

# **Welcome Pack**

Your Comprehensive Guide to Stem Cell Storage



Why are stem cells vital for my haby's future?



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Helping families to take full advantage of life-saving opportunities for their children.

# Dear Parents

Welcome to Cells4Life, a company dedicated to helping you secure greater health benefits for your children.

In many ways, stem cell treatment is seen as the future of human medicine. In fact, many seriously ill children and adults have already benefited from it over recent years. Extensive investment continues to be made into therapies to treat cancers, burns, diabetes, heart disease, strokes and many other conditions such as Alzheimer's disease and Parkinson's disease.

It was for these reasons that my colleagues and I wanted to store our own children's stem cells following their birth. If they became seriously ill later on in life, treatment with their own stem cells could optimise the chances of recovery.

As we examined the various storage services available, we soon discovered that they all used the 'volume-reduced' method, which simply extracts one type of blood-forming stem cell from a baby's umbilical cord blood following birth. However, we knew that storing the entire umbilical cord blood presented much greater health opportunities. It not only allows you to save more stem cells, it also captures more stem cell types. These two factors can greatly increase the chances of stem cell treatment success.

When it became clear that many other families wanted to take advantage of the same health benefits, we decided to launch Cells4Life in 2002. Since then, we have grown to be a full-service provider of stem cell storage services to families, offering both cord blood storage and an advanced volume-reduced method. Furthermore, we have committed ourselves to being the best provider of these services in the world.

This pack outlines the exceptional health benefits of storing stem cells. It also explains the various ways in which Cells4Life gives you the best service and peace of mind. If you have any questions, please feel free to get in touch. We'd be delighted to answer any queries or concerns you may have.

Yours faithfully,

Jeff Drew

Dr Jeff Drew BSc (Hons) PhD Scientific Director, Cells4Life





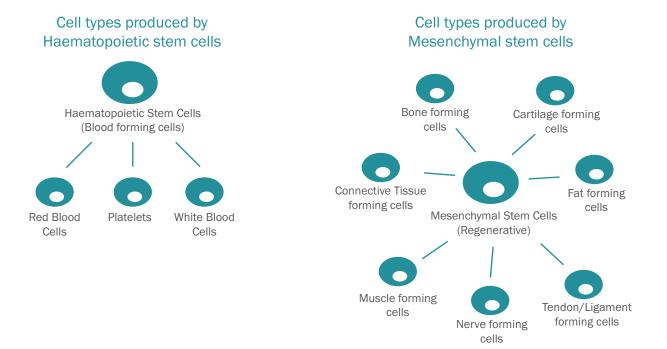
## What are stem cells?

Your baby's umbilical cord presents a once in a lifetime opportunity to capture a rich source of human stem cells.

The human body is made up of over 200 specialised cells. For example, the cells that make up your muscles are different to those found in your blood, which are different again to the cells that make up your hair. Stem cell is simply the name we give to a master or 'naïve' cell that can transform into these specialised cells depending on where in the body it is needed. These properties make them extremely valuable to medicine.

# Where are they found?

Stem cells can be found in various parts of the human body. However, the umbilical cord blood and tissue are a rich source of naïve stem cell types, which is why many parents choose to save their children's cord blood and tissue following birth. For example, cord blood contains mesenchymal stem cells (MSCs), haematopoietic stem cells (HSCs) and very small embryonic like stem cells (VSELs), all of which may be usable in stem cell treatment. The cord tissue also contains MSCs in addition to unrestricted somatic stem cells (USSCs), vascular endothelial stem cells and perivascular stem cells, which are also expected to have great therapeutic benefit in the future. Furthermore, the presence of hormones and 'growth factors' that help the baby to develop are believed to increase the overall success of stem cell treatment and provide additional therapies.



We are trusted by more parents to store more stem cells than any other private stem cell bank in the UK.



# Why store stem cells?

The stem cells from your baby's umbilical cord can be used to treat disease and injury, and are considered to be the cornerstone of regenerative therapies.

Although there are many fields of study, two stem cell treatments are receiving particular focus. These are Transplants and Regenerative Therapy.

## **Transplants**

## Available today to treat:

#### Metabolic Disorders

Krabbe Disease Hurler Syndrome

#### **Blood Cancers**

Leukaemia, Lymphoma Myeloma

#### Solid Tumours

Neuroblastoma

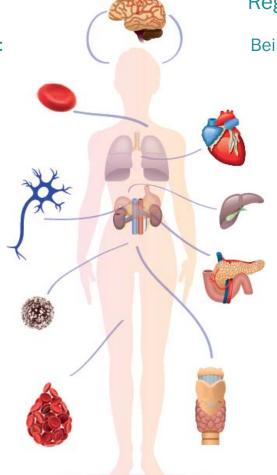
#### **Immune Disorders**

SCID

Wiskott-Aldrich Syndrome

#### **Blood Disorders**

Sickle Cells Anemia Aplastic Anemia Fanconi Anemia



## Regenerative Therapy

## Being researched to treat:

Cancer **Brain Injury** Multiple Sclerosis Cerebral Palsy Parkinson's Disease Alzheimer's Disease Cystic Fibrosis **Hearing Loss Bone Fractures** Burns Stroke **Heart Disease** Cardiac Regeneration Liver Failure Diabetes Spinal Cord Injury

## Transplants

Because haematopoietic stem cells (HSCs) can transform into any type of blood cell, they are currently being used in the treatment of various blood cancers and disorders. This includes leukaemia, lymphoma and myeloma.

## Regenerative Therapy

This groundbreaking medical field uses stem cells to repair or replace damaged tissues and organs. This exciting area of medicine promises some extraordinary medical possibilities within your children's lifetime, with mesenchymal stem cells (MSCs) considered to be an extremely important part of future developments.



# Why can my own child's stem cells be more effective?

Most stem cells used in treatment come from a public bank, which stores the stem cells of multiple donors. Whilst all donor samples are matched with the recipient, there is a risk that, when they are introduced into the human body during treatment, the donor's stem cells will be rejected. This is called 'graft versus host disease', and can be fatal.

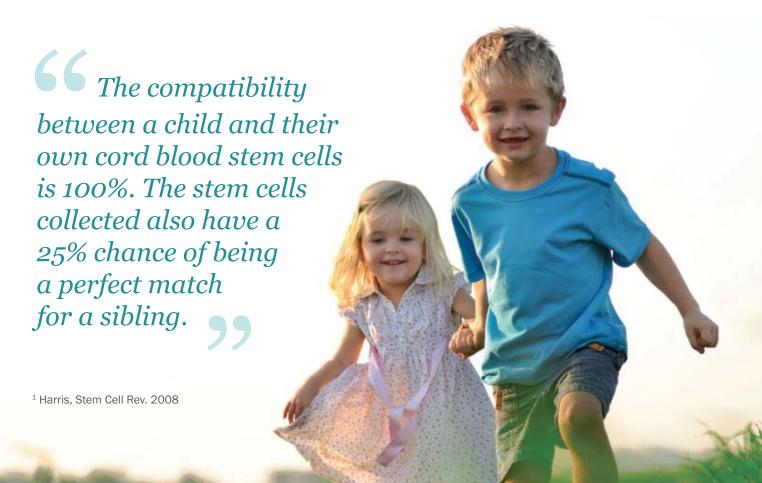
Storing your own child's umbilical stem cells increases the chance of successful treatment by ensuring that a perfect match is always available. Quite simply, if your child becomes ill or suffers injury, they can be treated with their own umbilical stem cells without the risk of rejection.

Naturally, storing stem cells is considered particularly important if a sibling is already known to suffer from a treatable disease. It is also valuable in situations where finding a suitable donor match is more difficult (e.g. for non-Caucasian, mixed race or certain ethnic groups).

# What are the chances of needing stem cells?

When Cells4Life launched in 2002, the chance of a child using their stored stem cells was 1 in 20,000. By 2008, it was estimated that 1 in 3 individuals might benefit from regenerative medicine therapy.<sup>1</sup>

Considering the expanding number of ways in which stem cells can be used to treat illnesses and injuries, there is a significant chance that your children will use some or all of their stored stem cells in their lifetime.





# World-leading stem cell services

Cells4Life offers Platinum and Gold Services to give you maximum choice when it comes to safeguarding the health of your child.

## Whole Cord Blood Storage

Cells4Life Platinum Service

The Cells4Life Platinum Service stores all of the blood from the umbilical cord after birth.

The Cells4Life Platinum Service captures a much greater number of stem cells and stem cell types, which enables your child to take full advantage of existing treatments and future developments in regenerative therapy. It also captures valuable hormones and growth factors, which are believed to lead to better and faster engraftment during treatment. A further benefit to cord blood storage is that it goes from collection to storage in the fastest time in the industry, which helps to maximise cell viability. In contrast, volume-reduced can be slower due to the extra time required for processing.

# Volume-Reduced Cord Blood Storage

+Cell Gold Service

Our Gold Service volume-reduced method focuses on extracting the maximum number of haematopoietic stem cells (HSCs) from the umbilical cord blood. Cells4Life's automated, computer-controlled processing system delivers the highest published cell recovery rates in the industry - 96%. Other processing methods have been shown to recover only 81% of cells.<sup>2</sup>

Because the volume is greatly reduced, this offers the benefit of lower storage costs. However, it potentially restricts future use of the sample to only those treatments that repair the blood system. However, if you choose volume-reduced storage with Cells4Life, you will benefit from our state of the art Cells4Life +Cell technology that ensures almost 20% more cells are retained than any volume-reduction technology used by other stem cell storage providers.

# **Umbilical Cord Tissue Storage**

+Cord Service

In addition to cord blood storage, Cells4Life can store a small section of the umbilical cord itself.

Storing a sample of the umbilical cord complements stem cell storage by capturing additional MSCs, as well as unrestricted somatic stem cells (USSCs), vascular endothelial stem cells and perivascular stem cells - all of which could become extremely useful in future therapies.

<sup>&</sup>lt;sup>2</sup> Kurtzberg J et al. - 2005

Cord blood stem cells can be stimulated to turn into other types of cell. This has important potential therapeutic implications for the treatment of conditions such as stroke and heart disease. The research evidence looks very exciting. - Dr Jeff Drew BSc (Hons) PhD - Scientific Director, Cells4Life

# Whole Cord Blood Storage Benefits

#### HSCs can treat

Leukemia Lymphoma Hodgkins Disease Multiple Myeloma

#### Plasma can treat

Hemophilia A and B Certain Cancers Antibody Theraphy

#### MSCs could treat

Heart Disease Cerebral Palsy Stroke Diabetes Type 1 and 2 Liver Failure Kidney Failure Alzheimer's Disease Parkinson's Disease Multiple Sclerosis Spinal Cord Damage Cartilage Injuries Burns

#### MSCs could regenerate

Bone Cartilage Muscle Marrow Tendon/Ligament Adipose Tissue Connective Tissue

#### VSELs could treat

Neural Cells Cardiac Muscle Blood Cells

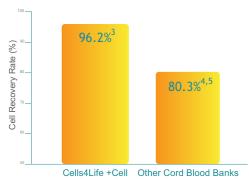


# Cells4Life +Cell Processing Benefits

Cells4Life +Cell Technology saves 96% of stem cells following our world-leading stem cell extraction method. This ensures almost 20% more cells are stored than any other storage provider.

Saving more cord blood stem cells could mean a better medical outcome.

Cells4Life stores almost 20% more cells vs. other processing methods



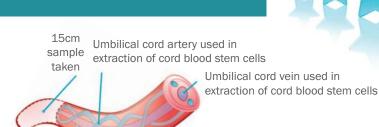


- \*Total Nucleated Cell Count (TNC) is a key clinical parameter that physicians use to identify if a sample can be used in therapy.
- More stem cells
- Better outcomes

- <sup>3</sup> Rosenthal J et al. 2008
- <sup>4</sup> Lapierre V et al. 2007
- <sup>5</sup> Papassavas AC et al. 2008

## Cells4Life +Cord Service

Cord tissue is a rich source of MSCs. Current research has demonstrated that these cells, together with the stem cells from cord blood, can form many if not all of the cell types necessary for tissue repair or replacement.

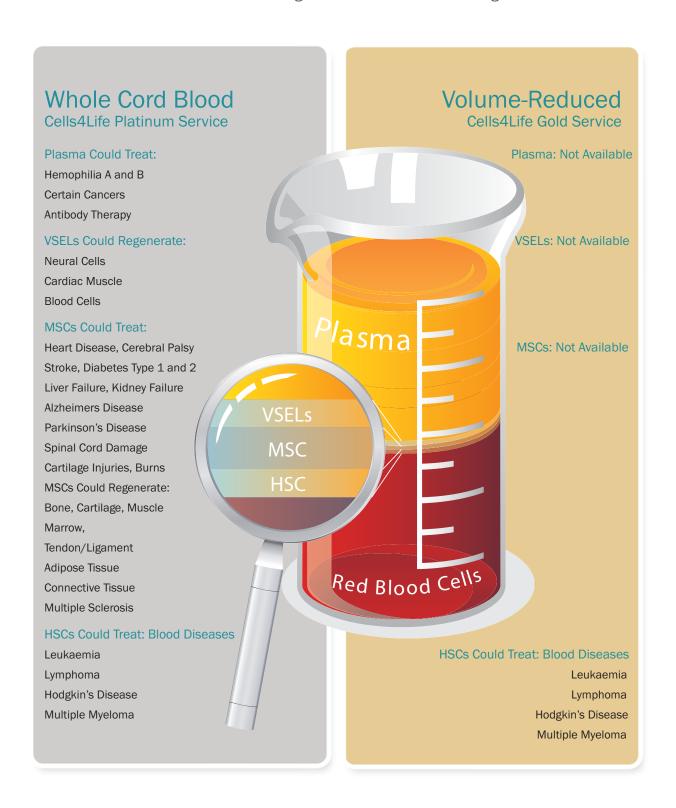


Wharton's jelly containing Mesenchymal Stem Cells



## When should I store whole blood?

Cells4Life offers Platinum and Gold services to give you maximum choice when it comes to safeguarding the health of your child. The table below presents a balanced comparison of the benefits of whole cord blood storage and volume-reduced storage.



A single opportunity to take out some additional physical health insurance for your children





# Whole cord blood and volume-reduced storage

## What is the difference between whole cord blood storage and volume-reduced storage?

Both whole cord blood and volume-reduced storage begin by collecting the available blood from the umbilical cord. The main difference between storing whole cord blood and volume-reduced storage is the methods used once the blood is received at the laboratory. Volume-reduction methods manipulate the sample to retain a proportion of one type of stem cell. In contrast, Cells4Life Platinum whole blood storage involves minimal manipulation with no separation of the blood. This optimises the number and types of stem cells stored.

## What is the benefit of storing whole cord blood compared to volume-reduced storage?

Umbilical cord blood contains several different types of stem cell. While storing the whole cord blood preserves all the key stem cell types and other factors, storing a volume-reduced sample preserves only one stem cell type: HSCs. Volume-reduction removes over 80% of the cells in the sample.

## Is there a downside to storing whole cord blood?

No. You will be able to benefit from any existing or future therapy that uses one of the stem cell types found in cord blood. The fact that Cells4Life has already released samples for use proves this.

## Are there any treatments that will only be available to me if I store whole cord blood?

Yes. The additional cell types found in cord blood allow you to take full advantage of any existing or future therapeutic developments. These cell types (including MSCs and VSELs) will prove to be critical for certain treatments such as tissue reconstruction and regeneration, and are important for successful engraftment, for the treatment of blood disorders today.

## Is there an upside to storing volume-reduced stem cells?

Volume-reduced storage was invented to reduce the cost of storage for public stem cell banks and the treatment of blood disorders. It has been adopted by most commercial stem cell banks for this reason. However, because of what the method discards, volume-reduced storage means that your child may not be able to take advantage of all future therapeutic developments. Even so, it does provide a more economical option and if you chose this option storing with Cells4Life means you could still have a higher cell count than with any other company.



# Why choose Cells4Life?

## Cells4Life is committed to an exemplary stem cell storage service.

We are a science-led organisation dedicated to delivering the best stem cell storage service in the world. Cells4Life stores more UK stem cell samples than any other private bank. We adhere to rigorous collection, storage, quality and safety procedures, and our customers receive support from a highly experienced team of doctors, scientists and specialists.

Furthermore, families trust our service because they know we use it to safeguard the health of our own children.



## Simple and safe procedure

Stem cell collection from umbilical cord blood is simple, painless and completely safe. It occurs immediately after the birth of your child, and is undertaken by a trained and licensed healthcare professional such as an obstetrician, midwife or phlebotomist.



## The only UK whole cord blood storage service

In addition to being one of the first UK companies to offer private stem cell storage to families, Cells4Life is the only one that stores whole cord blood. This superior method can greatly increase the success of treatment should your child need it.



## Most advanced separating technology

The Cells4Life +Cell technology stores almost 20% more HSCs than any other cord blood volume reduction technology.



## World leader in cord blood and cord tissue storage

We are also the only company in the world to offer a service for storing a section of the umbilical cord tissue with the whole cord blood or volume-reduced sample. This enables you to take advantage of all therapeutic opportunities that the umbilical cord and its blood provide.



## Regulated by the HTA

Cells4Life has been audited and licensed as a leading stem cell storage service in the UK by the Human Tissue Authority, the UK's regulatory body for tissue banking (licence number 11083). We also comply with the EU Tissue and Cells Directive and Human Tissue (Quality and Safety for Human Application) Regulations 2007.



#### Year-round collection

Your baby's stem cell samples must be frozen as quickly as possible after birth, which is why Cells4Life operates its collection service 24 hours a day, 365 days a year. We are the only UK stem cell storage service to offer this.



# 24/7

#### **Dedicated couriers**

We are also the only UK company to use a dedicated 24/7 courier service for collection. Samples are transported safely and promptly to our UK storage facility, achieving the fastest average collection-to-freezing time in the industry. We are also the only company to use state-of-the-art temperature controlled packaging for shipping from around the world.



## Unrivalled storage protection

We also differentiate ourselves by being the only UK company to store your child's stem cells in two separate, secure geographic locations in case an unforeseen event occurs at one of our facilities. Additionally, we store your sample in multiple portions so that if they are ever required, only the required amount is released for use. This allows us to preserve the remainder of the sample for future use.



## Stringent testing

On arrival at our storage facility, all samples are tested to ensure they contain a high number of living stem cells. All processing and testing is performed in our own laboratory, which enables us to provide our customers with clear evidence of the quality of their sample.



#### Guaranteed refund

Cells4Life charges an all-inclusive fee for collection, processing and storage. However, only samples that contain a high percentage of living cells are stored. If we find contamination when testing your sample, the all-inclusive fee will be refunded (minus any third party costs and the non-refundable deposit).



## Business continuity insurance

To ensure continued quality and safety of your child's samples, Cells4Life has also taken out additional insurance to cover the costs of moving it to another licensed storage facility in the unlikely event of a corporate failure.

We chose Cells4Life because of their UK based laboratory and the fact that they store in two separate locations.





# How does collection and storage work?

Cells4Life makes collection and storage as simple as possible. If you would like further information on any of the following steps, please feel free to call us on +971 4 3116613.



#### 1. Welcome Pack

Read all parts of the Welcome Pack to fully understand which of the Cells4Life services you require.



## 2. Service Agreement

We have enclosed two copies of our Service Agreement within this Welcome Pack. These are legal documents, so please read them fully and raise any questions you may have with us. Please complete and sign each section of the Service Agreement before returning it to us with your initial payment, payable by cash, cheque or credit card. Your payment should be made to your Cells4Life representative prior to the birth.



## 3. Advise Hospital

At your next hospital appointment, please make them aware of your desire to collect stem cells as part of your birthing plan.



#### 4. Collection Kit

Once we receive your signed Service Agreement and payment, you will be sent the Cells4Life Collection Kit. This will contain all of the equipment your healthcare professional requires to undertake the process, together with instructions. The kit will include the special equipment required for our +Cord service if you have chosen it. Delivery of the collection kit should be arranged well in advance of your expected due date. However, we can arrange a collection to be gotten to you in the event of an imminent delivery. Store the kit in a safe place and remember to take the kit to the hospital with you when you go into labour.





## 5. Collect Cord Blood

Following the birth of your baby, your healthcare professional will use the collection kit to collect the cord blood, tissue and a maternal blood sample before packaging them into our specially prepared transport bags ready for courier collection. The whole process should take only 20 to 30 minutes to perform. It is a legal requirement to take a maternal blood sample, and if this isn't possible at the time of the birth, one must be taken within 7 days of the birth and sent to our laboratory. They are placed into our mini medical fridge ready for collection.



## 6. Call your local Cells4Life representative

As soon as possible after the sample has been collected, call your representative who will arrange collection for you. Please make sure you keep the cord blood with you at all times and do not leave it at the reception.



## 7. Testing and cryopreservation

Upon arrival, we immediately start the processing and testing. First, we assess the viability of your child's stem cells, with initial viability results communicated to you the next business day. Then we create individual samples and store them using 'cryopreservation' - a process of freezing the cells and tissue in liquid nitrogen to stop all biological activity. The cells are preserved in this state until they are required.



## 8. Maternal sample testing

All maternal blood samples are tested using the latest instrumentation and assays. Cells4Life has access to specialist reference laboratories for additional testing if required.



## 9. Certificate of testing

Once testing is complete and full payment is received, you will receive a Cells4Life Umbilical Cord Blood (and Tissue) Testing Certificate for your child's samples. This is a record of the test results, and provides you with all information available about your sample test results.



#### 10. Contamination

In the event that the Cord Blood is found to be contaminated and is deemed unsuitable for storage or future use, we will reimburse all fees paid by you to us, excluding any third party costs and the non-refundable deposit.



Although we hope you never need the sample, if you do, it can be delivered anywhere in the world in a state-of-the art frozen container receipted by the appropriate person.





# Frequently asked questions

#### Does the UK Health Service store cord blood as whole blood or volume-reduced?

Whole cord blood storage is the process used by the UK Health Service when storing cord blood to treat a sibling. For non-related (allogeneic) use and where long-term storage is required, the volume-reduced method is used to lower costs. This means that the sample can only be used for blood-related disorders.

#### Can the cord blood still be collected if the birth is Caesarean or home birth?

The process is the same in either case. The important thing is to discuss the process in advance with your midwife and birth partner. For a Caesarean birth, cord blood is collected after delivery of the placenta in the same way as a natural birth.

## How quickly should the cord blood be collected?

The cord should be clamped and the collection should be carried out as soon as possible following delivery of the placenta to minimise cell loss due to the clotting process.

## Why is your initial Service Agreement limited to 25 years?

We have set the initial period at 25 years as current research has shown that cord blood stored and used after 28 years is therapeutically viable. As it is highly likely that it will be possible to store umbilical cord blood and tissue for much longer periods of time and retain clinical activity of the cells, we expect to be able to offer further storage periods at the end of the initial term. It is widely accepted in the scientific community that long-term cryogenic storage can be indefinite. We always recommend that the storage continues after the initial term to cater for possible medical advantages that arise later in life.

## Are there any medical risks to either the baby or myself?

Not at all, the cord blood and tissue collection is done after the baby's delivery and after the umbilical cord has been clamped and cut. It is a simple, quick and safe process. If there are any complications to the mother or baby during delivery, the doctor will not collect the cord blood.

## If I choose delayed cord clamping can I also have my cord blood collected?

Yes, you can. We have not experienced any issues associated with delayed cord blood clamping.



## What would happen if there were complications at birth?

The wellbeing of the mother and baby is always the primary consideration. Cord blood is collected after delivery of the placenta. Procurement neither affects the management of the labour nor does it change or interfere with the care needed at the critical time of delivery. However, it is made clear in both the instructions for procurement and within the contract that where collection of the cord blood will distract from the health of mother or baby, the procedure should not be carried out.

## Ongoing support:

If you have any questions or require further information please call us on: +971 4 3116613

# Some of the 80 medical conditions currently treated by UCB stem cells today:

#### Leukemias

Acute Leukemia Chronic Leukemia Myelodysplastic Syndromes Lymphomas Inherited Red Cell (Erythrocyte) Abnormalities Other Disorders of Blood Cell Proliferation

#### **Anemias**

Inherited Platelet Abnormalities Myeloproliterative Disorders Inherited Immune System Disorders- Severe Combined Immunodeficiency (SCID) Inherited Immune System Disorders Neutropenias Inherited Immune System Disorders- Other Phagocyte Disorders Cancers in the bone marrow Transplants for Inherited Disorders affecting the Immune System & Other Organs Transplants for Inherited Metabolic Disorders Mucopolysaccharidoses (MPS) Storage Diseases Leukodystrophy Disorders Lysosomal Storage Diseases Inherited Disorders- Other Severe Aplastic Anemia

#### Therapies in clinical trials

Auto-Immune Diseases
Transplants for diseases of the Central Nervous System
Transplants for Disorders of Cell Proliferation
Gene Therapy
Cellular Cardiomyoplasty
Transplants for Cancerous Tumors

#### **Experimental treatments**

Auto-Immune Diseases Gene Therapy Rheumatoid Arthritis

#### Nerve Cell Repair

Diseases of the Central Nervous System Traumatic Injury

#### Organ repair

Kidney Liver Lungs

Source: www.parentsguidetocordblood.org - Updated April 2009

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www.parentsguidetocordblood.org





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