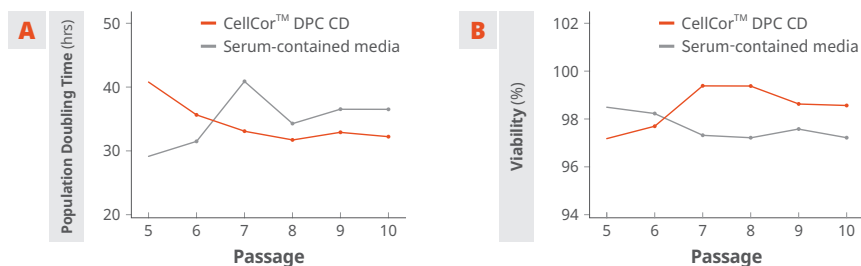


FIGURE 2

Comparison of cellular senescence in DPCs cultured with two types of media

Comparison of cellular senescence of DPCs cultured in serum(+) containing medium and CellCor™ DPC CD

- A** | β -galactosidase assay
- B** | SA- β -gal-positive values
- C** | Senescence-related genes (passage = 6)

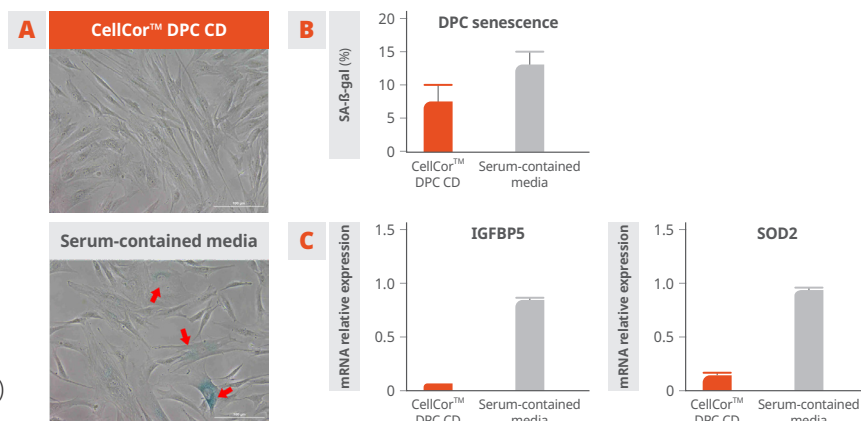
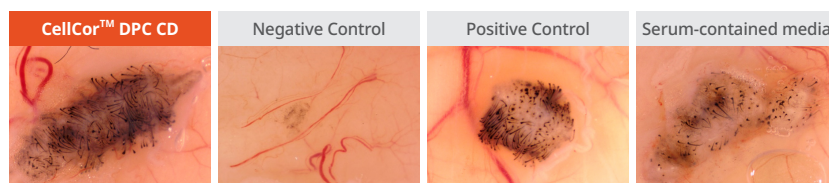


FIGURE 3

Hair reconstitution ability of DPCs cultured with two types of media

Comparison of hair follicle reconstitution ability of DPCs cultured in serum(+) containing medium and CellCor™ DPC CD (6-week-old nude mice [BALB/cA]cl-nu)

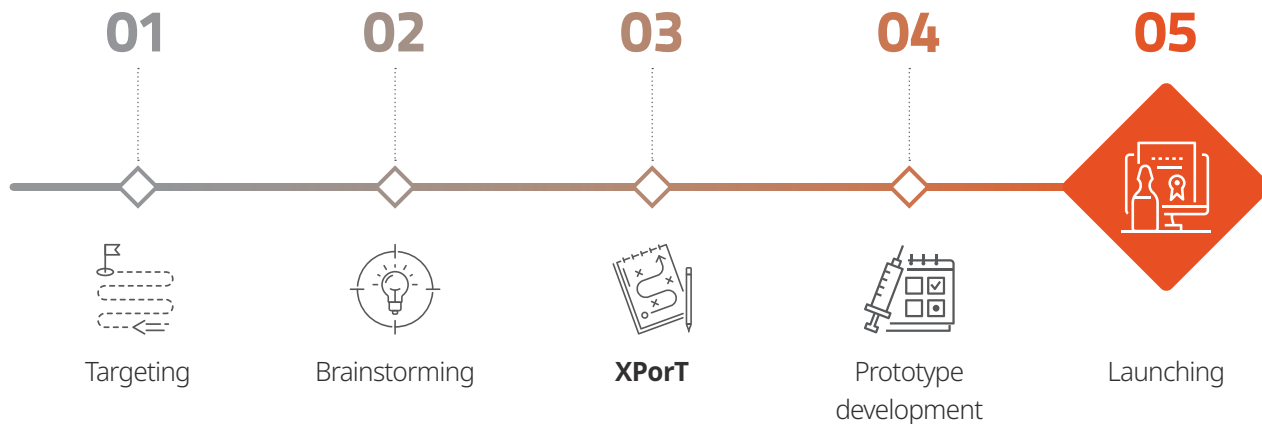


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Pipeline progress and portfolio of CellCor™

5 stage of product pipeline



Coming soon

Coming Soon		
Proliferation	T cell CellCor™ T CD AOF CellCor™ T XF	Bovine muscle satellite cells CellCor™ bMuSC ACF
	NK Cell CellCor™ NK CD	iEXO CellCor™ iEXO CD
	EXOSOME CellCor™ EXO CD AOF	iPSC CellCor™ iPSC CD
	MSC CellCor™ MSC CD AOF(phenol-red free)	iHSC CellCor™ iHSC CD
Differentiation		iHSC CellRo iHSC CD
		iRBC CellRo iRBC CD
		iPlatelet CellRo iPlatelet CD
		Bovine muscle satellite cells CellRo bMuSC ACF

* CD : Chemically Defined medium | XF : Xeno-Free medium | ACF : Animal Component Free medium | AOF : Animal Origin Free medium

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We understand
your cell culture needs

We're here to support every stage of your cell culture workflow,
from research to manufacturing

GMP COMPLIANT PRODUCTS

Our quality control (QC) system adheres to globally recognized standards, ensuring compliance with international regulatory guidelines throughout the product development pipeline.

This indicates that we can provide media and reagents that meet the regulatory requirements and are produced in a controlled environment.



Good Manufacturing Practice (GMP)
(Korean MFDS)



FDA 21 Code for Federal Regulations (CFR)
Parts 201 and 211 cGMP
(Current Good Manufacturing Practice)



EU GMP EudraLex - Volume 4 - Good
Manufacturing Practice (GMP) Part 1



ICH Q7 Good Manufacturing Practice Guide
for Active Pharmaceutical Ingredients



ISO9001 Quality management systems
ISO 13485 Medical Devices Quality Management Systems



* Annual production capacity

- 110,000 L (220,000 bottles):
500 L/day (220 work days)
- Max. 220,000 L (440,000 bottles):
500 L/day (220 work days × 2 shifts)



* GMP facilities

- Media Plant A/QC Lab : 477.5 m²
- Media Plant B : 260.8 m²
- Office : 410.4 m²

01

Quality Control System

Xcell Therapeutics is operating own GMP quality system in accordance with the KGMP, cGMP, EU GMP, and ICH Q7 (GMP management).

02

Quality Personnel

Workforce managed for reliable and error-free quality control (Quality personnel: 1/2 of production personnel)

03

Quality Control Items

- Raw material quality inspection
- In-process quality inspection
- Product quality inspection
- Shipment inspection
- Stability testing

04

Quality Testing Items

- 1 **Physicochemical testing** - Appearance, osmolarity, pH, conductivity, TOC, and airtightness tests
- 2 **Microbiological assays** - Sterility test, mycoplasma test, bacterial endotoxins test, and microbial limit test
- 3 **Biological assays** - Cell performance testing (PDT and differentiation), flow cytometry, colony forming unit (CFU) assay, and particle concentration

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FAQ

- 01 Thawing & storage** Thaw initially at room temperature for 1 hour, followed by an additional thawing at 37°C for 2–3 hours. Ensure thorough mixing by swirling in a 37°C water bath, and use after warming. Once opened, store at 4°C.
- 02 When cell attachment fails (Necessity of coating)** CellCor™ medium enables cell attachment without the use of coating materials or ECM. However, if the cell attachment is poor due to donor variation, we recommend adding 5–10 µg/mL of laminin coating.
- 03 Is a media change required after seeding?** There is no need for a media exchange step with our products. We recommended seeding at 3,000–4,000 cells/cm² to ensure cells do not overgrow, and then proceeding with subculture at 85% confluency.
- 04 Is an adaptation step to the new medium necessary if previously cultured in a different medium?** For cells established with FBS, it is necessary to perform a half-medium change. This involves removing half of the supernatant and replacing it with an equal volume of fresh medium, rather than completely replacing the medium. In the next passage of cultivation, please proceed with the culture using only our product. We also recommend adaptation even for cells established with XF/SF.
- 05 Precautions when using the detachment reagent** CellCor™ does not contain serum components that neutralize T-EDTA. Therefore, using T-EDTA may affect cell growth. We strongly recommend using TrypLE™ Express Enzyme (Gibco) for cell detachment.
- 06 If sedimentation or protein aggregation is observed after thawing the medium** Thaw initially at room temperature for 1 hour, followed by additional thawing at 37°C for 2-3 hours. Ensure thorough mixing by swirling in a 37°C water bath. Layer separation may occur, but this does not affect product performance. Please mix carefully so as to prevent foaming by gently inverting in the 37°C water bath.

CellCor™ Ordering Information

CellCor™	Catalog No.	Size	Additional Info
CellCor™ MSC CD AOF	YSP018	500 mL	RUO
CellCor™ MSC CD AOF	YSP023		GMP
CellCor™ EXO CD	YSP017		RUO
CellCor™ Kera CD AOF CD AOF	YSP019		RUO
CellCor™ DPC CD	YSP007		RUO

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