





Cord Blood and
Cord Tissue Banking
Guidebook

GUIDE FOR EXPECTANT PARENTS AND PRENATAL CARE PROVIDERS



## **CORD BLOOD & CORD TISSUE BANKING**

## **Guide for Expectant Parents & Prenatal Care Providers**

Expectant parents now have the option to store their newborns' cord blood and cord tissue after birth. Both cord blood and cord tissue are valuable sources of stem cells - powerful early stage cells which can be used to treat disease later in life. Learn more below.

An increasing number of expectant parents are storing their newborns' cord blood and cord tissue for future use. However, many parents still have a poor understanding of this important service, or are not aware of its benefits until after their baby's cord blood and cord tissue are discarded.

This guidebook aims to provide patients and their healthcare providers with objective answers to some of the most commonly asked questions about cord blood and cord tissue banking.

#### What are cord blood & cord tissue?

Cord blood is the excess fetal blood remaining in the umbilical cord after birth. Traditionally discarded after the baby is born, cord blood is now recognized as an important source of hematopoietic stem cells (HSCs).

Cord tissue is derived from the umbilical cord itself. Cord tissue is a rich source of mesenchymal stem cells (MSCs), which have the potential to regenerate cartilage, bone, muscle, nerves, and other mesenchymal tissues.

Due to their regenerative potential, stem cells can potentially be used to repair damaged organs and tissue in many diseases. Ongoing stem cell research has led to the possibility of treatments for diseases that cannot be cured using present-day methods.

Cord blood and cord tissue stem cells can only be collected at birth.

A child born today has the following lifetime degenerative disease risks:

1 in 2 HEART DISEASE

1 in 2 OSTEOARTHRITIS

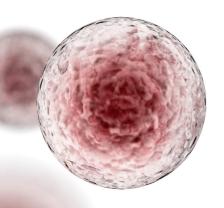
1 in 3 DIABETES

1 in 6 STROKE

1 in 6 DEMENTIA

87% CHANCE OF DEVELOPING AT LEAST ONE OF ABOVE DISEASES IN LIFETIME





## WHAT IS CORD BLOOD & CORD TISSUE BANKING?

Expectant parents with normal, healthy pregnancies have the option to collect and save their babies' cord blood and cord tissue for use in medical treatments later in life.

Cord blood and cord tissue are the only non-invasive and ethically acceptable sources of stem cells. The harvesting and storage of these cells is painless, and has no side effects for the mother or child. The regular delivery of the baby is not affected.

Cord blood and cord tissue can be stored for the lifetime of an individual for future use by the individual or his/her family members.

## **Diseases Currently Treated with Stem Cells**

#### **LEUKEMIA**

Acute Biphenotypic Leukemia
Acute Lymphoblastic Leukemia
Acute Myelogenous Leukemia
Acute Undifferentiated Leukemia
Chronic Lymphocytic Leukemia
Chronic Myelogenous Leukemia
Juvenile Chronic Myelogenous
Leukemia
Juvenile Myelomonocytic Leukemia

#### OTHER BLOOD CANCERS

Acute Myelofibrosis
Agnogenic Myeloid Metaplasia
Essential Thrombocythemia
Hodgkin's Disease
Multiple Myeloma
Non-Hodgkin's Lymphoma
Polycythemia Vera
Plasma Cell Leukemia
Waldenstrom's Macroglobulinemia

#### HISTIOCYTIC DISORDERS

Familial Erythrophagocytic Lymphohistiocytosis Histiocytosis-X Hemophagocytosis

#### **IMMUNE SYSTEM DISORDERS**

Ataxia-Telangiectasia
Kostmann Syndrome
DiGeorge Syndrome
Bare Lymphocyte Syndrome
Omenn Syndrome
Leukocyte Adhesion Deficiency
Severe Combined
Immunodeficiency
Common Variable
Immunodeficiency
Wiskott-Aldrich Syndrome
X-Linked Lymphoproliferative

#### **PLATELET DISORDERS**

Syndrome

Amegakaryocytosis Glanzmann Thrombasthenia

#### **RED BLOOD CELL DISORDERS**

Aplastic Anemia
Beta Thalassemia Major
Fanconi Anemia
Paroxysmal Nocturnal
Hemoglobinuria
Pure Red Cell Aplasia
Sickle Cell Disease

#### **METABOLIC DISORDERS**

Adrenoleukodystrophy
Beta-Glucuronidase Deficiency
Gaucher Disease
Hunter Syndrome
Hurler Syndrome
Krabbe Disease
Lesch-Nyhan Syndrome
Maroteaux-Lamy Syndrome
Metachromatic Leukodystrophy
Morquio Syndrome
Mucolipidosis II
Mucopolysaccharidoses
Niemann-Pick Disease

#### PHAGOCYTE DISORDERS

Chediak-Higashi Syndrome Chronic Granulomatous Disease Neutrophil Actin Deficiency Reticular Dysgenesis

#### **OTHER MALIGNANCIES**

Neuroblastoma Renal Cell Carcinoma Retinoblastoma



## WHY BANK CORD BLOOD & CORD TISSUE?

Cord blood stem cells are currently used to treat over 80 life-threatening diseases, including certain cancers and genetic disorders. Additionally, over 1000 clinical trials are currently evaluating the use of stem cells in the treatment of many diseases that were previously considered to be incurable. With rapid advances in stem cell research, the usage of cord blood and cord tissue stem cells in cell therapies will continue to rapidly increase during a child's lifetime.

## Diseases Currently Targeted by Stem Cell Research

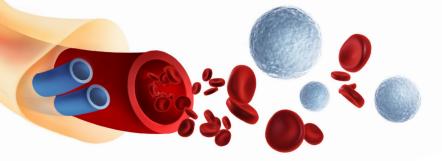
Cerebral Palsy Glaucoma Brain Tumour Blindness Autism Spectrum Disorder Hearing Loss Hypoxic Ischemic Encephalopathy Congenital Heart Defects Alzheimer's Disease Heart Attack Congenital Hydrocephalus Heart Failure Crohn's Disease Hypertension **Ewing Sarcoma Breast Cancer** Parkinson's Disease Stroke Crohn's Disease Huntington's Disease Type 1 Diabetes Multiple Sclerosis Type 2 Diabetes Traumatic Brain Injury Kidney Cancer Kidney Failure Adrenoleukodystrophy Arthritis Liver Cirrhosis Spinal Cord Injury Ovarian Cancer Cartilage Repair Amyotrophic Lateral Sclerosis (ALS) Lymphoma Lupus Osteoporosis Lysosomal Storage Diseases Melanoma Cartilage Repair Critical Limb Ischemia Sports Injury **Buergers Disease** Leukemia

Studies have demonstrated that cord blood has unique advantages over traditional bone marrow and peripheral blood transplantation, and can be life-saving in cases where a suitable bone-marrow donor cannot be found (50% of patients requiring a bone-marrow transplant will not find a suitable donor in time).



## **UMBILICAL CORD TISSUE**

the Latest Breakthrough in Stem Cell Banking



In addition to banking cord blood, expectant parents now have the opportunity to bank stem cells from their baby's umbilical cord tissue. While cord blood is a rich source of **Hematopoietic**Stem Cells (HSCs), a baby's umbilical cord tissue is a rich source of a different type of stem cell known as **Mesenchymal Stem Cells (MSCs)**.

MSCs are powerful multipotent stem cells that can heal and repair the body in different ways than cord blood. MSCs can rapidly divide and regenerate a wide range of cell types, including cartilage, bone, muscle and nerves.

MSCs are currently being studied for their use in the treatment of autism, cerebral palsy, heart attack, stroke, spinal cord injuries and many more degenerative and autoimmune diseases. Clinical trials are already underway for a variety of conditions, including stroke, rheumatoid arthritis, Parkinson's disease, Alzheimer's disease, Type I diabetes and wound repair.

Storing cord tissue today opens the door for more therapeutic options for the entire family in the future.

## MSCs are currently being studied for their use in the treatment of:



Type 1 Diabetes Gastrointestinal Disease



Sports Injuries (Cartilage) Skeletal Disease & Injury Rheumatoid Arthritis



Heart & Vascular Disease Vascular Damage



Retinal Disease



Liver Fibrosis
Damaged Tissue and Organs
Transplant Complications



Neurological Disease & Injury Parkinson's Disease



Cancers
Autoimmune and Inflammatory Disease



Wounds, Burns and Ulcers

Due to their potential, stem cells are a major area of research in nearly every branch of medicine. Currently incurable diseases caused by 'permanent' damage to bodily tissues, such as diabetes, arthritis, paralysis, heart disease, and even neurological disorders are prime candidates for cell therapy. Stem cells are thus widely perceived as being the key to the next major breakthrough in the medical field.

## **CORD BLOOD & CORD TISSUE BANKING PROCESS**



#### 1. Enroll

Enroll online at www.healthcord.com/register, or register by phone at 1-877-714-6361. Parents can also complete the Healthcord Registration Form and submit the completed form to Healthcord by fax, email or mail.



#### 2. Receive Kit

The collection kit will be shipped to the parents in 3 to 5 business days. For same-day delivery for emergency cases, overnight express or even same-day options are available in most cities throughout Canada.



### 3. Bring Kit to Hospital on Day of Delivery

The parents will be instructed to bring the collection kit to the hospital on the day of delivery and give the kit to the delivery team at the hospital.



#### 4. Healthcare Provider Collects Cord Blood & Cord Tissue

After the baby is born, the delivering physician will collect the cord blood and/ or cord tissue using the supplies provided in the kit. The kit is returned to Healthcord for processing.



## 5. Laboratory Processing and Freezing

At the laboratory, the stem cells are extracted, purified, concentrated, and cryogenically preserved. Once banked, the stems cells will remain intact for the lifetime of the child.



### 6. Receive Report

A certificate of banking indicating the number of stem cells, yield, and potency will be provided to the parents and the delivering physician along with retrieval instructions. Upon usage, the stem cells will be delivered directly to the treating hospital. Transportation can also be arranged for delivery to hospitals outside of Canada.

## LATEST ADVANCES IN CORD BLOOD & CORD TISSUE BANKING TECHNOLOGIES



## Cord Tissue Mesenchymal Stem Cell Extraction

Healthcord uses the latest technology to concentrate your baby's stem cells prior to freezing in order to maximally preserve stem cell recovery and function. This involves pre-freeze stem cell extraction, purification and concentration. Facilities without this technology will simply freeze large solid chunks of cord, resulting in massive cell death during freezing and thawing.





### **Closed-System Processing**

Healthcord uses a "closed-system" approach in order to maintain the highest level of sterility and safety for cord blood and cord tissue samples. This special method involves using specially designed instruments and tools to protect cord blood and cord tissue from contamination.



#### Stem Cell Quantitation

Healthcord uses a single-platform enumeration system for quantitation of CD34+ stem cells, the most accurate and advanced method available to date.



## **Computerized Controlled Rate Freezing**

One of the most important aspects of cryopreservation is proper cooling. As can be seen from frostbite, uncontrolled freezing can cause tissue death. Computer-controlled freezing precisely drops the temperature in highly regulated increments, allowing biological processes in a cell to gradually slow down to zero and suspending the cell in time. Controlled rate freezing prevents cell damage. All cord blood and cord tissue at Healthcord are frozen using controlled rate freezers.





### **Next-Generation Vapour Phase Storage Tanks**

**Next-Generation Vapour Phase Storage** is the most advanced and safest technology in cryogenic storage, and eliminates the risk of contamination caused by liquid storage.



Next-Generation Vapour Phase Storage Tank

Older liquid storage tanks immerse cord blood bags directly in liquid nitrogen, exposing every cord blood bag to thousands of cord blood sample bags from different children bathing in the same liquid. If a micro-fissure develops in one of the blood bags, all of the other bags floating in the same liquid may become contaminated. Some laboratories attempt to reduce this risk by double-bagging their cord blood, but even so, the risk still exists as long as the blood bags are submersed in the same liquid.

The latest storage technology uses specialized computer-controlled vapour phase tanks which suspend the cord blood bags in liquid nitrogen vapour. This state-of-the-art technology prevents the risk of cross-infection from other samples. Healthcord guarantees the use of vapour phase storage for all cord blood and cord tissue samples.

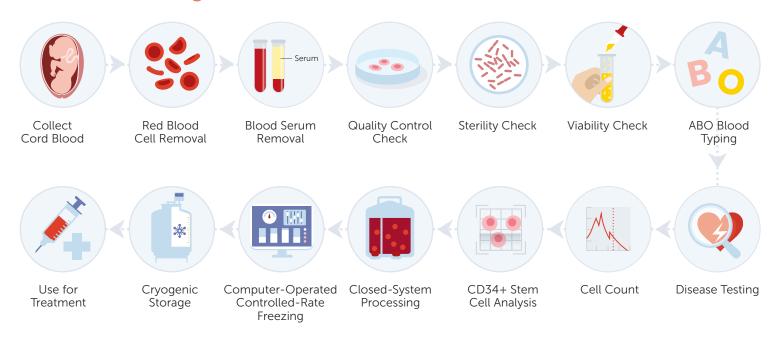
#### **Summary of Key Points**

- ✓ Cord blood and cord tissue are rich in potentially life-saving stem cells.
- ✓ Many life-threatening diseases are currently treated with stem cells.
- ✓ Potential uses of cord blood and cord tissue are increasing every year, and every child born today may potentially benefit from cell therapy in his or her lifetime.
- ✓ Cord blood and cord tissue banking allows expectant parents to store their newborns' stem cells for future potential medical use.
- ✓ Cord blood and cord tissue banking is safe; there is no harm to either the mother or child.
- ✓ Private (family) cord blood banking allows parents the ability to save their child's cord blood and cord tissue for their own future use.
- ✓ Cord blood and cord tissue can only be saved at birth.
- ✓ Healthcord is Health Canada approved, and a leader in cord blood and cord tissue banking.

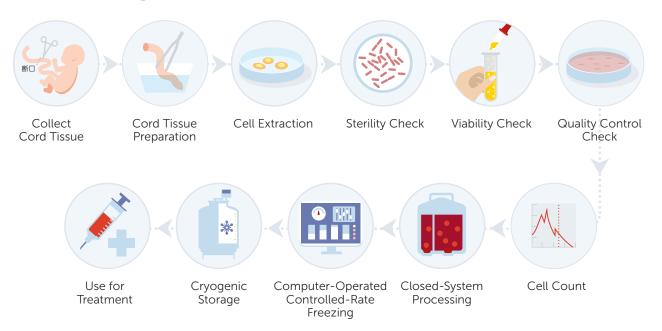


## WHAT HAPPENS AT THE LABORATORY?

### **Cord Blood Storage Process**



## **Cord Tissue Storage Process**



#### Did you know?

There have already been an increasing number of stem cell research breakthroughs in recent years, including the use of stem cells to regenerate segments of trachea, to generate rudimentary kidneys and livers, and to regrow damaged eye tissue. Applications of stem cells involve the treatment of diseases of tissues cannot repair or regenerate on their own.



## WHAT'S IN THE CORD BLOOD & CORD TISSUE COLLECTION KIT?

After registration, a collection kit will be delivered directly to the expectant parents. The parents are instructed to bring the kit to the hospital on the day of delivery and give the kit to the delivery team. The Cord Blood and Cord Tissue Kit contains the following items:

## **Cord Blood Collection Bag**

The delivering physician uses the cord blood bag to collect cord blood into a closed-system. The cord blood bag is the ideal approach for sterile blood collection and is compatible with both natural and caesarean section deliveries.

### **Cord Tissue Collection Vessel**

Cord tissue is collected into a Cord Vessel which contains tissue culture media and antibiotics.

## Temperature Datalogger

The temperature datalogger stays with the sample during transport to continuously monitor the sample and ensure sample quality.

## Thermal Regulated Transporter

The collection kit is designed to prevent temperature fluctuation during transportation. This ensures that the cord blood and cord tissue are maintained at the correct temperature, even if the kit is exposed to extreme temperatures.

#### **Professional Medical Courier**

Healthcord uses professional medical couriers that can pick up samples from the bedside and ensure timely delivery to Healthcord.

## CORD BLOOD & CORD TISSUE BANKING REGULATIONS



#### Health Canada

Cord blood and cord tissue banking is strictly regulated in Canada. All cord blood and cord tissue banks must be approved by Health Canada. Health Canada inspections include onsite visits by Health Canada auditors to inspect and approve every aspect of the laboratory, including the cord blood collection kit, the collection process, transportation of the stem cells, stem cell processing at the laboratory, freezing, long term storage, and future retrieval of the stem cells for use. This is one of the most stringent qualifications anywhere in the world.

## as Accredited

#### **AABB**

The AABB Cord Blood Banking Accreditation program is a voluntary laboratory accreditation program. Laboratories conforming to the AABB Cord Blood Banking guidelines submit to biennial inspections by AABB external auditors to ensure independent verification of facility quality.

# CAP Proficiency Testing Program of the College of American Pathologists

## College of American Pathologists

The College of American Pathologists offers a graded proficiency testing program to cord blood banking laboratories to ensure accurate diagnostic test results.



## Food and Drug Administration

The FDA offers registration for cord blood banking laboratories and their cord blood collection kits.

## **ABOUT HEALTHCORD**

Healthcord is Health Canada inspected and approved and FDA registered. Our laboratory has proudly achieved the highest level of accreditation with the AABB, the leading international accreditation body for blood banks, and participates in the College of American Pathologists Proficiency Testing Program to ensure the highest quality laboratory testing and processing.





## FREQUENTLY ASKED QUESTIONS

### How long can cord blood be stored?

Once banked under cryogenic conditions, cord blood and cord tissue stem cells remain viable for

the lifetime of a child.

#### Who can use the cord blood?

A child's own cord blood and cord tissue stem cells are a perfect match to the child and are available for immediate use with no need to search for a donor. A baby's stem cells have high chance of being a match with immediate family members, including parents, grandparents, and siblings. This means the entire family may potentially benefit from a child's banked cord blood and cord tissue.



#### What are the benefits of banking both cord blood and cord tissue?

Cord blood and cord tissue have different types of stem cells which have different regenerative potentials. Banking both types of stem cells provides the maximum potential for access to future stem cell therapies.

#### How likely is it that a child will use its stored cord blood or cord tissue?

The likelihood that a child will use his/her own cord blood or cord tissue equals the likelihood that the child will develop a disease that can be treated with cell therapy in his/her lifetime. Diseases such as diabetes, heart attack, arthritis, Parkinson's, paralysis, and stroke, are all primary targets for cell therapy, and nearly every person will likely encounter one of these diseases in his or her lifetime.

#### How many times can a child use its cord blood?

Most diseases currently treated with cord blood are life-threatening, and the transplant physician will use as many stem cells as are available to maximize the chance of success. This may change in the future as methods are being developed that enable stem cells to be 'expanded' up to 100-fold. Most advances in the use of stem cells will also likely be in the treatment of non-blood/immune diseases and will require much smaller doses of stem cells; thus cord blood will likely become a multi-dose/ multi-use product.

#### Who is involved in cord blood and cord tissue banking?

Parents and pre- and perinatal care providers play important roles in making cord blood and cord tissue banking a success. At the heart of this process is the cord blood bank, which not only processes and securely stores cord blood and cord tissue, but coordinates the entire process. The cord blood bank also liaises with the transplant hospital in the future when the stem cells are used for the child or his/her family members.

## 3 Easy Ways to Get Started

- 1 Register Online
  - The most convenient way to register. Go to www.healthcord.com/register
- Register by Phone
  Call toll free 1.888.802.0706
- Register by Email or Fax

  Complete the Registration form and Email to support@healthcord.com or Fax to: 1.888.655.8877

## Canada-Wide Services

Healthcord is Canada's nation-wide cord blood bank, processing samples from coast to coast. Our specialized medical couriers can pick up from the hospital bedside anywhere across Canada and deliver to our facility within hours.



#### **Customer Service**

If you have any questions about cord blood and cord tissue banking, please call toll free: 1.888.802.0706

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