



Clinical Adipose Tissue Processing Platform

June 2014

■ About American CryoStem

Cellular Platform Highlights

A biotechnology pioneer in the fields of Regenerative and Personalized Medicine, American CryoStem operates a state-of-the-art, FDA-registered, clinical laboratory dedicated to processing, bio-banking and development of cellular applications using autologous adipose (fat) tissue and adipose derived stem cells (ADSCs). Through its scientific efforts, the Company has built a strong, strategic portfolio of intellectual property, patent applications, and proprietary operating processes that form its core standardized cellular platform.

Operating within an industry which aims to repair, replace or regenerate organs and tissue that have been damaged or diseased, American CryoStem has centered its patented, cellular platform on providing consumers and institutions with standardized, clinical grade solutions using adipose derived adult stem cells (ADSCs).



American CryoStem Corporation
1 Meridian Road
Eatontown, NJ 07724
info@americancryostem.com
USA 732-747-1007



■ A Turn-Key cGMP Laboratory Solution

Why Choose an American CryoStem Laboratory?

- Immediate access to turn-key Standard Operating Procedures (SOP's) required to operate a clinical cGMP tissue processing facility.
- Our facility was the originator of the international nucleated cell designation with ICCBA for labeling tissue products to ISBT 128 standards.
- Access to research through the Company's on-going development programs with leading universities and private institutions.
- Experienced team of scientific support to troubleshoot and overcome laboratory challenges.
- Opportunity to manufacture cellular products developed at American CryoStem for local distribution.
- Pre-designed marketing and sales support literature available for use and customization to local market.
- In depth consulting on how to market and sell tissue products to the medical and consumer markets.

■ Adipose Tissue Based Platform



Available Source

A simple liposuction performed by a cosmetic or plastic surgeon is required to obtain a minimum of 60mL of tissue.

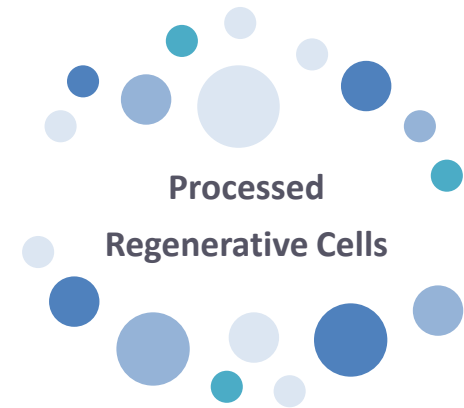
This procedure may be completed in less than 40 minutes and requires no down time by the patient.



Multiple Uses

Received tissue can be processed into multiple products and/or stored for future treatments.

- Stored Adipose Tissue for grafting
- Stromal Vascular Fraction
- ATCELLs (Adipose Derived Stem Cells)
- Personalized Skin Care



Regenerative Medicine

Processed adipose tissue may be isolated into Stromal Vascular Fraction or ATCELLs (Adipose Derived Stem Cells) and expanded for future use.

■ Standardizing a Fragmented Industry

1

Repeatability

Specially designed processing supply kits that are validated and tested for all aspects of the collection, processing and cryopreservation of individual autologous tissue samples. Each supply kit is pre-packaged and contains GMP/GTP grade sterile components for the continuous quality control of the laboratory and finished products.

2

Consistency

Each process is separately tracked and documented to monitor processing results to ensure consistency across individual samples. Our goal is to limit outside variables such as age, health and harvesting techniques by making our core process the same each time.

3

Security and Quality

An unbroken chain of custody tracking methodology with the creation of client and sample identification numbers that are globally recognized under the ISBT 128 Standards and Technical Specification by the ICCBBA.

Multiple in-process quality control protocols check each sample for cell viability and sterility.

Why standardization matters?

Regulatory agencies around the globe (FDA, EMA, FACT-JACIE, ISO, USP, etc.) have developed and enforce certain standards for the creation and usage of cellular therapies. We have incorporated these requirements and developed our standardized methods to obtain adipose tissue, process, expand and store adipose tissue and ADSC's to generate repeatable results and meaningful data to these standards. Records are maintained according to US FDA cGMP processing standards.

These standardized methods provide the clinical information necessary to create the highest quality cellular products which supports local approval where required.

■ A Turn-Key Processing Solution



Standardized Cellular Processing Modules

- I - Whole Adipose Tissue Collection, Processing, Storage and Delivery
- II - Stromal Vascular Fraction (SVF) Processing, Storage and Delivery
- III – ADSC, Processing, Expansion, Storage and Delivery
- IV – ADSC Cell Culturing, Conditioned Media Creation and Storage

Cellular Platform Highlights

- Clinical cGMP Tissue Processing & Bio-Banking Facility
- Conforms with American Association of Tissue Banks & American Association of Blood Banks
- Operates under current FDA guidance
- Multiple in-process quality management controls
- Transparent processing batch records and reporting
- Complete end to end record keeping
- Proprietary chain of custody methodologies

■ Validated General Standard Operating Procedures

A Complete and Validated Set General Standard Operating Procedures (SOPs)*

Administrative SOPs

- Standard Operating Procedures Manual
- Health Information Privacy
- SAE Reporting
- Product Complaints
- Quality Program
- Product Recalls
- Facilities
- Vendors
- Business Continuity Plan

Equipment SOPs

- Equipment Certification and Maintenance
- Selection and Qualification of Equipment
- Control Rate Freezer
- Cell Counter
- Rapid Sterility Testing
- Cryopreservation Tank
- Daily Preparation and Use of BioSafety Cabinets
- Minus 80 Freezer
- Centrifuge
- Incubator
- Aspiration Pump Assembly
- Radio Frequency Sealer
- Scales and Balances
- Laboratory Monitoring System
- Refrigerator

Administrative SOPs

- Training Manual
- Obtaining Adipose Tissue Samples for Product Development
- Creation and Shipping of Collection Kits to Providers
- Receipt of Client Sample
- Change Control of Processing Equipment
- Obtaining Adipose Tissue for Commercial Processing
- Contaminated Sample Protocol
- Validation of New Disposables Lots
- Receipt and Check in of Processing Supplies
- Receipt and Check in of General Supplies
- Daily Laboratory Sanitation
- Supplier Qualification and Approval
- Hazardous Waste Disposal
- Safety Manual-Lab Safety
- Creation of Disposable Supply Kits for Processing
- Approval of an SOP
- Management of SOPs
- Transportation of Frozen Client SVF Samples
- Shipping of Viable Cultures-Medium
- Product Insert and Labeling
- Use of Biosafety Cabinet
- Using Control Rate Freezer
- Storing and Retrieving from Liquid Nitrogen Vapor Phase Storage Tank
- Use of pH Meter

*** The above list is a sample and does not reflect the complete list of provided SOPs**

Sample General SOP Batch Record



SOP.BI.223.FORM.A Freeze Recovery and Sterility Testing of Cryopreserved SVF Cells

Quality Control Steps The required SOP's and quality control procedures for daily setup, maintenance of all equipment, and cleanliness of the clinical facility are required to have been completed before this process has been initiated.

Preparing Technician: _____
Preparation Date: _____
Supervisor: _____

Sample ID _____

Bill of Materials

All items below are required to complete this process, as determined by the Master Bill of Materials, please see the approved Master SOP.

Equipment

Update the Activity log of the BSC that you are using for this process. You are required to include the process ID of this procedure on the activity list. Update the activity and inventory logs of all equipment whenever they are used. This section lists all equipment used in this process, by internal ID and Master Specification.

Ancillary Materials Data sheets and specifications are included in the Master Specification Sheet of their controlling Equipment.

Name	ACS Specification	Ancillary Materials
Biosafety Cabinet (BSC)	Class 2A/B3, ISO 7 Environment, Single User, Non-Critical	
Name:	_____	Vacuum Pump, GE
Quantity:	1	Motors/Gast, Line Master
Approved Vendor:	_____	Aspirator Bottle, Pyrex
Manufacturer:	_____	Side Arm Flask, VWR
Manufacturer Number:	_____	No. 8 Stoppers, VWR
		Vacuum Tubing, VWR
Internal ID Number:	_____	Foot Control, McMaster
		2mL Tube Rack
		Drierite Dessicant, 8 mesh

Name	ACS Specification	Ancillary Equipment
Cryo Tank	Maintain -180 C full auto, with controlled module, Multi-User, Critical.	
Name:	MVE 815P-190F Full auto Control Vapor Phase N2 Tank	Controller Unit
Quantity:	_____	5 mL Cases
Approved Vendor:	_____	5 mL Racks
Manufacturer:	_____	2 mL Cases
Model Number:	815P-190F	2 mL Racks
Internal ID Number:	_____	Face Mask, Eyewear
		Forceps, Cryogloves

Supervisor Review Date: _____ 1 of 17
Supervisor Initials: _____

Confidential
SOP.BI.223.Form.A Batch Record



81 Place box for 2mL vials

Name	ACS Specification	Ancillary Materials
Water Bath	37° Water bath	
Name:	_____	
Quantity:	_____	
Approved Vendor:	_____	
Manufacturer:	_____	
Manufacturer Number:	_____	
Internal ID Number:	_____	

Name	ACS Specification	Ancillary Materials
Microbial Detection System	Incubation of Aerobic, and Anaerobic Culture bottles, at 30°-35° C for 2 weeks.	
Name:	BacT/ALERT Microbial Detection System	BacT/ALERT Microbial
Quantity:	1	Detection System Incubation
Approved Vendor:	BioMeriueX	Module, BioMeriueX
Manufacturer:	BioMeriueX	
Manufacturer Number:	003CM6676	
Internal ID Number:	_____	

Name	ACS Specification	Ancillary Materials
Pipet Aid System	Tissue Culture Filter, 1-100mL adaptable, Single-user, Non-critical	
Name:	Pipet-aid	All sterile serological pipets
Quantity:	1	
Approved Vendor:	_____	
Manufacturer:	Drummond Scientific Co.	
Manufacturer Number:	_____	
Internal ID Number:	_____	

Name	ACS Specification	Ancillary Materials
Cell Counter	Dual Fluorescence Capable, Single User, Non-Critical	
Name:	Cellometer Vision Trio Cell Profiler	Cell Counting Chambers,
Quantity:	1	Nexcelom
Approved Vendor:	Nexcelom	Nexcelom Computer
Manufacturer:	Nexcelom	
Manufacturer Number:	Vision-003-0171	
Internal ID Number:	_____	

Supervisor Review Date: _____ 2 of 17
Supervisor Initials: _____

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SOP.BI.223.Form.A Batch Record

Validated Product Standard Operating Procedures

A Complete and Validated Set of Product Specific Standard Operating Procedures (SOPs)*

CELLECT® Tissue Collection System

- Adipose Tissue Collection Forms
- Creation and Shipping of Collection Kits to Physicians
- Receipt of Client Sample at the Laboratory
- Information Exchange for Commercial Processing

ATGRAFT™ Adipose Tissue Storage

- Preparation and Cryopreservation of Adipose Tissue for Autologous Transfer
- Freeze Recovery and Viability Testing of Adipocytes
- Sterility Testing

ATCELL™ Cellular Processing

- Processing Adipose Tissue for SVF Isolation
- Cryopreservation of SVF
- Freeze Recovery and Sterility Testing of Cryopreserved SVF
- Preparation and Dispensing of Roche Liberase
- Viability Testing of Cryopreserved SVF cells
- Concurrent ASC Culture Establishment and SVF Cryopreservation
- Recovery of Cryopreserved SVF or ASC for Expansion

The screenshot shows a 'Lab Summary' form for 'CryoStem' under the heading 'Cryopreservation of Adipose Tissue'. The form contains the following sections:

- Client Information:** Client ID# W375013000047K30, Client/ Donor Name: _____, Collection Date: 9/19/2013, Client/ Donor D.O.B. 10/30/1959, Cryopreservation Date: 9/20/2013, Physician ID: 34658A, Physician Name: Fredric Stern MD.
- Pre-Cryopreservation:** AT Weight Upon Receipt: 95.8 grams, Washed AT Weight: 68.76 grams, Bacterial Test Results (Aerobic and Anaerobic): Pass, Yes, Fail, ---, Adipocyte Assay: Average Viability: 89.10%, Average Total Cells/mL: 9.79 x 10⁵.
- Cryopreservation:** A table with 4 columns: Cryo-Bag #, Fat Dispensed (mL), QC Vial #, and Physician's Request.
- Post Cryopreservation:** Adipocyte Assay: Average Viability: 90.2%, Average Total Cells/mL: 9.79 x 10⁵.
- Footer:** Ruth Goldman, Laboratory Supervisor, Report Date, AMERICANCRYOSTEM.COM, 1-888-519-3554.

Cryo-Bag #	Fat Dispensed (mL)	QC Vial #	Physician's Request
1-5	1.5mL	NO	NO
6	3mL	YES	NO
7,9,10	4.5mL each	NO	NO
11	4.3mL	YES	NO

* The above list does not reflect the complete list of provided SOPs

Sample Product SOP Batch Record



SOP.BI.223.FORM.A Freeze Recovery and Sterility Testing of Cryopreserved SVF Cells

Quality Control Steps The required SOP's and quality control procedures for daily setup, maintenance of all equipment, and cleanliness of the clinical facility are required to have been completed before this process has been initiated.

Preparing Technician: _____
Preparation Date: _____
Supervisor: _____

Sample ID _____

Bill of Materials

All items below are required to complete this process, as determined by the Master Bill of Materials, please see the approved Master SOP.

Equipment

Update the Activity log of the BSC that you are using for this process. You are required to include the process ID of this procedure on the activity list. Update the activity and inventory logs of all equipment whenever they are used.

This section lists all equipment used in this process, by internal ID and Master Specification.

Ancillary Materials Data sheets and specifications are included in the Master Specification Sheet of their controlling Equipment.

Name	ACS Specification
Biosafety Cabinet (BSC)	Class 2A/B3, ISO 7 Environment, Single User, Non-Critical

Name: _____
Quantity: 1
Approved Vendor: _____
Manufacturer: _____
Manufacturer Number: _____

Internal ID Number: _____

Ancillary Materials

Vacuum Pump, GE
Motors/Gast, Line Master
Aspirator Bottle, Pyrex
Side Arm Flask, VWR
No. 8 Stoppers, VWR
Vacuum Tubing, VWR
Foot Control, McMaster
2mL Tube Rack
Drierite Dessicant, 8 mesh

Name	ACS Specification
Cryo Tank	Maintain -180 C full auto, with controlled module, Multi-User, Critical.

Name: MVE 815P-190F Full auto Control Vapor Phase N2 Tank
Quantity: _____
Approved Vendor: _____
Manufacturer: _____
Model Number: 815P-190F
Internal ID Number: _____

Ancillary Equipment

Controller Unit
5 mL Cases
5 mL Racks
2 mL Cases
2 mL Racks
Face Mask, Eyewear
Forceps, Cryogloves

Supervisor Review Date: _____
Supervisor Initials: _____

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SOP.BI.223.FORM.A Batch Record



81 Place box for 2mL vials

Name	ACS Specification
Water Bath	37° Water bath

Name: _____
Quantity: _____
Approved Vendor: _____
Manufacturer: _____
Manufacturer Number: _____

Internal ID Number: _____

Ancillary Materials

Name	ACS Specification
Microbial Detection System	Incubation of Aerobic, and Anaerobic Culture bottles, at 30°-35° C for 2 weeks.

Name: BacT/ALERT Microbial Detection System
Quantity: 1
Approved Vendor: BioMeriux
Manufacturer: BioMeriux
Manufacturer Number: 003CM6676

Internal ID Number: _____

Ancillary Materials

BacT/ALERT Microbial
Detection System Incubation
Module, BioMeriux

Name	ACS Specification
Pipet Aid System	Tissue Culture Filter, 1-100mL adaptable, Single-user, Non-critical

Name: Pipet-aid
Quantity: 1
Approved Vendor: _____
Manufacturer: Drummond Scientific Co.
Manufacturer Number: _____

Internal ID Number: _____

Ancillary Materials

All sterile serological pipets

Name	ACS Specification
Cell Counter	Dual Fluorescence Capable, Single User, Non-Critical

Name: Cellometer Vision Trio Cell Profiler
Quantity: 1
Approved Vendor: Nexcelom
Manufacturer: Nexcelom
Manufacturer Number: Vision-003-0171

Internal ID Number: _____

Ancillary Materials

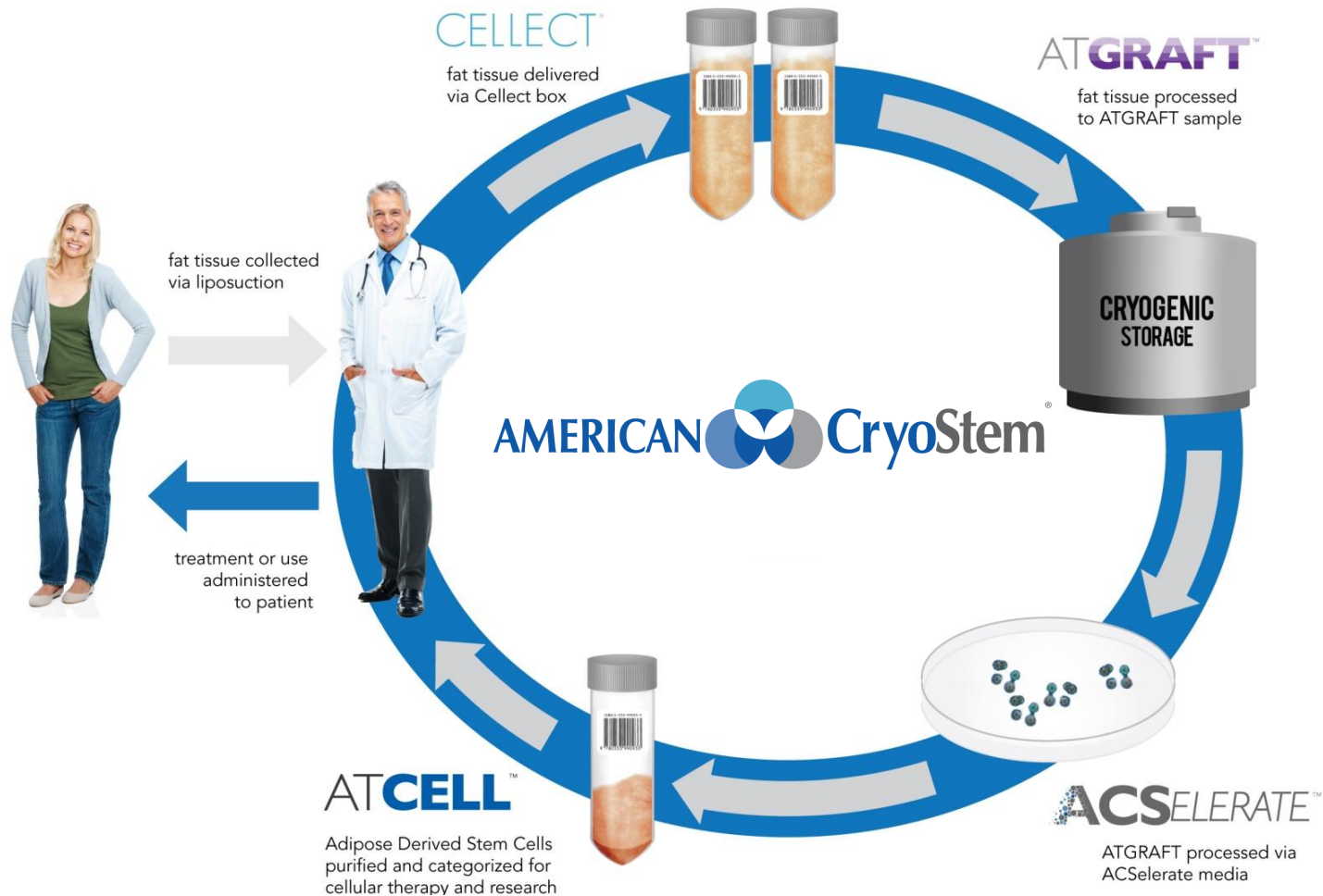
Cell Counting Chambers,
Nexcelom
Nexcelom Computer

Supervisor Review Date: _____
Supervisor Initials: _____

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SOP.BI.223.FORM.A Batch Record

■ Adipose Tissue Products and Services



■ Modular Adipose Tissue Products

CELLECT®

Validated tissue collection and transportation system

Patent Pending PCT/US2011-39260 (June 6, 2011)

Product Highlights

- Unbreakable “chain of custody” between sample collection and American CryoStem laboratory
- ICCBBA labeling with facility identifier (#W3750)
- Collect® system is used for all American CryoStem cGMP tissue collection and products
- Proprietary methods and materials to ensure highest cell viability during transportation



■ Modular Adipose Tissue Products

ATGRAFT™

Tissue storage service to perform multiple fat transfer procedures

Patent Pending PCT/US13/44621 (June 7, 2012)

Product Highlights

- Requires use of the Collect® tissue collection system
- Autologous fat tissue storage and retrieval to be used as a natural filler for cosmetic and reconstructive surgical procedures
- FDA and PHS 361 compliant
- Stored fat can be further processed into any of our additional products or services.
 - ATCELL™
 - Autokine-CM®
 - Regenerative Medicine applications



■ Modular Adipose Tissue Products

ATCELL™

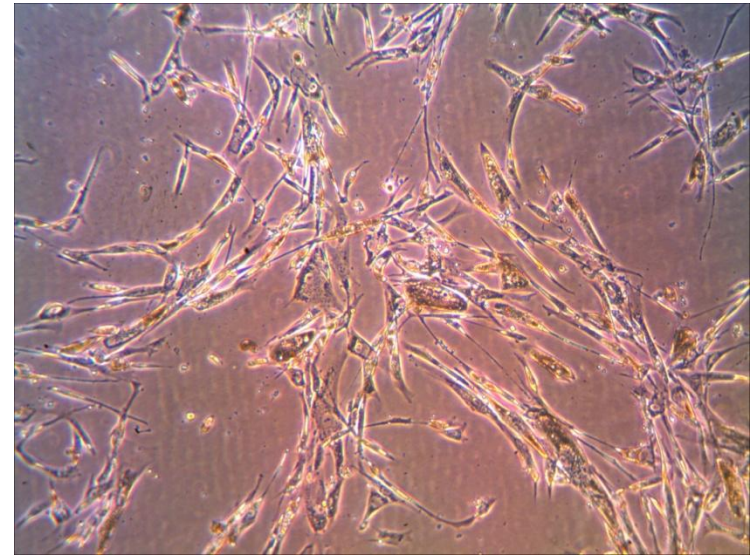
Clinical grade adipose derived adult stem cells

Patent Pending #13/646,676 (October 6, 2011)

- IRB Approved Process June 27, 2013

Product Highlights

- Isolated from stored ATGRAFT™ samples or newly collected tissue during liposuction.
- Single donor, low passage, cGMP processed cells for research or therapeutic use
- 96%+ ADSC purity confirmed by third party flow cytometry*
- ATCELLS™ can be further expanded or differentiated using our ACSelerate™ media products.



ATCELL™ (clinical human adipose derived stem cells)

(*University of Rochester)

■ ATCELL™ Purity and Expansion

ATCELL's are validated hADSCs through surface marker flow cytometry and differentiation analysis. The validation studies were conducted with multiple cell lines over multiple passages to ensure that ATCELL lines maintain their identity during culture assuring purity and reliably in clinical applications.

Protein markers expressed by ATCELL

Antigenic Marker	Significance	Expressed?
CD14	Innate immune system cells	No
CD19	B-cell marker	No
CD29	Innate immune system cells	Yes
CD31	PECAM-1 (Platelet Endothelial Adhesion Molecule)	No
CD34	BMDSC (Bone Marrow Derived Stem Cells)	No
CD44	Hyaluronic acid receptor	Yes
CD45	Lymphocyte common antigen	No
CD49d	Integrin $\alpha 4$	Yes
CD73	Conversion of AMP to adenosine	Yes
CD90	Thy-1; stem cell marker	Yes
CD105	Endoglin; role in angiogenesis	Yes
CD146	MCAM (Melanoma Adhesion Molecule Marker); MSC marker	Yes

Maintaining cellular identity though culture

Antigenic Marker	Initial Expression	Third Passage (P3)	Fourth Passage (P4)
CD14	No	No	No
CD19	No	No	No
CD29	Yes	Yes	Yes
CD31	No	No	No
CD44	Yes	Yes	Yes
CD45	No	No	No
CD49d	Yes	Yes	Yes
CD73	Yes	Yes	Yes
CD90	Yes	Yes	Yes
CD105	Yes	Yes	Yes
CD146	Yes	Yes	Yes

■ Adipose Tissue Processing Products

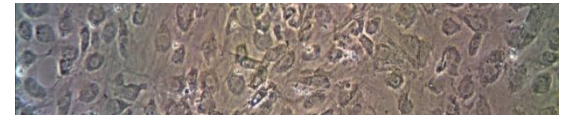


Cell media line for transporting, growing, differentiating and storing human cells.

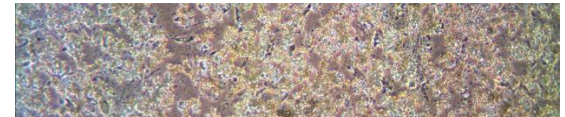
Issued Patent # 7,989,205 (August 2, 2011)

Product Highlights

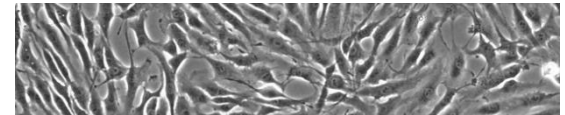
- Specifically designed for use with adipose tissue and adipose derived cells
- Superior growth and differentiation capabilities compared to industry competitors
- Animal product free, GMP manufactured.
- Suitable for human clinical and therapeutic uses
- Research grade versions for application development
- Additional Defined Versions in development



ACSelerate-CYTM (Cartilage)



ACSelerate-OBTM (Bone)



ACSelerate-MYTM (Muscle)

ACSelerate-GYTM (Storage media)

ACSelerate-TRTM (transport media)

■ Adipose Tissue Processing Products

Autokine-CM[®]

Adipose Derived Conditioned Media containing autologous growth factors, matrix proteins and cytokines



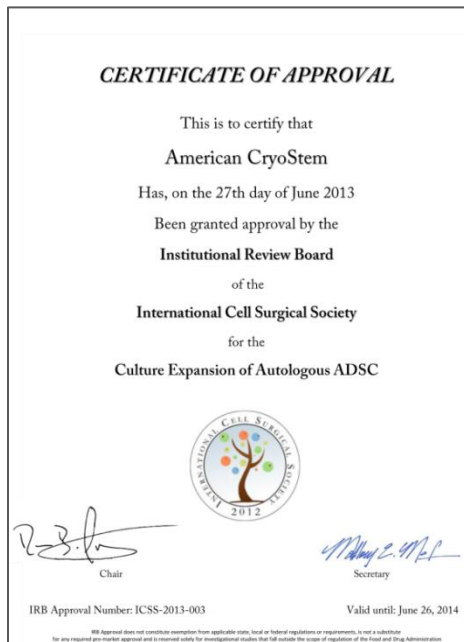
- Manufactured product for Personal Cell Sciences, U-Autologous skincare product suite
- Tissue is obtained using our Collect[®] collection system
- Tissue processed and cells expanded using our ACSelerate[™] “non-animal” cell culture media

personal
CELL SCIENCES

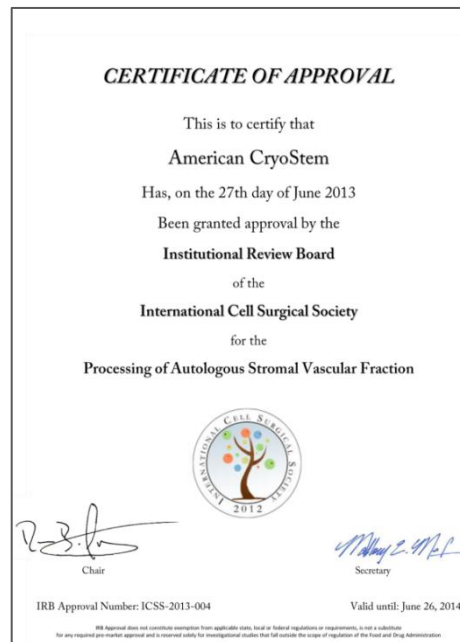


■ IRB Approved Protocols

Our products are developed and processed under the Institutional Review Board (IRB) of the International Cell Surgical Society (ICSS). These IRB studies are maintained to allow for ongoing standardization and cell line processing, and to further advance our transparency in providing outcome data for clinical studies, clinical trials and peer reviewed research publications.



ATCELL™



ATCELL-SVF™



ATGRAFT™

Access to Pipeline Cellular Products

American CryoStem is currently working with leading Universities and private institutions to develop novel cellular products and applications. As a partner licensing our core technology the opportunity to offer products and applications into each local market represents a significant value-added opportunity for long term growth.

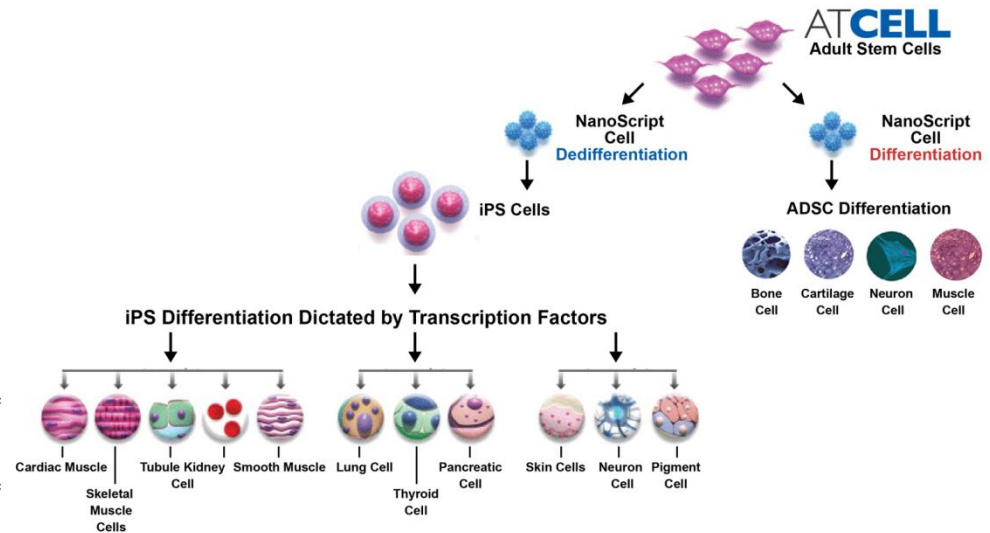
ATCELL™ & NanoScript™ Cell Differentiation Platform



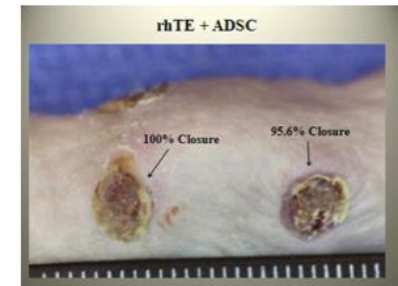
American CryoStem has entered into a series of agreements with leading research scientists at Rutgers University who are focused on utilizing American CryoStem's proprietary ATCELL™ Adipose-Derived Stem Cells (ADSC) and patented ACSelera™ animal serum free, GMP grade, cell culture and differentiation mediums with their multi-functional nanotechnology and biomaterial platforms (NanoScript™) that are capable of directing adipose-derived stem cell differentiation. The combined technologies create a Regenerative Medicine platform which can be used to treat a wide range of degenerative diseases and orthopedic injuries.

ATCELL™ & Tropoelastin™ = "Living Bandage"

Our partnership with Protein Genomics has resulted in the formation of Autogenesis Corporation to combine ATCELL™ with Tropoelastin™ (synthetic human elastin) for the development of a "Living-Bandage" that provides full depth healing of diabetic and decubitus ulcers and traumatic wounds.



6-mm full thickness wound control 6 days



6-mm wound scaffold treated 6 days

■ International Licensing Program

Our platform is designed so that each module can be licensed individually on a country by country basis exclusively or non-exclusively.

Cellect®

Tissue collection and transportation SOPs

Initial proper creation of the Cellect® kit, collection of tissue from physician, and initial sample receipt at laboratory.

ATGRAFT™

Tissue Processing and Storage SOPs

Core tissue processing and storage SOPs for cosmetic fat grafting applications and future cell processing.

ATCELL™

SVF Processing and Storage SOPs

SVF separation and storage

ADSC Isolation and Expansion

ADSCs isolation, culturing and differentiation

ACSelerate™

Licensing and contract manufacturing for global distribution

Our patented line of cell processing, growth, differentiation and storage media

Autokine-CM®

Autologous Conditioned Medium SOPs

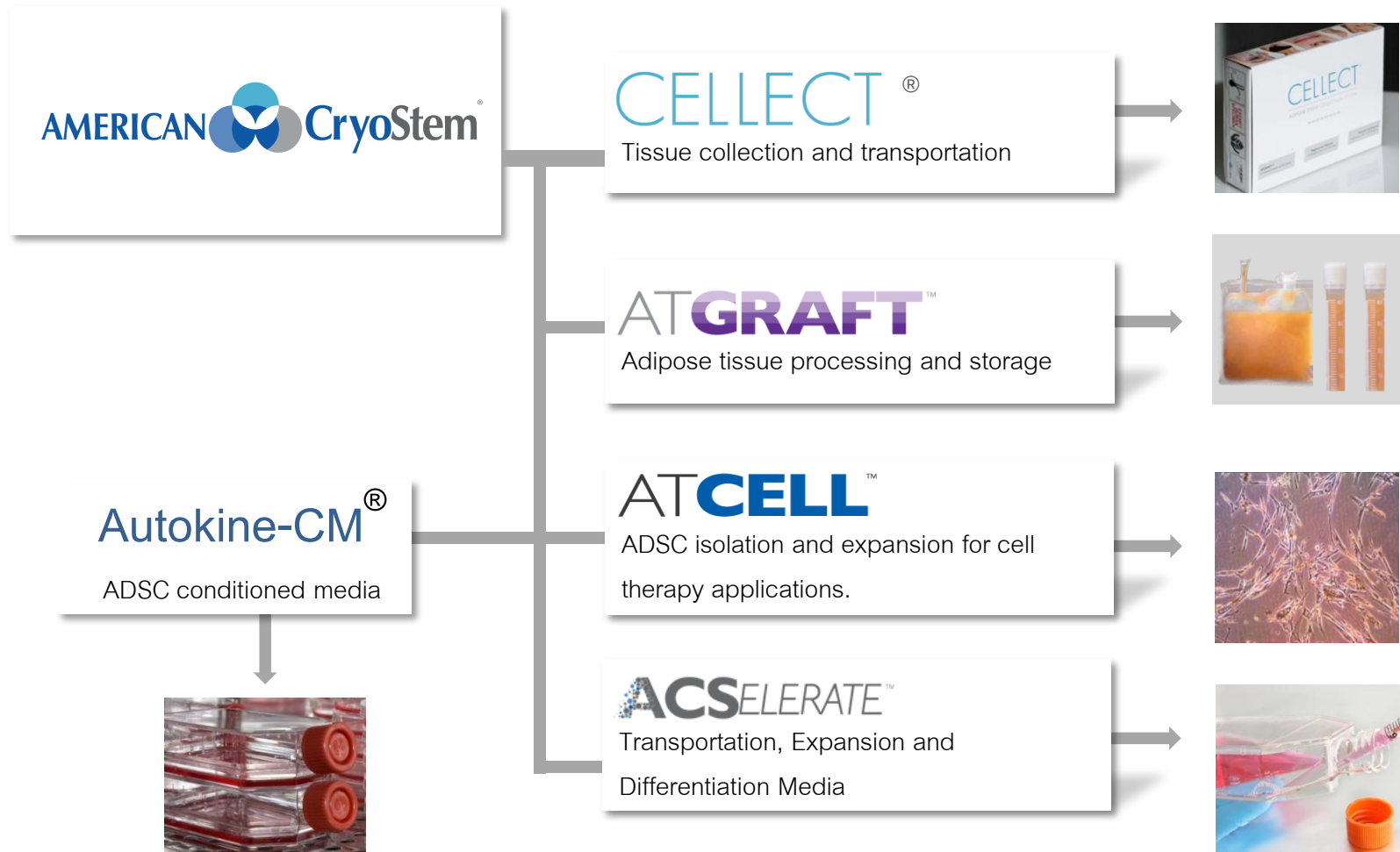
Expansion and culturing methods to create autologous conditioned medium for topical applications

ACS Laboratories

Laboratory Build-Out SOPs

Complete laboratory facility setup and configuration to process our licensed technology

■ Turn-Key Clinical Processing and Products





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