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AABB/ABHH Accredited Blood Centers and Transfusion Services

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- AABB Accredited Hematopoietic Progenitor Cell (HPC) Facilities
- AABB Accredited Somatic Cell Facilities
- AABB Accredited Cellular Therapy Clinical Services

AABB Accredited Immunohematology Reference Laboratories

AABB Accredited Molecular Testing Laboratories

AABB Accredited Perioperative Services

AABB Accredited Relationship (DNA) Testing Facilities

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Umbilical Cord Blood Donation FAQs

Foreword: These questions are intended to assist with educating the public. They are not intended to be used as part of marketing material by any entity. Furthermore, the content reflected herein represents commonly asked questions and are not reflective or representative of AABB *Standards*.

What are umbilical cord blood cells?

Umbilical cord blood (UCB), once regarded as biological waste, has become an accepted source of hematopoietic stem cells/hematopoietic progenitor cells (HSCs/HPCs), similar to those found in bone marrow and peripheral blood. These cells can be used to replenish a patient's immune system by providing stem cells for transplantation, just as bone marrow or peripheral blood stem cell transplants can be used to treat malignant diseases such as leukemia and non-malignant diseases such as immune deficiencies and severe aplastic anemia, and congenital disorders such as sickle cell anemia and thalassemia. UCB contains many types of blood cells but only the hematopoietic — or blood-making — stem cells in the UCB are currently useful for transplant. Other uses of UCB stem cells are currently undergoing research. Each source of HPCs (bone marrow, peripheral blood or cord blood) has advantages and disadvantages associated with its use in a transplant. Decisions about the most appropriate source of stem cells — which must be matched by tissue type to some degree with the recipient — must be made by each patient in consultation with his or her physician based on available options.

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How are cord blood cells collected? (See Video)

After the delivery of a newborn, the umbilical cord is clamped and then cut. A needle is then used to draw the blood from the umbilical cord vein into a collection bag. Since this happens after delivery, there is no pain or risk to mother or infant. The collection may take place either before or after delivery of the placenta, and techniques vary slightly among physicians. The UCB product is labeled and shipped to the processing facility for processing, freezing and storage. The volume collected varies but usually ranges from 50 to 200 ml (about one-half to one cup).

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Is every cord blood unit collected?

No. Each mother must be informed about cord blood collection and give consent for collection and testing. This ideally happens after reviewing information with her obstetrician during the last trimester. For private storage, the mother may enter into an agreement at any point during the pregnancy. This would include consent for storage and infectious disease testing. In public donation, consent should begin before the onset of labor when the donating mother is able to fully understand what is involved and is not distracted or under anesthesia. If this is not possible, other options such as partial consent before delivery and follow-up after delivery may be utilized for public banking.

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The facilities I've contacted all use different processing and storage techniques. How do these techniques work? What is the best way to process and store cord blood?

Cord blood banks use a variety of processing and storage techniques, with each option offering advantages and disadvantages.

When UCB is received at a processing facility, the unit and accompanying paperwork are inspected and reviewed. The product is then reduced of the red cell and/or plasma components in preparation for cryopreservation (freezing). Procedures and methods for this part of the process vary. It is very important for facilities to validate the procedures used. Validation provides data to demonstrate the procedure works consistently and effectively at each facility.

Generally, there are three processing methods utilized in the field. Some programs use a density gradient solution to separate the different cell layers based on the principle of gravity. Though this method results in overall cell loss, it results in a more pure population of the layer that includes the stem cells — the mononuclear cell population of the white blood cells — and contains only a few red blood cells. Another widely employed method uses a starch solution to facilitate the depletion of red blood cells. These procedures are performed because the red blood cells do not contribute any therapeutic benefit in a transplant and lyse, or rupture, upon thawing and are generally not desirable for the patient to receive. Other processing facilities reduce the volume of the product by depleting the liquid portion or plasma. Both processes result in a smaller volume for freezing while still recovering the stem cells. The process of plasma depletion minimizes stem cell loss but results in a larger volume for cryopreservation and storage and contains more red blood cells. Red blood cells are lysed during cryopreservation, and subsequent thawing

and the cell particles and their contents remain in the product for infusion.

A freezing solution, usually containing dimethyl sulfoxide (DMSO), is added to the product, which is then frozen at a controlled rate to slowly freeze the cells without damaging them. DMSO is a cryoprotectant that helps protect the cells during this process and when stored at cold temperatures. The product is then cooled before placing into the storage freezer to avoid the shock and subsequent damage of immediate transfer into liquid nitrogen. Cooling at a controlled rate had been shown to result in better viability (more live cells) when thawed. Controlled rate freezing involves the use of equipment, including a computer, to freeze cells at an ideal, set rate for the cooling process. Alternative methods may be used for freezing that do not include a controlled rate freezer. In these cases, facilities should have validated their procedure to demonstrate the procedure results in a viable product upon thawing. In general, methods used in clinical laboratories involve bringing the cells to -80 C or colder prior to transfer into a storage tank. The storage tank contains racks or boxes into which the labeled, frozen product is placed. Nitrogen in its liquid state is at -196 C (-320 F) and is used to keep the product frozen. The cord blood storage facility should have a system to monitor the temperature and to alert staff in the event of a failure so that products may be transferred to another tank if necessary.

When a patient is identified for transplant, the selected product is shipped to the transplant facility and eventually thawed for infusion into the patient. Some transplant centers wash UCB products and others do not. Washing removes the lysed red blood cells but also results in some overall cell loss in the product. The lysed red blood cells may or may not have an adverse effect on the patient, and the decision whether to wash or not may be based on the processing facility's recommendations, the patient age and condition, and transplant center's practices.

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Should cord blood be stored in bags or vials?

AABB encourages innovations and improvements in technology and does not endorse any one method or manufacturer over another. This includes encouraging improvements in the collection, processing and storage of UCB products. Since most products are collected into a bag or other container before transfer to a processing facility, no system is completely "closed." Even the product (UCB) entering the container may not be sterile. Therefore, facilities operate on a spectrum of semi-closed or functionally closed processing (including collection) and there is no uniformly accepted definition or criteria to define such a system. The practice is based on the theoretical deduction that the number of entries or exposures to the environment that a product receives, the higher the chance for accidental contamination.

The bag versus vial storage debate is quite controversial. Early work with cord blood processing in research labs included the use of "cryovials." These small vials are about the size of an adult pinky and are relatively inexpensive. The UCB product is divided among several vials, which are usually placed into small boxes for storage. Proponents of this storage container assert that if science ever advances to the point where only some of the product is needed, the entire UCB unit will not have to be thawed. Products can generally only be thawed once without losing a significant number of live stem cells. The vials also occupy relatively less storage space and, therefore, permit more products (patients) to be stored in the storage tank. On the other hand, the small vials may be more difficult to label with all of the required information.

Specially designed bags intended for cryostorage have also been developed. These bags cost more and

may occupy a larger amount of freezer space than vials. One advantage of using bags is that they render a more “closed” rather than an “open” system, thereby reducing the risk of accidental contamination. Another advantage to the bag system is that it permits the unit to have integral segments of tubing. AABB requires that integral segments be attached to cord blood units for subsequent testing. Integral segments are created when the tubing leading from the storage container is sealed to provide little portions or “segments” of product, which can be used for subsequent or confirmatory testing of the product if needed. This is important because banks sometimes receive several products at once, and while procedures are in place to prevent mix-ups, questions regarding identity may occur. The availability of attached segments or an equivalent system provides a higher level of assurance that the test sample material can be traced to the original product if needed for confirmatory or additional testing before the product is distributed for transplant.

Other containers: As technology evolves, other containers or processes may be developed which meet the intent of the *Standards*. The intent is to ensure that the sample for additional testing is from the product. Such methods would currently require review and approval by the AABB Cellular Therapy Standards Program Unit.

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Are all UCB banks the same?

No. There are both private and public cord blood banks. Some facilities may offer both services, but the products are specifically dedicated for one use or another. In both cases, the mother gives consent, but the screening and testing of the mother and product may differ. The Food and Drug Administration, which regulates this industry in the United States, requires registration of both public and private cord blood banks.

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What are public cord blood banks?

Public cord blood banks process and store UCB products for public use. The facility has a minimum volume (and cell number) it will accept. These minimums are based on what will likely be adequate for a transplant patient. Products that do not meet these or other requirements are discarded or used for research (according to the consent that was signed). Some public banks state that one-third to three-quarters of the products they receive are not adequate for a transplant for one reason or another. Since it will most likely be many years before the product is used, a very thorough medical history and screening is performed on the mother. A family history must also be included to reduce the risk of conferring a genetic disorder through the transplant product. Blood samples from the mother and product are required for a variety of tests, including infectious disease testing and tests for the detection of contamination by bacteria. All information regarding the donating family is maintained in strict confidentiality.

Each person has a unique tissue or Human Leukocyte Antigen (HLA) type. Likewise, each UCB donation is a unique combination of the donor’s parents. Each UCB unit is HLA-typed and its cellular contents characterized. This information is entered into a database so that physicians will have access to it when looking for a patient “match.” These products are available to anyone who needs them and are not set aside for the specific use of the donor or the donor’s family members. Public cord blood banks do not charge a fee to the donor and recover their costs by charging the patient (or insurance) a fee when the unit

is used. Unfortunately, not every hospital is associated with a public bank, so not every donor may be able to participate.

The U.S. Congress has passed legislation allocating resources for a national cord blood inventory program. One purpose of this legislation is to increase the number and diversity of cord blood products available to the public. Minority populations are significantly underrepresented in the public inventory, so patients from a minority population may have more difficulty finding a matched cord blood unit.

Quick Link:

Be the Match

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What are private banks?

Private banks process and store the UCB product specifically for the donor and/or family. Since the bank may not be associated with a particular hospital, the mother is sent a collection kit to give the health care provider on the day of delivery. The kit contains the collection bag, labels and other materials needed for collection and shipping to the processing facility. The parent(s) pay an initial processing fee and then typically an annual storage fee. The details of this arrangement, including transport, shipping responsibilities, ownership and liability issues, should be described in the contract between the donor and bank. Since the product is intended only for use within the family, donor screening, tissue typing and other tests may or may not be performed on the unit. These policies vary among private banks. It is important to note that units stored in a private bank cannot be "crossed over" for public use unless all of the consent process, screening, infectious disease testing, and tissue typing are complete and acceptable. The cord blood bank should be able to provide a report with laboratory data for any test results as well as consultation on interpretation of these results.

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What does AABB accreditation mean?

AABB publishes voluntary standards for cellular therapy product services, including cord blood banking. These standards augment, rather than replace, any federal or state requirements. The standards describe the minimum acceptable requirements for facilities providing these services. These stringent standards cover all aspects of operation, including:

- A process for approval of vendors providing supplies.
- The consenting, donor screening and collection process.
- Product qualification, testing, processing, storage and release.
- Equipment and facility maintenance.
- A process for personnel selection and training.
- A process to monitor and improve quality of services.

While the AABB standards cover these items, it should be noted that the standards require a framework, plan and system for each item. The system includes written policies, processes and procedures. Except in a few cases such as testing for infectious diseases, the standards do not specifically prescribe how each of these may be done. The process is analogous to baking a cake. AABB would require a recipe, the proper

materials, and a beautiful, iced, tasty cake at the end of the process. AABB would not specify which brand of eggs to use and whether a boxed cake mix might also be acceptable.

When a facility believes it complies with these standards, it applies for accreditation by AABB. This involves a detailed and lengthy application process. The facility is then assessed by an objective team with experience in the cord blood field. Any evidence the team finds of non-compliance with the standards is brought to the attention of the bank, and corrective action must be taken before accreditation is granted. Accreditation is then granted for two years. AABB tracks customer complaints and follows up on any reported deficiencies. Only cord blood banks with a current accreditation have permission to use the AABB logo, and AABB investigates reports of misrepresentation or fraudulent use once the misuse is brought to its attention.

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How long can cord blood be stored?

No one knows for sure the shelf life of cord blood. Successful bone marrow transplants have been reported with products stored for more than 10 years, though the final expiration date for such products has not been established. Published studies indicate that UCB stem cells cryopreserved for 21-23.5 years have manifested biologic qualities equal to those at the time they were frozen.[1] AABB requires stability studies so that facilities can begin to collect this data.

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What are the chances I will need my child's UCB product?

Most transplant physicians discourage using an autologous cord blood unit in the cases of childhood leukemia and other disorders as the stem cells in the unit may also have a genetic defect or predisposition to disease. Also, cells from another person might better fight the leukemia than the child's own when used for a transplant. Some of the products collected for private storage are used for allogeneic sibling transplants. Cord blood transplants in children with malignant or non-malignant disease from an HLA-matched or one antigen disparate donor demonstrate a 10-fold lower incidence of graft-versus-host disease than that seen after transplantation with an HLA-matched bone marrow obtained from a sibling.[2] Calculations vary among statisticians and organizations regarding the chances of using a stored cord blood product. The Center for International Blood and Marrow Transplant Research (CIBMTR) has published data on the likelihood a single individual would qualify for an autologous or allogeneic HCT according to current indicators. This statistic is 1/200 by the time an adult reaches 70 years of age (www.CIBMTR.org). Others report a likelihood of one in 2,700.[3]

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I've heard that they may be able to use cord blood to treat heart disease, spinal injuries and other disorders. Is that true?

It remains to be seen if new technology derived from stem cell transplantation will lead to the treatment of disorders such as multiple sclerosis (MS) and Parkinson's disease as well as spinal cord injuries. So far, these efforts have primarily been limited to the research laboratory and have not produced benefits in patients. Conceptually, stem cells needed to treat disorders such as MS, Parkinson's and injuries

responding to regenerative treatment such as heart attacks can be derived from the patients themselves when needed.

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What if there is a genetic disease in my family?

While several organizations including the American Academy of Pediatrics and the Royal College of Obstetricians and Gynaecologists recommend public banking over private, exceptions are made for cases in which a sibling has a disease that can be treated with a stem cell transplant as in the case of some genetic diseases. This could include diagnoses such as pediatric malignancies, congenital immunodeficiency syndrome, a hemoglobinopathy or lysosomal storage disease. Each family should discuss these issues with a health care provider familiar with the situation.

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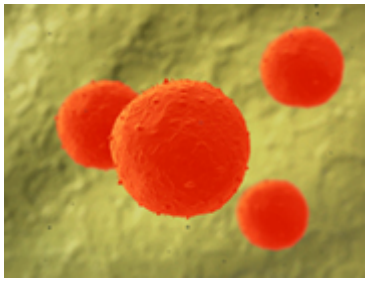

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