Florida Cord Blood Company Seeing Significant Improvement in Bone Marrow Engraftment Times

By Donald Hudspeth, BS(CLS), MT(ASCP) and Sara Irrgang, MD, FCAP

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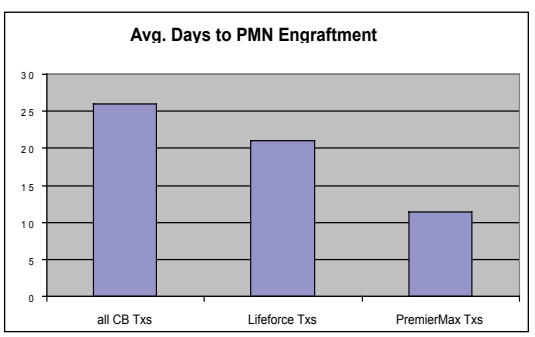
Located in Altamonte Springs, Lifeforce Cryobank Sciences, Inc. is a local umbilical cord blood bank that specializes in public and private stem cell processing and cryopreservation. Lifeforce has operated in the Central Florida area since 1993, and to date has processed over 15,000 cord blood units from across the United States. In addition to collecting, processing and banking umbilical cord blood stem cells, the company provides consulting services to help organizations develop and operate high-quality cord blood banks, and offers educational training programs for healthcare professionals.

Recently, Lifeforce launched its Cord For LifeSM cord blood banking program. Under this program private clients can store their baby's cord blood stem cells (CBSC) for future needs or moms-to-be can donate their baby's cord blood to the general public through the National Marrow Donor Program's (NMDP) Be The Match® Registry. Public donation, which has no cost to the donor, makes CBSC available to anyone in the world in need of a stem cell transplant to treat over 75 diseases.

The Cord For LifeSM program utilizes a revolutionary new processing system, branded as PremierMax-CBSM, which significantly reduces red cell contamination in the transplant product while recovering an equal or higher number of stem cells (when compared to other automated and traditional methods). PremierMax-CBSM also reduces the level of DMSO required to adequately preserve the cells during the freezing process, thereby reducing potential recipient exposure to this sometimes toxic cryoprotectant.

PremierMax-CBSM uses 2 unique reagents combined with individual unit Quality Control by highly trained technicians, to produce a superior final transplantation product. The processing reagent is PrepaCyte®-CB, which demonstrates an unrivalled ability to remove red blood cells over any other method on the market today. Red cell reduction reduces the amount of free hemoglobin in the thawed product infused to the recipient, thereby increasing the safety of the infused product. Additionally, PrepaCyte®-CB has shown in clinical trial and independent evaluation to increase the final stem cell population recovered, most significantly in the post-thaw colony forming assay which indicates functionality of the stem cells for engraftment.

The second key reagent in PremierMax-CBSM is the freeze media, CryoStor® CS10. CryoStor is specifically designed to protect cells at ultralow temperatures, unlike traditional cryopreservation reagents. This results in improved cellular transition through phase change from a liquid blood product to the frozen state for long-term storage, and again during thawing prior to infusion. During our validation of CryoStor® CS10, it was demonstrated that a less concentrated amount of the cryoprotectant reagent DMSO could be used in the freezing process while maintaining acceptable cellular functionality post-thaw.



The most important aspect of any change in status quo is the resulting effect of the change. Historically, the lower stem cell dose of a CBSC product when compared to a bone marrow or peripheral blood stem cell collection resulted in a longer time for bone marrow reconstitution (or engraftment). This led to early beliefs that CBSC could only be useful for pediatric patients or small adults. It was also realized that CBSC would typically result in longer periods of non-immunity, resulting in longer hospital stays for the recipient, even though GvHD is typically reduced.

Current data from over 20,000 CBSC transplants worldwide, shows an average time to PMN engraftment (PMN cell count >500 for 2+ days) is 25-27 days. In fact, our own historical data shows a comparable average PMN engraftment time of 21 days for units processed before our change to PremierMax-CBSM. Following our change in processing method, we are currently seeing an average time to PMN engraftment of only 11.33 days. Even more exciting is that independent data from another NMDP member cord blood bank that also uses PrepaCyte®-CB as it's processing reagent mirrors our data from Lifeforce (poster abstract to be published at AABB Annual Meeting 22-25 Oct., 2011).

As you can appreciate, a nearly 10 day reduction in the length of hospital stay, especially for a critically ill patient with no immune function, is highly significant. Having a readily available stem cell source product that can rival the engraftment time of marrow or peripheral blood sources, with a reduced risk of GvHD, and a significantly increased HLA-matching potential would create a major shift in the paradigm. Cord blood products have already begun to outpace marrow as a source for stem cell transplantation. With significant results such as these and new, exciting therapies being developed worldwide, the usefulness of cord blood stem cells will only increase over time. As more and more PremierMax-CBSM processed CBSC units are transplanted worldwide, Lifeforce will continue to monitor and analyze the engraftment data. A 2-site joint publication is expected in 2011 to further analyze the significance of the findings over a broader range of CBSC units, diseases, and transplant centers to eliminate other possible factors for the decreased engraftment time. We feel this finding could create a new excitement in the cord blood transplantation industry and provide a remarkable benefit to patients in need of life saving stem cell transplants.

Lifeforce Cryobanks is located at 270 Northlake Blvd., Suite 1012 in Altamonte Springs, FL 32710. For additional information please call 1-800-869-8608 or visit www.LifeforceCryobanks.com.

Donald Hudspeth BSCLS, MT (ASCP) is Chief Operating Officer, Lifeforce Cryobanks.Mr. Hudspeth has over 17 years of clinical laboratory experience as a certified Medical Technologist (ASCP), including ten years with the University of North Carolina Hospitals. Mr. Hudspeth is licensed by the State of Florida as a Clinical Laboratory Supervisor in Immunohematology, Hematology, Serology, Clinical Chemistry, Molecular Pathology and Microbiology as well as a Clinical Laboratory Scientist, is a registered Technologist with the American Society of Clinical Pathologists and a member of the American Society of Blood and Marrow Transplantation (ASBMT). He has also enjoyed teaching Immunology to Clinical Laboratory Science and medical school students at UNC while working in the UNCH clinical labs.

At Lifeforce Cryobanks, Mr. Hudspeth serves as Chief Operating Officer, overseeing all operations and the daily laboratory operations to ensure that the highest quality in all aspects of donor selection and cord blood collection, processing, and storage is maintained. He also works with Quality Assurance to ensure full compliance by Lifeforce Cryobanks to all applicable regulations. Additionally, Mr. Hudspeth served as the Clinical Investigator for Lifeforce Cryobanks as they evaluated and approved a new processing methodology to isolate stem cells from cord blood while depleting the unwanted red cells.

Mr. Hudspeth works with groups, individuals, or government agencies to bring cord blood banking to countries around the world. He is responsible for training medical professionals worldwide in cord blood processing. In addition, he travels overseas to assist in the initial setup and implementation of the new facilities to ensure their compliance and quality. Mr. Hudspeth has assisted in opening new cord blood facilities in Europe and in Southeast Asia.

Sara Irrgang, MD is Chief Medical Director, Lifeforce Cryobanks. During the last two years of Medical School, Dr. Irrgang was in the United States Navy 1915 Ensign Program and completed a clerkship at the Naval Hospital at Charleston, South Carolina as well as a research clerkship at the Naval Aerospace Institute at Pensacola, Florida. Dr. Irrgang completed her four year Pathology residency at Baylor University Medical Center, and her internship at the University District Hospital, Rio Piedras in San Juan, Puerto Rico. Currently, Dr. Irrgang is Board Certified in Anatomic and Clinical Pathology and licensed in the states of South Carolina, Texas, New Jersey and Florida and she is an Associate Medical Examiner at the District Nine Medical Examiners Office. Dr. Irrgang is a fellow at numerous organizations including; The College of American Pathologists, National Association of Medical Examiners, Florida Association of Medical Examiners, Seminole County Medical Society, and the Florida Medical Society. ■