# ATGRAFT™

## Fat Tissue Storage for Natural Beauty

2014

American CryoStem Corporation





# About American CryoStem

Located in the United States, American CryoStem is a biotechnology pioneer in the fields of Regenerative and Personalized Medicine, that 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).


FDA REGISTERED FACILITY

BBB ACCREDITED BUSINESS

ISBT 128 More than Identification SUPPORTED

ICCBBA

# A Validated Fat Storage Solution


## ATGRAFT™ Platform Highlights

- Clinical cGMP Tissue Processing & Bio-Banking Protocols
- 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

# Fat Transfer Industry

## A Growing Market

- Fat Transfer has been used since the 19th century
- Introduction of liposuction fueled a renewed interest in fat transfer
- Medical community is continually optimizing harvesting, processing and grafting techniques

# Market Demand for Fat – United States

***"The idea of taking your own fat and recycling it to augment your body has captured the attention of both consumers and the media"***

American Society of Plastic Surgeons

**2012 ASPS**
**Liposuction** Statistics
**- 202,000** procedures

**2012 ASAPS**
**Fat Transfer** Statistics

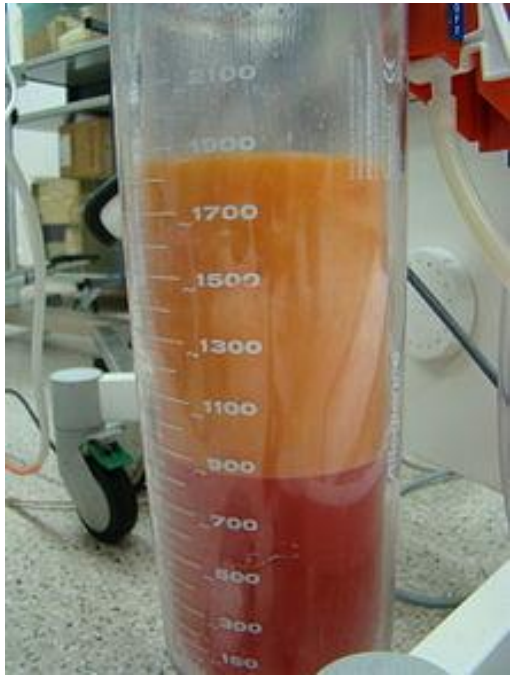
**- 72,000** procedures

**2012 ASPS**
**Fat as a Soft Tissue Filler**
Statistics
**- 63,128** procedures

# Every Liposuction is an Opportunity

**Throwing fat away is throwing business away.**

Every patient should know the option of storing fat and the multitude of cosmetic procedures that are currently available or may be available in the future.



# Benefits of Fat Transfer vs Fillers

- Autologous fat (from your own body), as opposed to dermal fillers, removes the chance of allergic reactions to foreign substances.
- Fat transfer results are natural, long lasting and safe.
- Fat transfer is a noninvasive method for achieving facial rejuvenation.

# Current Fat Transfer Method

**1. Liposuction**

Occurs with each fat transfer

**2. Fat Washing**

Occurs with each fat transfer

**3. Fat Transfer**

**Single use**, excess harvested tissue is **WASTED**!

**4. NEW method with Fat Storage**

**One Liposuction = Multiple Procedures**

# A Standardized Fat Product = Reliable Results

## 1 Repeatability

- Specially designed validated processing supply kits for the collection, processing and cryopreservation of individual samples.
- Each supply kit contains GMP/GTP grade sterile components for the continuous quality control of the laboratory and finished products.

## 2 Consistency

- Individually tracked processes and documentation to monitor processing results
- Limit outside variables such as age, health and harvesting techniques by making core process the same each time.

## 3 Security and Quality

- Unbroken chain of custody tracking methodology
- Globally recognized client ID numbers using ISBT 128 Standards and Technical Specification by the ICCBBA.
- Multiple in-process quality control protocols check each sample for cell viability and sterility.

# Patient Safety and Quality Management

Multiple sterility tests are performed on each tissue sample to identify tissue viability and any possible contamination, aerobic (bacteria) & anaerobic (fungi &yeast)

1 **Physician Sample QC**

- Sample is tested upon receipt at laboratory

2 **Final Processing QC**

- After processing the tissue and prior to cryopreservation a QC is taken again.

3 **Cryopreserved QC**

- 7 days post cryopreservation a QC sample is retrieved and tested ensuring tissue viability and sterility.

# One Liposuction = Multiple Procedures

Inventory of Patient's Fat

- Start thinking of fat as an off the shelf injectable.
- An inventory of patient's autologous fat for multiple procedures.
- Plan a fat transfer schedule without additional liposuctions.

**Multiple Procedures from One Liposuction**

# Building a Loyal Patient Base

**Set a fat transfer schedule with stored tissue to ensure long term patient retention.**

- Multiple Procedures, Multiple Storage Configuration
  - Breast (25mL-100+mL)
  - Hands (4mL-25mL)
  - Face (4mL)
  - Buttocks (100+ mL)
- Lower overall internal costs by not performing additional liposuctions
- Patient retention

# How Fat Storage Works

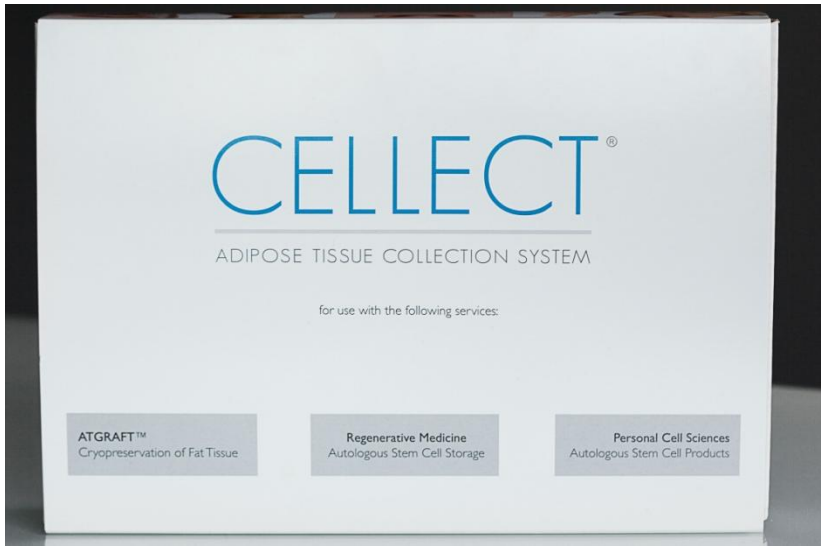

- Harvest fat
- Excess fat placed in supplied collection bag

- Fat processed same day in FDA registered facility
- Tested for cell viability and sterility

- Fat stored in physician's selected configuration for future procedures

- Requested fat sample removed from storage
- Fat sample thawed
- Sample delivered next day for injection.

# Fat Collection Kit





## ATGRAFT Collection Kit Components

- Disposable 60mL syringes
- Syringe caps
- Disposable cannula
- 250mL collection bag with transport media
- 95kPA transport bag
- CooLiner™ specimen bag
- Log Tag™ Temperature tracker

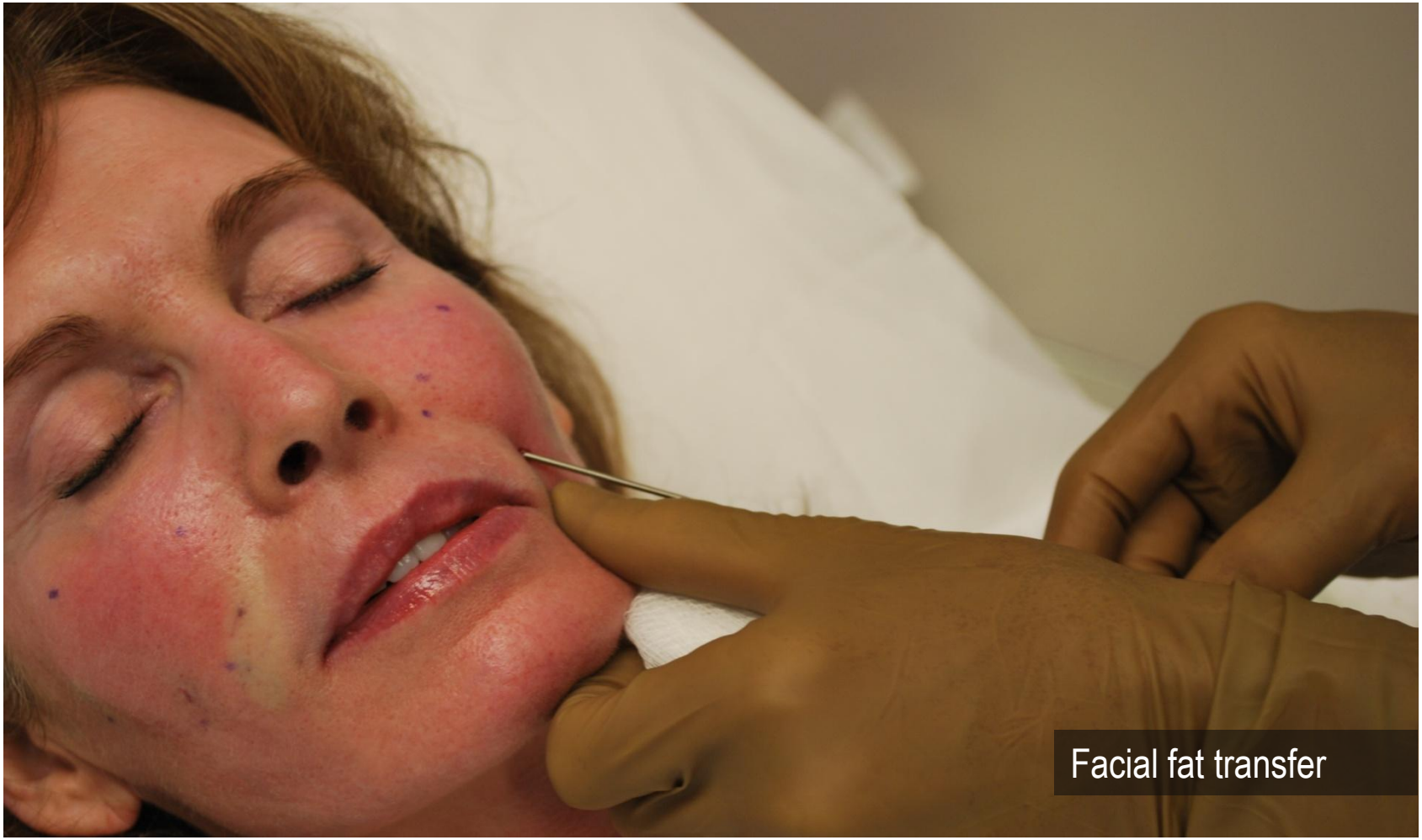
# Fat Collection


Photos courtesy of Fredric A. Stern, MD, FACS, The Stern Center for Aesthetic Surgery, Bellevue, WA, USA

# Fat Removal


Photos courtesy of Fredric A. Stern, MD, FACS, The Stern Center for Aesthetic Surgery, Bellevue, WA, USA

# Fat Transfer




Photos courtesy of Fredric A. Stern, MD, FACS, The Stern Center for Aesthetic Surgery, Bellevue, WA, USA

# Excess Fat for Storage


Photos courtesy of Fredric A. Stern, MD, FACS, The Stern Center for Aesthetic Surgery, Bellevue, WA, USA

# Excess Fat Transfer into Collection Bag


Photos courtesy of Fredric A. Stern, MD, FACS, The Stern Center for Aesthetic Surgery, Bellevue, WA, USA

# Preparing Fat Collection Bag

Filled collection bag

Collection bag placed in biohazard bag

Photos courtesy of Fredric A. Stern, MD, FACS, The Stern Center for Aesthetic Surgery, Bellevue, WA, USA

# Preparing Fat for Transportation

Fat placed in outer wrap


Fat sample ready for shipping

Photos courtesy of Fredric A. Stern, MD, FACS, The Stern Center for Aesthetic Surgery, Bellevue, WA, USA

# Fat Processing at cGMP Laboratory

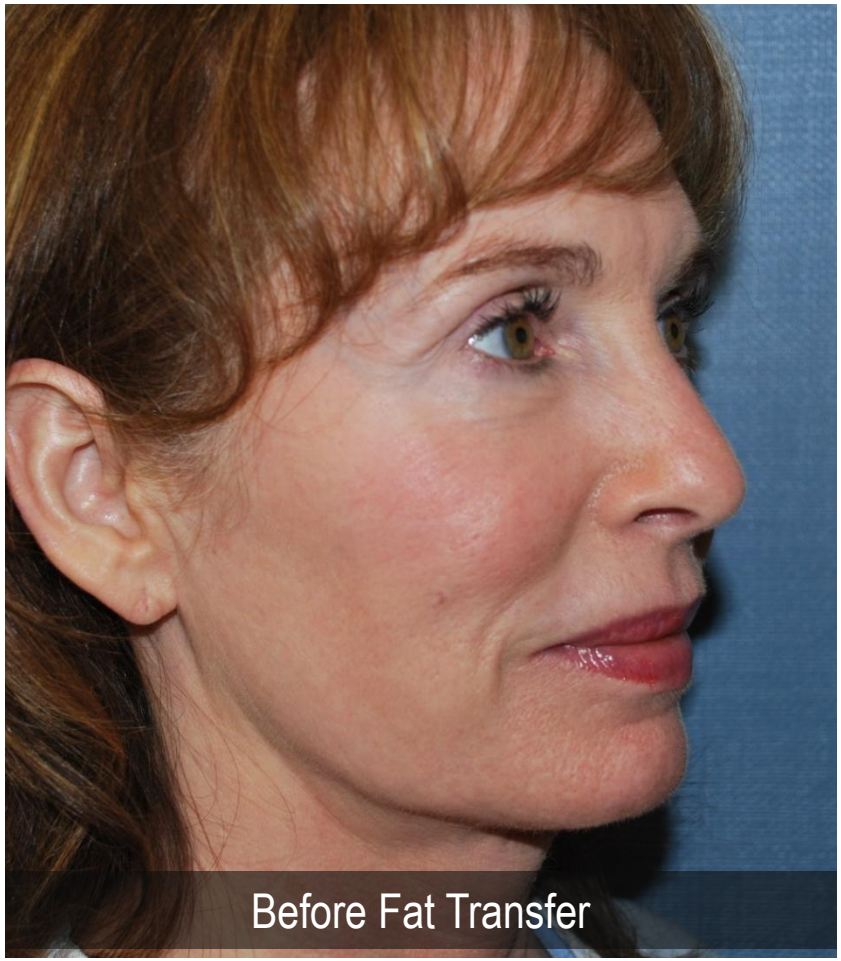

cGMP Fat Processing

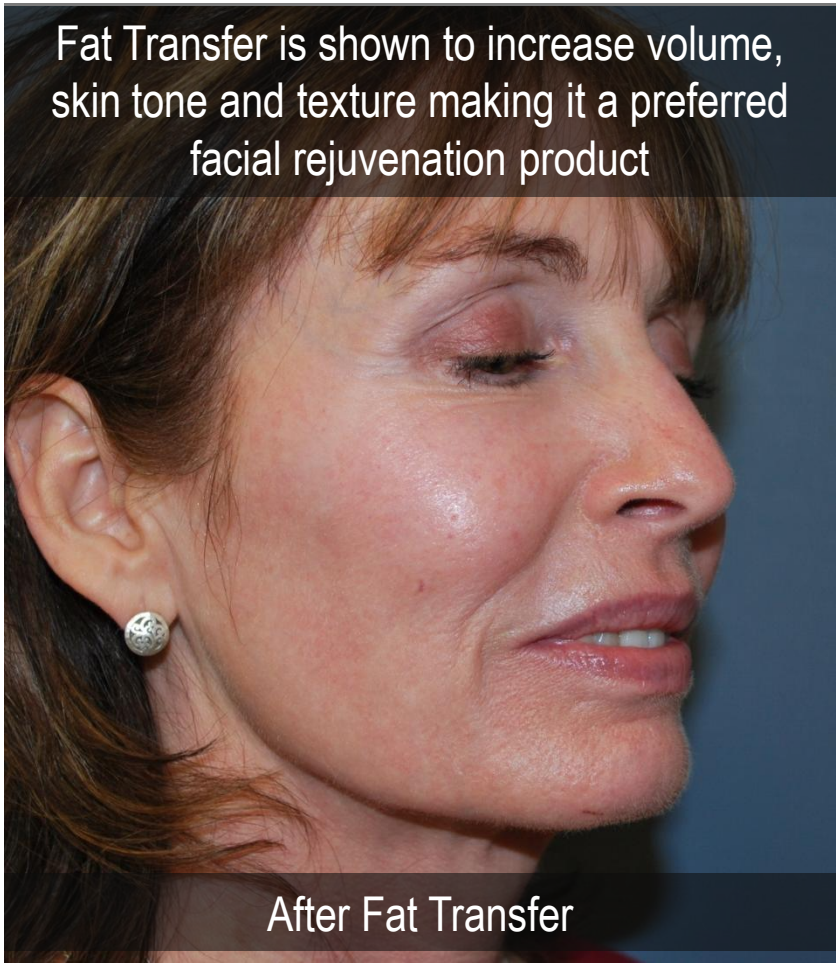

Removing Excess Fluid and Debris From Sample


Washing Fat


Cryogenic Storage of Fat

# Before & After Fat Transfer

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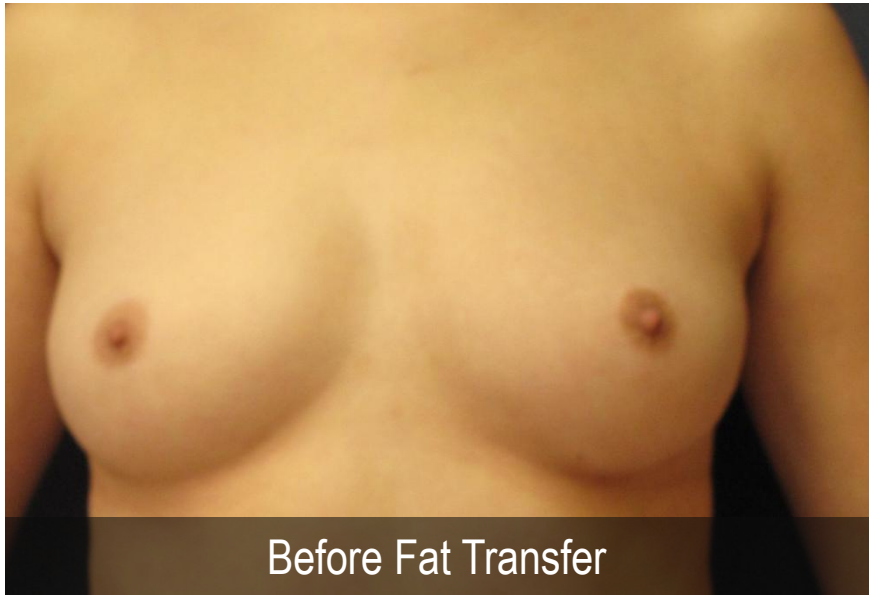
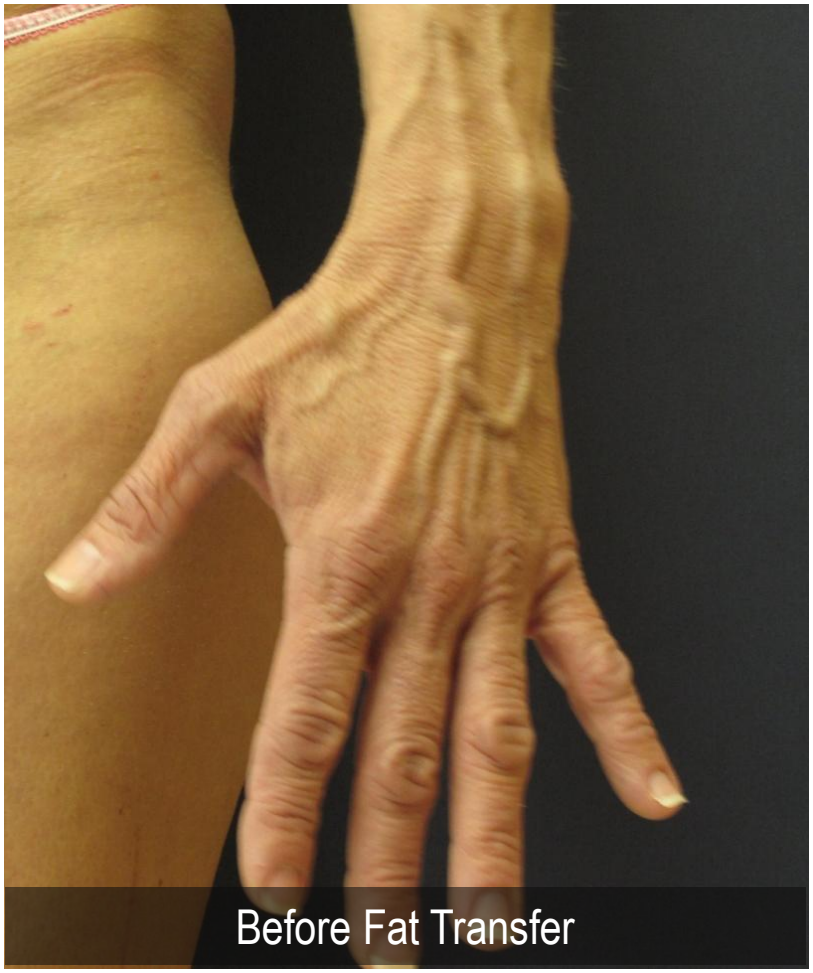
# Before & After Fat Transfer





Photos courtesy of Richard Goldfarb, MD, FACS, Langhorne, PA, USA

# Before & After Fat Transfer





Photos courtesy of Richard Goldfarb, MD, FACS, Langhorne, PA, USA

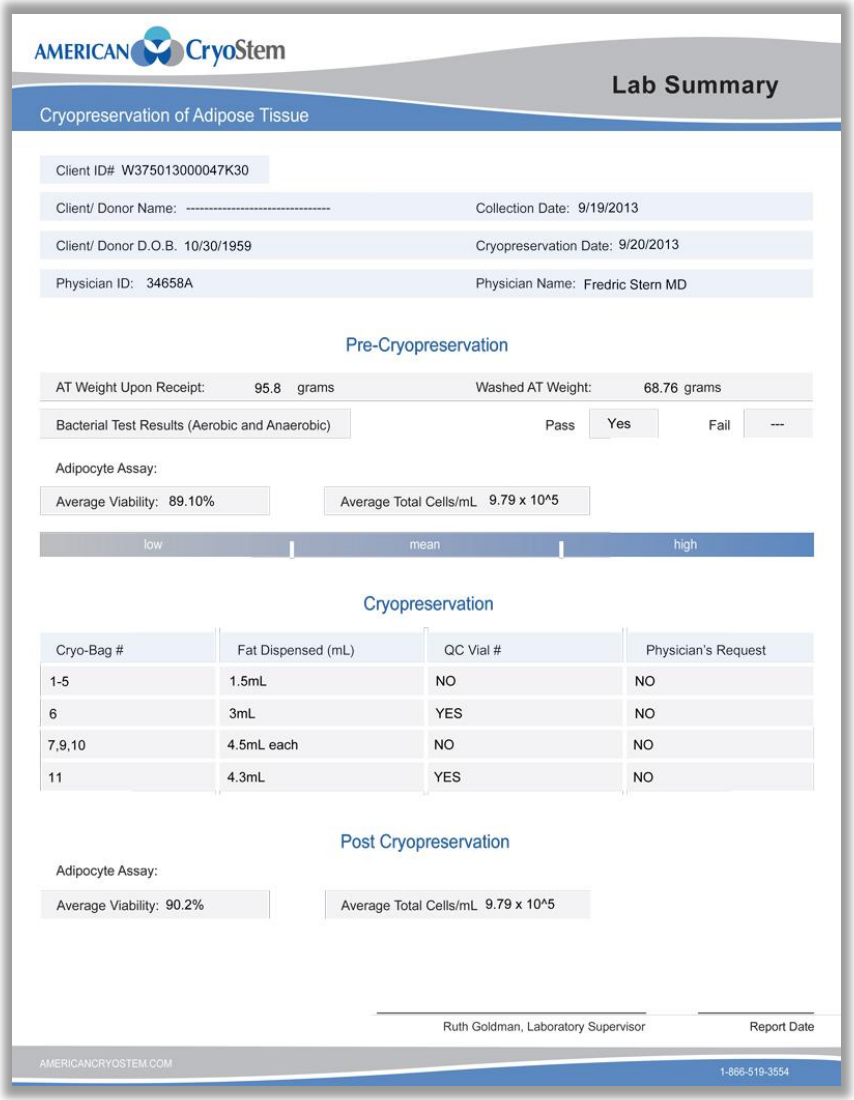
# Fat Storage Sample Report

Information on each received sample is available within 24 hours of receipt

**Fat "Score Card" Information:**

- Sample weight upon receipt
- Sample weight post-wash
- Pre-cryopreservation adipocyte assay results
- Adipocyte viability percentage

Post cryopreservation adipocyte viability and full FDA bacterial test results available upon completion



AMERICAN CryoStem

Lab Summary

Cryopreservation of Adipose Tissue

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 10^5

low mean high

Cryopreservation

| 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 |

Post Cryopreservation

Adipocyte Assay:

Average Viability: 90.2%

Average Total Cells/mL 9.79 x 10^5

Ruth Goldman, Laboratory Supervisor

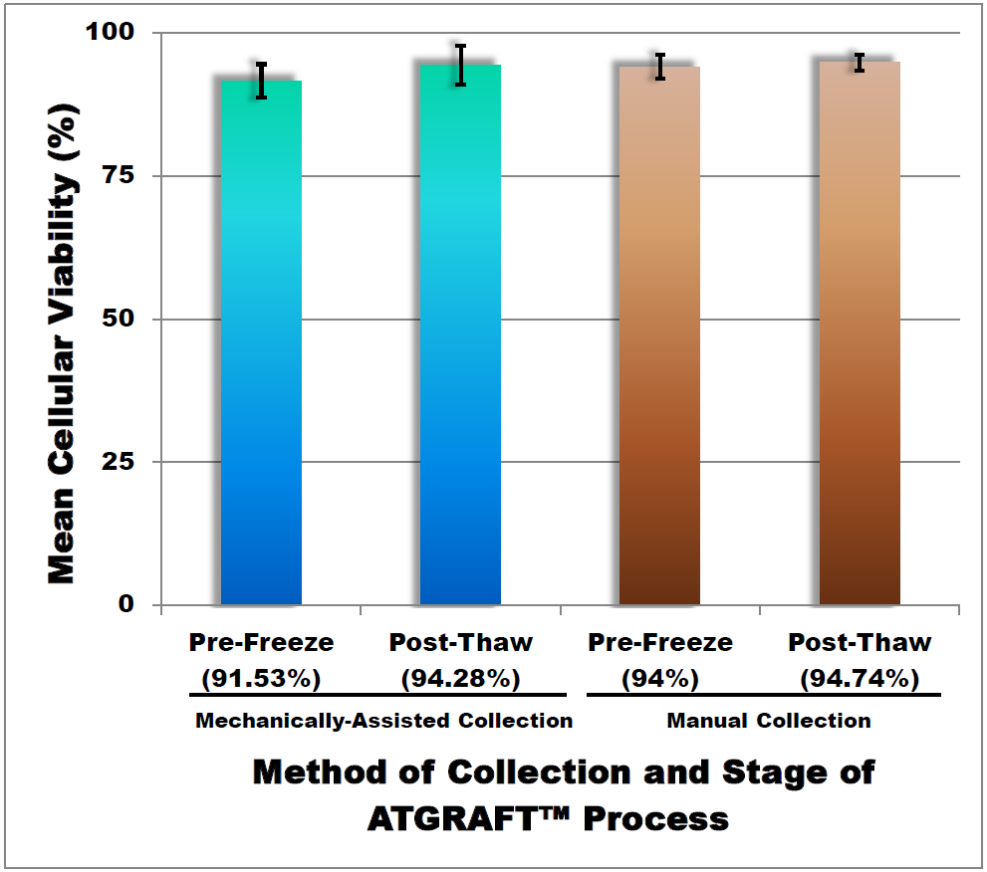
Report Date

AMERICANCRYOSTEM.COM

1-866-519-3554

# Fat Storage Sample Report

"*Tissue viability is not affected during the ATGRAFT ™ cryopreservation and thawing process.*"




Data from American CryoStem's white paper titled:
**Maintaining Viable Lipoaspirates in Cryostorage with ATGRAFT™**

# Retrieving Stored Fat Samples

**Request individual samples for the scheduled procedure.**

**A small 100mL storage represents up to 11 additional procedures.**

Example of Retrieved Fat Samples

**25mL Bag** **25mL Bag** **4mL Vials**

# Generate a Sustainable Fat Transfer Business

**Focus on setting up a fat transfer schedule with patients to reach their desired outcome.**

**Long Term Revenue from a Single Patient**

1. Liposuction with fat transfer to breast (*same day*)
2. Patient returns for adjustment to breast area ( *using stored fat*)
3. Patient returns for fat transfer to the hands (*using stored fat*)
4. Patient returns for facial fat transfer (*using stored fat*)

# Financial Impact of Fat Storage

**Example 1** (Stored Excess Tissue)

<u>100mL Medium Fat Transfer Storage Configuration</u>

- (5) 4mL vials = 5 facial fat transfers @ $600 ea. = **$3,000**
- (3) 25mL± bags = 3 hand fat transfers @ $1,500 ea. = **$4,500**

**Total $7,500 in additional revenue**

**Up to 8 Additional Patient Appointments**

# Financial Impact of Fat Storage

**Example 2** (Stored Excess Tissue)

<u>300mL Medium Fat Transfer Storage Configuration</u>

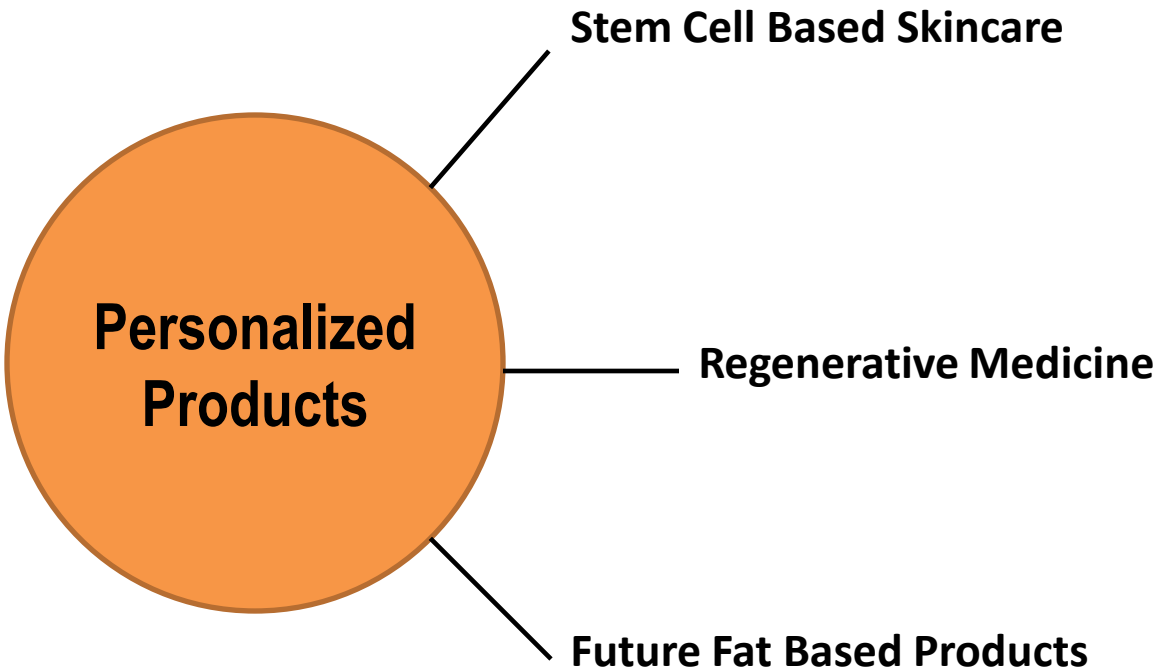
- (5) 4mL vials = 5 facial fat transfers @ $600 ea. = **$3,000**
- (3) 25mL± bags = 3 hand fat transfers @ $1,500 ea. = **$4,500**
- (2) 100mL± bags = 2 breast fat transfers @ $2,500 ea. = **$5,000**

**Total $12,500 in additional revenue**

**Up to 10 Additional Patient Appointments**

# Additional Practice Building Services

## "Stored Fat Samples Provide Additional Future Revenue"



# Conclusion

**Good medicine = Preparing patient's for their future health needs**

**One liposuction with fat storage = multiple fat transfer procedures**

**Stress to patient storage of excess tissue from a liposuction**

**Layered fat transfers provide optimal results**

- **Patient satisfaction**
- **Increase in revenue**
- **Patient retention**
- **Preparing your patient for the future = GOOD MEDICINE**