



GeneCell™

INTERNATIONAL

Processing • Storage • Research

STEM CELL LABORATORY



GeneCell International's laboratory is headquartered in Miami, Florida with laboratory subsidiaries or satellite offices in Central Florida, Venezuela, Colombia, Costa Rica, Dominican Republic, Honduras, Panama, Peru and Puerto Rico. The Company continuously seeks to expand into other countries.

## GeneCell International, LLC.

GeneCell International is a privately owned laboratory specialized in collecting, processing and cryogenically storing stem cells derived from umbilical cord blood, cord tissue, dental pulp, adipose tissue, and other cells and tissues that can later be used to treat a variety of diseases. The laboratory is also involved in scientific research and development with a range of stem cells from various adult tissues. GeneCell International and its subsidiaries have deep roots internationally and more than a decade of experience in helping patients make informed decisions that can lead to potentially life-saving possibilities. The groups of laboratories include GeneCell International, Genetics and Cord Blood Services, Celulas Madre, and the Laboratorio Venezolano de Celulas Madre, C.A. The laboratories objectives are to continue furthering the education and awareness by expanding into new markets.

We operate state-of-the-art laboratories and storage facilities for thousands of clients who have placed their trust in us for handling their adult stem cells from various sources which have the potential for treating a variety of diseases and disorders. Our laboratory's purpose is to provide our clients with the best customer service experience, the highest quality stem cell products and services as well as unparalleled scientific excellence and innovative leadership in the areas of stem cell collection, processing, research and cryopreservation.

GeneCell International is committed to the educational growth of its stem cell portfolio which will guarantee greater levels of awareness and expansions nationally and into other countries. Beside our commitment to educating the public on the benefits of adult stem cells, our laboratory is always on the forefront in providing clients with information on current and future potentials for the use of stem cells in medical treatments.

## Stem Cells

Stem cells are the body's "master cells". They have the ability to divide (self-replicate) and they also have the potential to develop into many different cell types that make up the human body, such as organ tissue, blood, and the immune system. Stem cells also serve as a form of internal repair system, dividing and differentiating to replace damaged or dead tissue.

## Types of Stem Cells

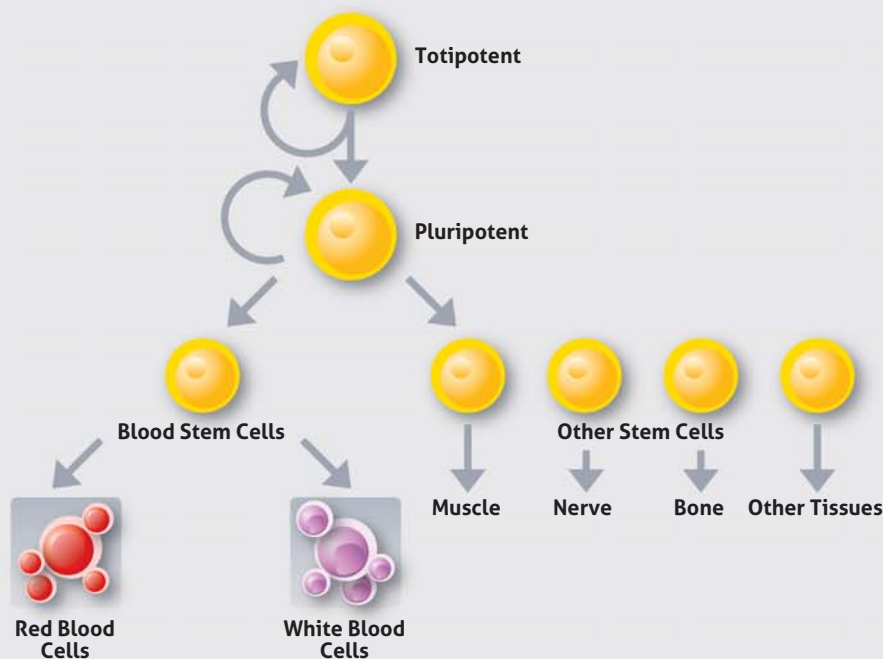
Hematopoietic Stem Cells are multipotent stem cells that give rise to all the blood cell types from the myeloid (monocytes and macrophages, neutrophils, basophils, eosinophil, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells). The hematopoietic tissue contains cells with long-term and short-term regeneration capacities and committed multipotent, oligopotent, and unipotent progenitors.

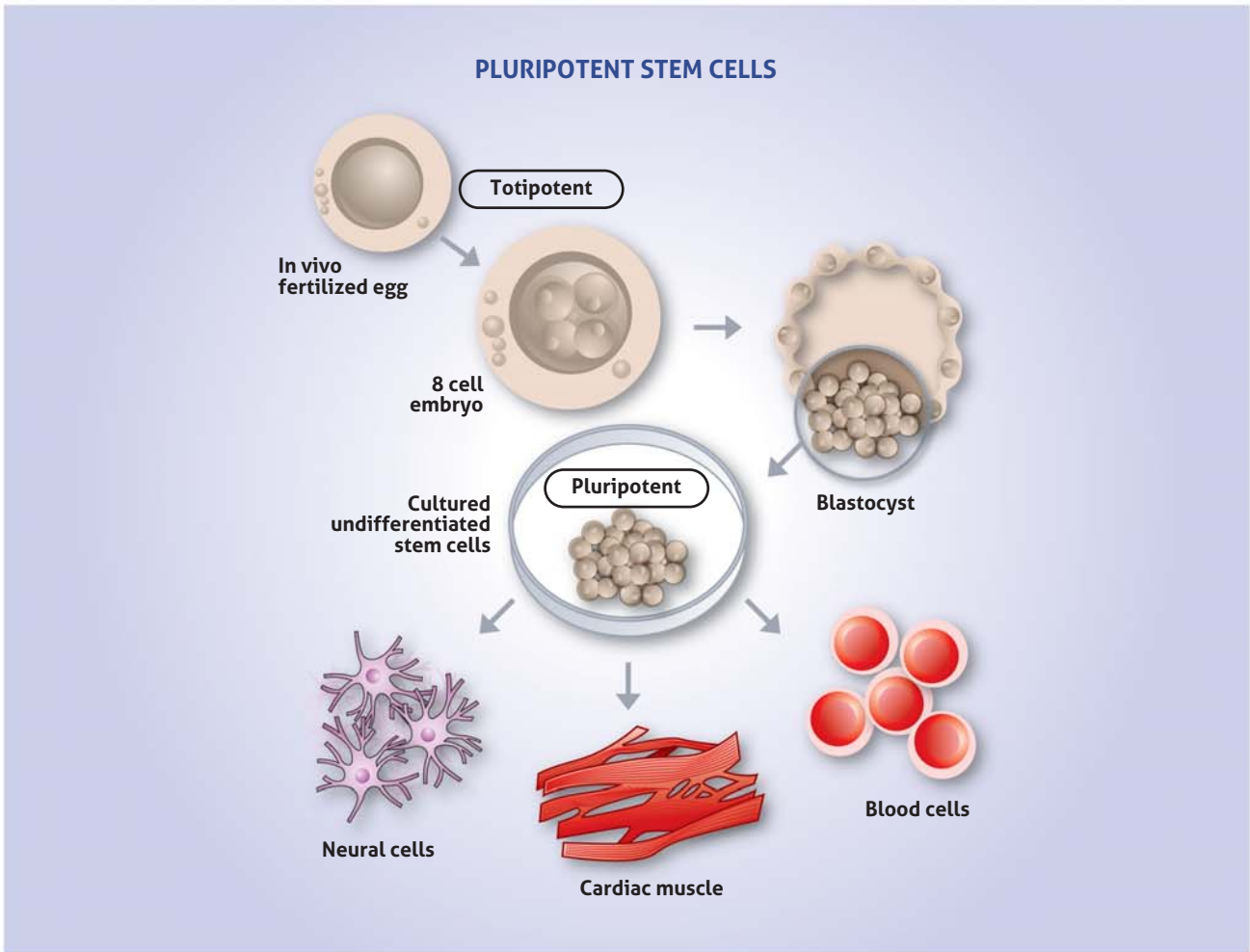
Mesenchymal Stem Cells are pluripotent stem cells, which means that they have the potential to differentiate into a variety of other cell types, including myocytes (to repair muscle), cardio myocytes (to repair damaged cardiac tissue), neurons (to generate nerve and brain tissue), osteocytes (to generate bone) and chondrocytes (to generate cartilage). Mesenchymal stem cells have shown great promise in the potential treatment of diseases like Parkinson's, Alzheimer's, type I diabetes, heart attack, stroke, multiple sclerosis, ALS, spinal injury and many more.

## Potency of Stem Cells

Stem cells are classified by their ability to differentiate into different cell types. These classifications are **Totipotent** - the ability of the cell to differentiate into all cell types. Examples include the first few cells after the division of the zygote, **Pluripotent** - the ability of the cell to differentiate into almost all cell types. Examples include embryonic stem cells, **Multipotent** - the ability of the cell to differentiate into a closely related family of cells. Examples include HSC and MSC, **Oligopotent** - the ability of the cell to differentiate into a few cells. Examples include myeloid stem cells, and **Unipotent** - the ability of the cell to differentiate into only one cell type.

### HIERARCHY OF STEM CELLS





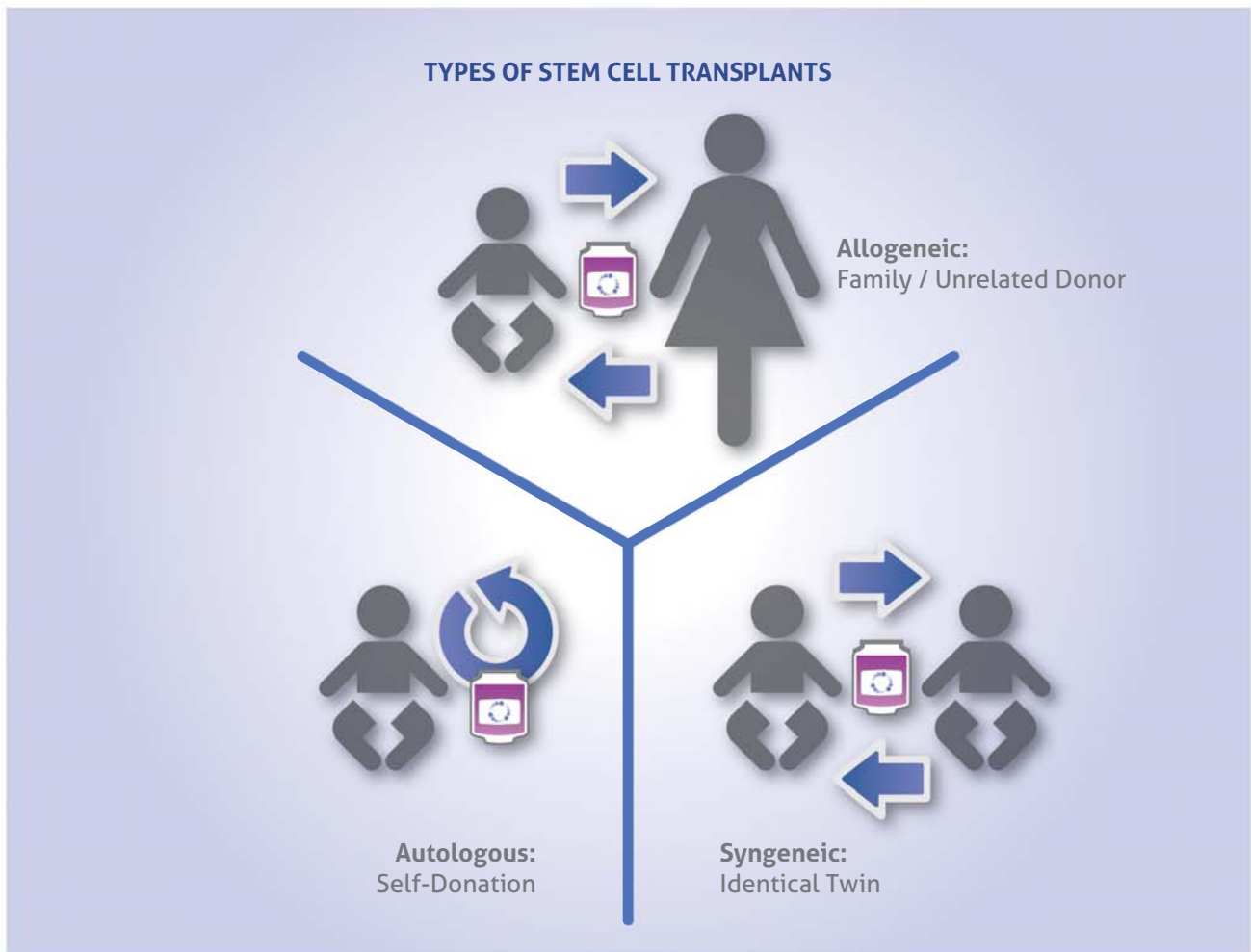
## Regenerative Medicine

Regenerative Medicine is an emerging field involving stem cell therapy. Regenerative Medicine will employ methods to restore the function of damaged tissue and organs. The four main aspects in regenerative medicine are medical devices and artificial organs, tissue engineering and biomaterials, cellular therapies, and clinical translation.

## Cellular Therapies

The concept behind cellular therapies is to use one's own stem cells to re-populate specific cells that may be defective or dead. There are several disorders that require the transplant of new cells to replace dead or damaged cells. These include blood system disorders, Type I Diabetes, Parkinson's disease, Alzheimer's disease, heart attack, and ALS.

The requirements to treat these disorders are genetically matched stem cells. The amazing functionality of most stem cells is their ability to "hone" in on the site of damage. Most stem cell can be administered systemically (intravenous) and they will migrate to the site of injury. Once there, the stem cells will receive chemical "communications" from the cells of the damaged tissue which will cause the stem cells to differentiate into the cells of the damaged tissue to repair said tissue.



## Types of Stem Cell Transplants

**Allogeneic** (Allotransplantation) (allo- from the Greek meaning "other") is the transplantation of cells, tissues, or organs, to a recipient from a (genetically non-identical) donor of the same species.[1] The transplant is called an allograft or allogeneic transplant or homograft. Most human tissue and organ transplants are allografts.

**Autologous** (Autotransplantation) is the transplantation of organs, tissues or even proteins from one part of the body to another in the same individual. Tissue transplanted by such "autologous" procedure is referred to as an autograft or autotransplant. It is contrasted with xenotransplantation (from other species) and allotransplantation (from other individual of same species). A common example is when a piece of bone (usually from the hip) is removed and ground into a paste when reconstructing another portion of bone.

Our laboratory's philosophy is to provide our clients with the highest quality transplantable stem cell units via our collection, processing, research, cryogenic storage and bio-repository expertise. Should a debilitating disease manifest itself, our clients and their families will have a potential therapeutic option with the stem cells they have stored at our facility.



## Our Laboratory

Our laboratory is committed to excellence in collection, processing and cryogenic storage of adult stem cells. Utilizing advanced equipment and highly qualified personnel, we ensure the highest quality standards are upheld thus providing the best possible service for our clients. The laboratory currently holds all required permits, licenses, accreditations and certificates for collection, processing and cryogenically storing adult stem cells.

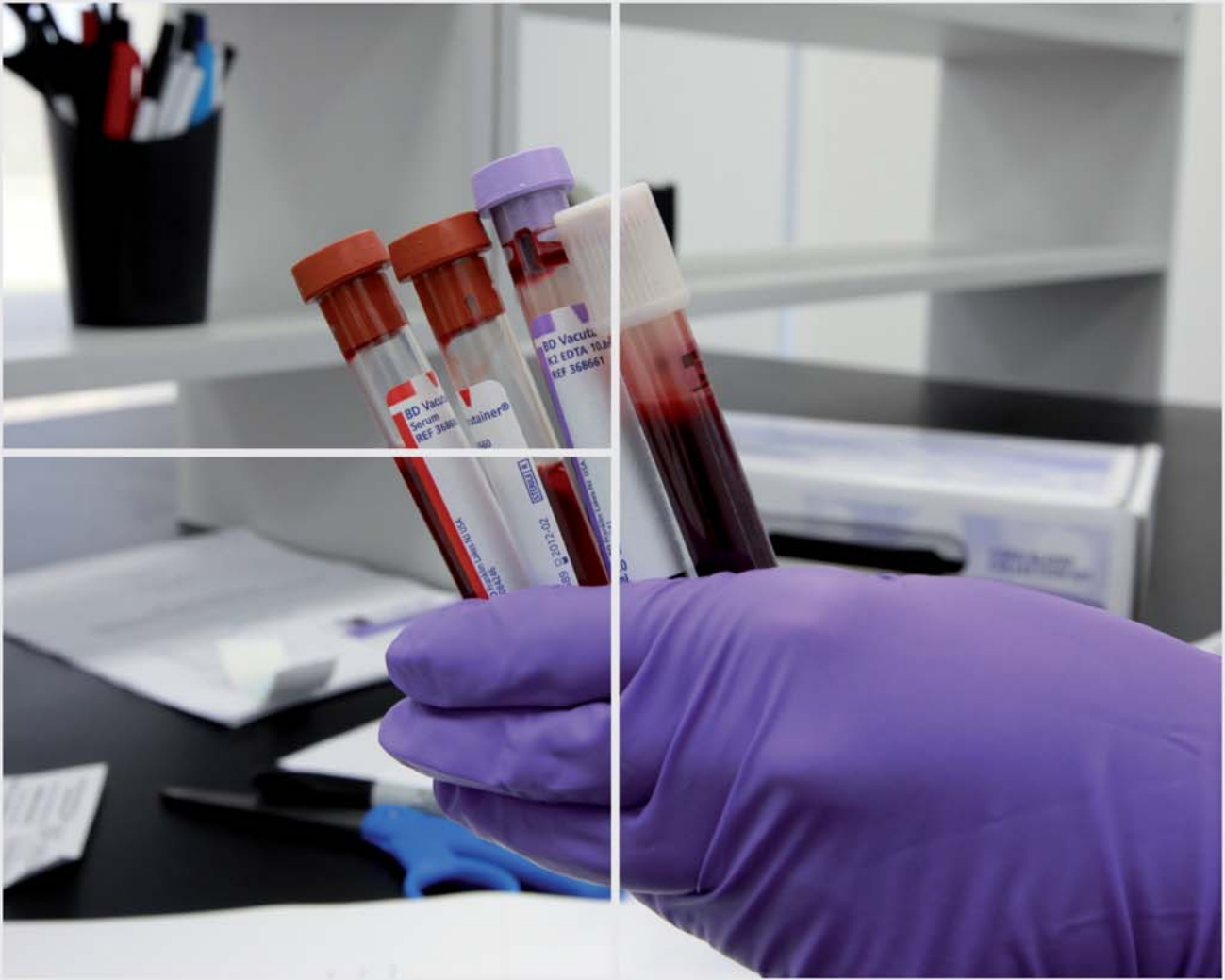
**Location:** Our laboratory is based in Miami, Florida, the business and cultural hub of the Americas. By making South Florida our home we have access to a very diverse clientele, providing us with the unique opportunity of working in a world class city known for being a bridge to international communities.

**Highly Qualified Staff:** Our highly qualified laboratory director has overseen tens of thousands of processed cord blood units, and has also supervised the release of a large number of units for transplant procedures. Our Laboratory Director has overseen numerous cord blood, dental and adipose tissue samples processed and cryopreserved. The laboratory stem cell technicians are highly experienced in processing, cell separation and storage of cord blood, dental pulp, and adipose tissue samples.

**Security:** Our clients can rest assured that their stem cells will be stored under proper temperatures at all times. Our cryogenic storage devices are connected to an alarm system, they video monitored and backed up by our reliable generators and nitrogen tanks.



The laboratory stem cell technicians are highly experienced in processing, cell separation and storage of cord blood, dental pulp, and adipose tissue samples.



## Our Processing

Samples can be shipped to our facility immediately after the collection has taken place. Our laboratory uses all state-of-the-art processing methods for all tissue types. These methods are very efficient in recovering a high number of total nucleated cells. As part of our processing procedures we test samples for cell viability and Stem Cell Analysis using flow cytometry. Samples are also tested to determine the sterility and total nucleated cell count (TNC). All our processing and testing takes place under strict quality control conditions.

## Our Cryogenic Storage

An important aspect to maintain viability of Stem Cells and other tissues throughout the processing and cryopreservation is controlling the rate of freezing and the subsequent sustained cryogenic temperature of the cells or tissue once they are in cryogenically stored. Our laboratory uses a staged freezing process that ensures the cell or tissue's future viability. Once the cells are brought to the optimum temperature, they are placed in cryogenic storage tanks.

## Our Services

# The Continuation of Life<sup>SM</sup>

### ► Umbilical Cord Blood Stem Cell Preservation

Umbilical cord blood preservation is a process by which blood is collected from the umbilical cord of a newborn baby and is stored cryogenically in a specially-designated bank. According to the National Marrow Donor Program, cord blood contains cells that can be transfused to a patient to treat various diseases, including lymphoma and leukemia. The list of illnesses that can be treated with cord blood continues to grow. In addition, the cord blood can be used to treat the child from whom the blood was collected as well as some first-degree relatives who are a close genetic match, such as immediate family members.

Since the first successful umbilical cord blood stem cell transplant was performed in 1988 to treat a patient with Fanconi Anemia, there have been incredible medical advances in stem cell biology. Currently, there are over 80 diseases treated with umbilical cord blood stem cells. These diseases include Parkinson's disease, cerebral palsy, type I diabetes, heart disease, stroke and ALS. The awareness and importance of stem cell banking is becoming more and more evident as time goes on.

According to a recent study published in the Journal of Reproductive Medicine 37% of the expecting parents had no knowledge, whatsoever, about cord blood banking. Of patients indicating familiarity with umbilical cord blood banking, 2.6% felt "extremely knowledgeable," while 74% felt "minimally informed." Fifty percent of the patients were misinformed that umbilical cord blood banking was only for "the child that I will deliver." Seventy-one percent of patients were not planning umbilical cord blood banking, with "expense" and "insufficient knowledge" as the primary reasons cited. Only 14% of patients were educated about umbilical cord blood banking by their nurse or obstetrician, although 90% of patients expected their obstetrician to answer their questions on umbilical cord banking.

Cord blood banking is regulated by the U.S. Food & Drug Administration and each year more and more parents choose to save their children's cord blood should the medical need arise. Treatable diseases include cancers, bone marrow failure syndromes, blood disorders/hemoglobinopathies, metabolic disorders, immunodeficiencies and others. Cerebral palsy, neonatal brain injury and Type I Diabetes are currently under regenerative clinical trials.

### ► Cord Tissue Stem Cell Preservation

In the umbilical cord tissue is a gelatinous substance, which functions as the primary connective tissue of the umbilical cord and is referred to as Wharton's Jelly. These cells have an excellent potential for tissue engineering, gene therapy applications and regenerative medicine. Mesenchymal stem cells have shown great promise in the potential treatment of diseases like heart attack, Parkinson's disease, Alzheimer's disease, Type I Diabetes, assist in bone and dental regeneration as well as expedite wound healing. In the past, the umbilical cord has been viewed as medical waste and discarded, resulting in the loss of this potential life-saving resource. Now you can save these stem cells through GeneCell International's Cord Tissue Banking Program, so that your child can potentially benefit from new developments in cellular therapy in his or her lifetime. By storing the stem cells extracted from your umbilical cord tissue along with your baby's cord blood, you'll have access to a wider variety of stem cells as new scientific discoveries are made.





### ► Dental Pulp Stem Cell Preservation

The discovery that human dental pulp tissue contains a population of multi-potent mesenchymal dental pulp stem cells with the ability to reproduce quickly for self-renewal and the ability to differentiate into functional odontoblast has revolutionized dental research and opened new avenues in particular for reparative and reconstructive dentistry and tissue engineering in general. One of the major advantages one gets from harvesting stem cells from his own body is that there will be no refusal of these cells when they are harvested and subsequently re-implanted. In the future, medical researchers anticipate being able to use technologies derived from stem cell research to treat a wider variety of diseases including Parkinson's, Alzheimer's, spinal cord injuries, diabetes, heart diseases, liver disease, Lou Gehrig disease, multiple sclerosis, muscle damage, bone regeneration, tissue or skin regeneration for burned victims and many other diseases.



### ► Adipose Tissue Stem Cell Preservation

Adipose (fat) tissue is a dynamic multi-functional tissue that is found throughout the human body. The stem cells originated from adipose tissue are mesenchymal stem cells which have the ability to differentiate into bone, muscle, fat, nerve, and cartilage. Preliminary research performed at GeneCell International has shown the presence of early stem cells markers as well. Adipose-derived stem cells are easy to obtain through a simple and localized liposuction process using local anesthesia and with minimal patient discomfort. These autologous adult stem cells show the same morphology, immune phenotype and differentiation capacity as stem cells obtained from bone marrow and umbilical cord blood. They are free of ethical debate, use tissue which is abundant and easy to access and have shown a great promise in the potential treatment of breast soft tissue reconstruction after a tumor surgery, cartilage repair in joint defects, plastic reconstruction of ear and nose defects, skeletal regeneration of inherited and tumor or trauma-induced bone defects, dystrophic muscle disorders, heart muscle regeneration, heart failure, myocardial infarction, neovascularization, ischemic diseases, brain injury, stroke, peripheral nerve injury, type I diabetes, chronic liver failure, hepatic regeneration, GVHD, bone marrow support and other diseases.



### ► Bio-repository Services

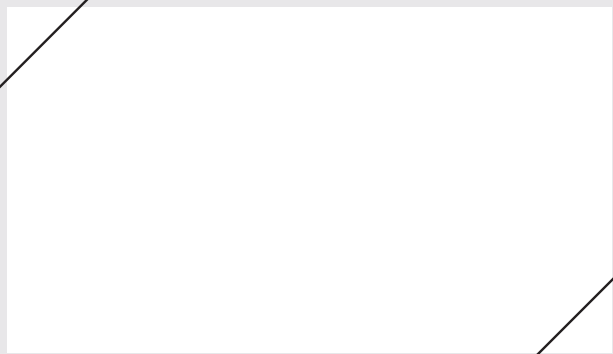
As a premiere, global provider of comprehensive sample management GeneCell International Bio-repository provides you with affordable outsourced management of your clinical and scientific assets. We offer you highly qualified and validated storage equipment, resource experts and best-in-class sample management. Our aim is to provide our clients with the highest grade clinical and or research samples to maximize therapy outcomes and reproducibility in your research endeavors. The GeneCell International Bio-repository was designed to facilitate safe handling, receipt, processing, storage, inventory control, packaging and distribution of biological specimens and reagents. Our Bio-repository is regulatory compliant and the services include the receiving and processing biological specimens, long-term cryogenic storage of clinical and research samples, bio-repository inventory management, 24 hour temperature and alarm management and cold transport of samples from our facility to another. We use specialized cryogenic methods for the product you wish to store at our facilities. We use a controlled-rate freezing process to prepare the cells for long-term storage. This technique is very important for maintaining the viability of all stem cell products and for achieving the subsequent and necessary sustained cryogenic temperature in our cryogenic storage facility. Once the cells are brought to the optimum temperature, and placed in a specialized cryogenic compartment, the cells then goes into the cryogenic storage tanks. Once the stem cells are properly and safely stored, you have control over their use and disposal. No stem cells can be released without your consent. Based on current research, stem cells can be successfully stored for 25 years in a cryopreserving storage. Although not enough years have passed to assert the maximum length of time viable stem cells can be stored with certainty, bone marrow, another similar source of cells, has been successfully stored for decades and has remained viable throughout that time.

### ► Research and Development

In addition to all the tissue banking activities, the laboratories include an active Research and Development program in which we are actively involved in characterizing the different sub-populations of adult stem cells found in the above tissue types as well as differentiation studies in attempts to identify the right differentiation conditions in order to differentiate these adult stem cells into many different mature cell types that can be potentially used to treat a wide range of different conditions.



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**GeneCell International LLC**  
8785 SW 165th Avenue • Suite 101 • Miami, Florida 33193  
**1-888-99-GENECCELL (1-888-994-3632)**  
Tel.: 305-382.6737 • 305-382.6750 • Fax: 305-382.6062  
info@genecell.com

[www.genecell.com](http://www.genecell.com)

