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### Welcome...

Dear Parent

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 believed that storing all cells from the umbilical cord blood presented much greater future potential. 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 to families, offering both whole cord blood storage and

an advanced volume-reduced method and cord tissue storage.

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

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

Jeff Drew



"A simple and totally safe procedure for mother and baby."

# 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 types of therapy 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 Cell Anaemia Aplastic Anaemia Fanconi Anaemia

# R

### 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 child's lifetime, with mesenchymal stem cells (MSCs) considered to be an extremely important part of future developments.

### 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.

### What are 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.

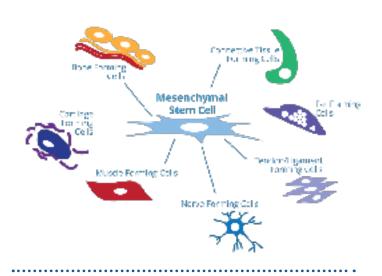
### Where are they found?

Stem cells can be found in various parts of the human body. However, 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)<sup>(1,2,3)</sup>, haematopoietic stem cells (HSCs)<sup>(4)</sup> and very small embryonic like stem cells (VSELs)<sup>(5)</sup>, all of which may be usable in stem cell treatment.

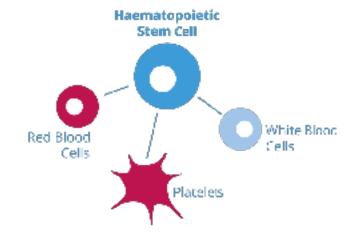
The cord tissue also contains MSCs in addition to unrestricted somatic stem cells (USSCs)<sup>(6)</sup>, vascular endothelial stem cells and perivascular stem cells, which are also expected to have great therapeutic benefit in the future.

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.

'Cells4Life stores more UK cord blood samples than any other private bank and offers the most comprehensive service available.' Cell types produced by mesenchymal stem cells



Cell types produced by haematopoietic stem cells



# Cells4Life - At a glance

- Cells4Life stores more UK samples than any other bank.
- Quality assured we have released samples for use in the UK NHS and the USA. <sup>1</sup>
- We store the cord blood stem cells which may be used in regenerative medicine
- <sup>1</sup> Imperial NHS Trust. Duke University

- Stores all types of stem cells in cord blood
- Reduced Volume and Whole Cord Blood storage
- 24/7 365 day a year laboratory
- Dual storage locations and multiple samples
- Dedicated medical courier collection
- Additional security with our unique +PROTECT insurance





# 'Giving your child the best opportunities for transplant and regenerative medicine'.

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

Currently most stem cells used in treatment come from a public bank, which are anonymously donated. Whilst all donor samples are matched to the recipient, there is a risk that when they are introduced into the human body during treatment, they will be rejected. This is called 'graft versus host disease' and can cause extremely serious side-effects, including death.

Storing your own child's umbilical stem cells ensures that a perfect match is always available. Quite simply, if your child becomes ill or suffers injury, they may 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. This service is provided by the NHSBT or Anthony Nolan Trust in the UK.

It is also valuable in situations where finding a suitable donor match is more difficult (e.g. for non-Caucasian, mixed race or black, Asian and minority 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 predicted 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.



<sup>1</sup> Harris DT, Badowski M, Ahmad N, Gaballa MA - Expert Opin Biol Ther. 2007 Sep. 1311-22.

'The compatibility between a child and their own cord blood stem cells is 100%. These stem cells also have a 25% chance of being a perfect match for a sibling'.

# World-leading services



# Cells4Life Platinum Service Whole Cord Blood Storage

# What is it?

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

### Why choose it?

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 whole cord blood storage is that it goes from collection to storage more quickly than volume-reduced, which helps to maximise cell viability.



### Cells4Life Gold Service Volume Reduced Storage

### What is it?

Our Gold Service volume-reduced method focuses on extracting the maximum number of haematopoietic stem cells (HSCs) from the cord blood, after which the remaining cord blood components are discarded.

### Why choose it?

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. If you choose volume-reduced storage with Cells4Life, you benefit from our state of the art Cells4Life +Cell technology that ensures more cells are retained than the volume-reduction technology used by other stem cell storage providers.<sup>(1)</sup> This is the same technology used by NHSBT Cord Blood Bank.



### Cells4Life +Cord Service Umbilical Cord Tissue Storage

### What is it?

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

### Why choose it?

Storing a sample of the umbilical cord complements stem cell storage by capturing additional MSCs, as well



as unrestricted somatic stem cells (USSCs)<sup>(2)</sup>, Vascular Endothelial Stem Cells (VESCs) and Perivascular Stem Cells (PVSCs)<sup>(3)</sup> - all of which have been indicated as potentially useful in future therapies.

<sup>&</sup>lt;sup>1</sup> http://www.ncbi.nlm.nih.gov/pubmed/23058859

<sup>&</sup>lt;sup>2</sup> http://www.ncbi.nlm.nih.gov/pubmed/24460716

<sup>&</sup>lt;sup>3</sup> http://www.ncbi.nlm.nih.gov/pubmed/21220956

# With Cells4Life, 100% of your baby's stem cells can be stored...

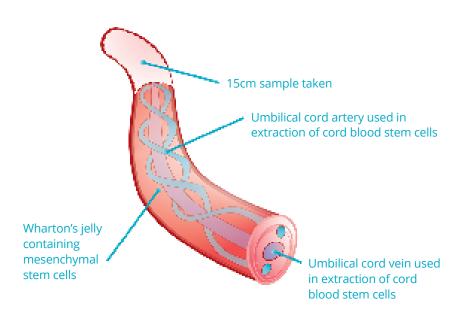
- ✓ Storing whole cord blood ensures that all the stem cells collected are stored for future use.
- ✓ Volume reduction was invented for public banking to save costs by removing the plasma and red blood cells prior to cryopreservation. A side effect of volume reduction is that other stem cell types cruicial to regenerative medicine are removed during the process.
- NHSBT stores whole cord blood for directed donations where the anticipated duration of storage is less than two years.(1)
- ✓ Volume reduction is used by the NHS for long term storage of blood forming cell types and this is where it would be expensive to store whole cord blood. (2)
- The Cells4Life Gold service uses the same processing technology as NHSBT. Cells4Life is the only private bank in the UK with this technology.

"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

### Cells4Life +Cord

Cord tissue is a rich source of MSCs (3). Current research has demonstrated that these cells, together with the stem cells from whole cord blood, can form many if not all of the cell types necessary for tissue repair or replacement.



- <sup>1</sup> Oxford NHS Trust. Transfer Protocol
- <sup>2</sup> Armitage et al. 1999 <sup>3</sup> http://www.ncbi.nlm.nih.gov/pubmed/23895058

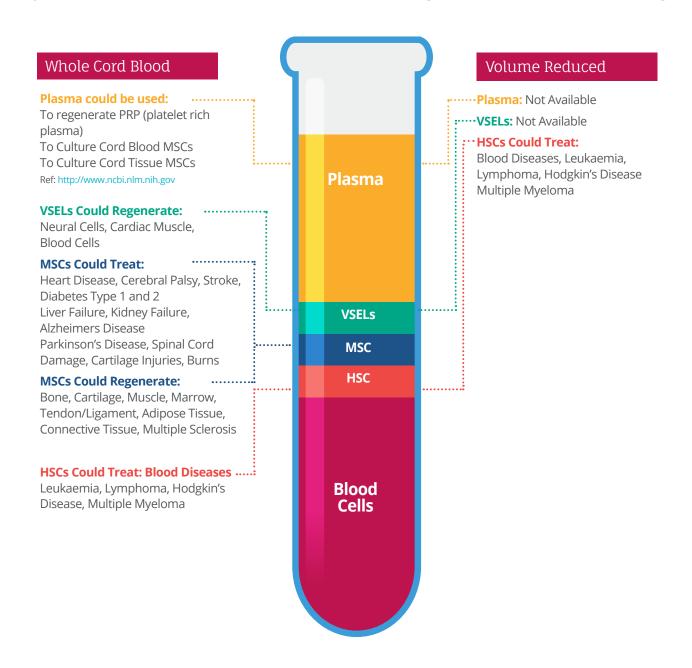
### Clinical Trials using stem cells from Cord Tissue

Alzheimer's **Aplastic Anaemia Multiple Sclerosis** Traumatic Brain Injury **Cerebral Palsy Graft-versus-Host-Disease** 

> Cardiomyopathy **Multiple Sclerosis** Spinal Cord Injury

## 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.





# Whole cord blood and volume-reduced storage: frequently asked questions

# 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 whole cord blood and volume-reduced storage is the methods used to process the blood at the laboratory. Volume-reduction methods consist of separating the sample to retain a proportion of one type of stem cell. In contrast, the Cells4Life Platinum whole blood storage does not separate the blood, and retains all types of stem cells in the stored sample.

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

Stem cell populations lost during volume reduction processing range between 27-39% in comparison to unprocessed whole cord blood. (ref: Basford et al. doi 10.1038/nprot.2010.88).

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

Whole cord blood storage is the process used by NHSBT when storing cord blood to treat a sibling. For non-

related (allogeneic) use the volume-reduced method is used to lower storage costs. The NHS samples are only used to treat blood disorders.

### 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 three samples for use proves this (at September 2014).

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

Volume-reduced storage was invented to reduce the cost of storage of samples for public stem cell banks when treating blood disorders<sup>(1)</sup>. It has been adopted by most commercial stem cell banks for this reason. However, this method discards cells, so 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 storing with Cells4Life means you could still have a higher cell count than with any other company.

<sup>&</sup>lt;sup>1</sup> P Rubinstein, Cord blood banking for clinical transplantation, 2009

# 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 safe. It occurs immediately after the birth of your child and is undertaken by a trained healthcare professional (e.g. obstetrician, midwife or phlebotomist) who is licensed by Cells4Life using the Cells4Life kit.



# 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 method ensures more stem cells are stored, which may greatly increase the success of treatment should your child need it.



### +PROTECT

Underwritten by Lloyd's of London, Cells4Life is the first UK cord blood bank to offer this unique insurance cover to partner stem cell storage. Up to £250,000 of cover towards stem cell treatment expenses and £30,000 of cover for non-treatment costs are provided.



# World-leader in cord blood and cord tissue storage

Cells4Life offers the most comprehensive range of services for umbilical cord tissue with either whole cord blood or volume-reduced blood samples. This enables you to take advantage of all therapeutic opportunities that the umbilical cord and blood provide.



### Regulated by the HTA

Cells4Life has been inspected and licensed as a stem cell storage service in the UK by the Human Tissue Authority, the UK's regulatory body for tissue banking (licence number 11083).



### Year-round collection

Your baby's stem cell samples should be frozen as quickly as possible after birth, which is why Cells4Life operates both its collection service and laboratory 24 hours a day, 365 days a year.



### **Dedicated couriers**

We only use a dedicated 24/7 courier service for collection. Samples are transported safely and promptly to our laboratory. We use state-of-the-art temperature controlled packaging where transit times are lengthy.



### **Unrivalled storage protection**

We also differentiate ourselves by storing 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 lab, all samples are tested to ensure they contain more than 70% of living stem cells. We count the number of nucleated cells in a sample and report this to you. Our laboratory operates under the UK NEQAS quality control system.



### **Guaranteed refund**

Cells4Life charges an all-inclusive fee for collection, processing and storage. However, only samples that contain at least 400,000 cells are stored. If your sample fails to achieve this result, 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 them to another licensed storage facility in the unlikely event of a corporate failure. This is underwritten by Lloyd's of London brokerage and under agreement with a separate HTA licensed facility.





# How does collection and storage work?

Cells4Life makes cord blood 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 decide which of the Cells4Life services you require.

### 2. Service Agreement

We have enclosed the Service Agreement within the Welcome Pack. These are legal documents, so please read them fully and raise any questions you may have with us before signing.

Please complete and sign each section of the Service Agreement before returning it to us with your initial payment.

### 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. Please be aware that some hospitals may not permit the collection of stem cells on their premises. We will check this before committing our service to you.

### 4. Collection Kit

Once we receive your signed Service Agreement and payment, you will be sent an appropriate Cells4Life Collection Kit. This will contain all of the equipment the licensed healthcare professional requires to undertake the process, together with instructions for the service you have chosen. Delivery of the Collection Kit should be arranged well in advance of your expected due date.

### 5. Collect Cord Blood

Following the birth of your baby and delivery of the placenta, your procurer 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 takes between 20 and 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 birth and sent to our laboratory. Without this cord blood cannot be stored.



### 6. Call Cells4Life Representative

As soon as possible after the sample has been packaged, please call the Cells4Life representative. We will then assist you in booking a pick-up with the medical courier.

### 7. Testing and cryopreservation

All samples are processed as soon as they arrived at the lab. First, we assess the viability of your child's stem cells, and communicate these to you the next business day. We prepare individual portions and store these 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 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 sample(s). This is a record of the test results.

### 10. Contamination

Despite all precautions, contamination may occur, and if you choose to destroy contaminated sample(s) you will not be charged for the processing of these. Deposits and third party costs are non-refundable.

### **Ongoing support:**

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



# Frequently asked questions

# Can we store part of the cord blood for our own use and the rest for public use?

The amount of cord blood collected will determine the size of a person that can be treated for a haematological disease - a procurement of 60ml will treat a child of up to 21kg<sup>(1)</sup>. Augmentation<sup>(2)</sup> (cell multiplication) technologies will mean that small numbers of stem cells can be expanded, but the reality is that these technologies are several years away. Until this technology is proven, Cells4Life does not recommend splitting the sample.

# Can the cord blood still be collected if the birth is a 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 close to the baby and cut below the clamp. The collection should be carried out as soon as possible following delivery of the placenta to minimise cell loss due to blood clotting.

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

Yes you can. We advise procuring umbilical cord blood after the placenta has been delivered (after the third stage of labour). A recent NHS study<sup>(3)</sup> showed that delaying clamping for 1-2 minutes did not significantly impact on collection volume or TNC. If you opt to delay the clamping period beyond 2 minutes the cord blood will start to clot making collection difficult.

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

When the Cells4Life protocol is followed this does not add any risk to the mother or baby at birth. It is a simple, quick and safe process and occurs after child birth. The person procuring the sample is trained in the process to ensure the safety of the mother and baby and the integrity of the sample.

<sup>&</sup>lt;sup>3</sup> NHSBT Effect of delayed clamping on cord blood donation



 $<sup>^{\ 1}</sup>$  www.parentsguidecordblood.org - How much cord blood is needed for transplant

<sup>&</sup>lt;sup>2</sup> DOI: 10.1089/ten.tea.2013.0073

### How is cord blood collected?

Following the birth of your baby, your obstetrician or midwife uses the Cells4Life Collection Kit provided by us to clean the umbilical cord.

Your healthcare professional will then insert the blood bag needle into the umbilical vein and collect the blood which flows into the bag by gravity. After the collection, the blood bag tubing is clamped, sealed and labeled. The bag is then placed back into the Cells4Life Collection Kit box. The whole process takes only a few minutes.

### How is cord tissue collected?

Following the collection of your baby's umbilical cord blood, your obstetrician or midwife uses the Cells4Life +Cord Collection Kit provided by us to select, clean and cut approximately 10-15cm of the umbilical cord.

Your obstetrician or midwife will then place the length of cord into a sterile container and label it before placing it together with the blood bag inside the Cells4Life Collection Kit box.

# 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, where collection of the cord blood may distract from the care of mother or baby, the procedure should not be carried out.

# What is the difference between private and public cord banks?

Mothers who give birth at certain hospitals can choose to donate cord blood voluntarily to the public cord bank. However, once donated, the sample will be used for anyone with a clinical need.

The sample will not be available for use by the donor, as this is prohibited under these banks' accreditation standards. Private storage is the only way to guarantee a perfectly matched sample and ready availability should your child need it.

<sup>&</sup>lt;sup>1</sup> Broxmeyer, H.E., Lee, M-R, Hangoc, G., Cooper, S., Prasain, N., Kim, Y-J, Mallett, C., Ye, Z., Witting, S., Cornetta, K., Cheng, L., and Yoder, M.C. 2011. Hematopoietic stem/progenitor cells, generation of induced pluripotent stem cells, and isolation of endothelial progenitors from 21- to 23.5-year cryopreserved cord blood. Blood. 117:4773-4777. PubMed: PMC3100689

<sup>&</sup>lt;sup>2</sup> DOI: 10.1089/ten.tea.2013.0073

<sup>&</sup>lt;sup>3</sup> NHSBT Effect of delayed clamping on cord blood donation



# Checklist Keep the following checklist to hand to ensure you have our contact details within reach. We're here if you need assistance, so please don't hesitate to contact us. Call us to confirm your chosen hospital's policy and to discuss who can procure your sample. Ask details about the service options and your needs. Review, complete and return the Service Agreement. Receive your state-of-the-art Collection Kit from Cells4Life. Pack Collection Kit with your maternity bag. Call your Cells4Life representative when you start labour. **Contact Details** We recommend you note the name of your Cells4Life contact. You may also like to store this information in your mobile phone. Your Cells4Life contact is: ..... Their telephone number is: ..... Your Collection Kit will only be dispatched when you provide informed consent for the service and

payment of the initial deposit.

# January 2015 - Details correct at the time of going to print

# the experts in stem cell processing...

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