GE Healthcare

ThermoGenesis AXP AutoXpress Platform and BioArchive System for Automated Cord Blood Banking

thermogenesis

*Ludy Dobrila, Ph.D.[1], Shanlong Jiang, M.D.[1], **John Chapman, Ph.D.[2]**, Dennis Marr, Ph.D.[2], Karen Kryston, B.S., M.T.[2], Pablo Rubinstein, M.D.[1],*
[1]National Cord Blood Program, New York Blood Center, New York, NY, U.S.A [2]ThermoGenesis Corp., Rancho Cordova, CA U.S.A.

BACKGROUND: Good tissue practices (cGTP) in cord blood banking require product uniformity and reproducible mononuclear cell recovery and viability, suggesting that automation could be critical to facilitating cGTP-compliance for cord blood banks. Processes that lend themselves to automation are cord blood volume reduction, controlled rate freezing, storage and retrieval that avoids unnecessary transient warming events. We have evaluated the AXP AutoXpress™ Platform (AXP) that allows for automated volume reduction in a closed system. The AXP consists of a micro-processor-controlled device and a disposable closed blood bag set that provides for the separation of cord blood into a freezing bag, an erythrocyte bag and an excess plasma bag. The mononuclear cell product is concentrated into a uniform volume in the freezing bag, ready to be cryoprotected and fully compatible with the BioArchive™ System, a system that allows the controlled-rate freezing, liquid nitrogen storage and retrieval of approximately 3,600 cord blood units.

Figure 1

Figure 2

STUDY DESIGN: The efficiency with which cord blood hematopoietic progenitor cells can be concentrated into the freezing bag of the AXP bag set was determined using the CD34 cell marker and colony-forming unit (CFU) counts as principal indices. The product was cryoprotected with 10% DMSO, frozen in the BioArchive system, stored for 3-4 weeks and then retrieved and thawed using the standard clinical protocol. Twenty-eight consecutive cord blood units were evaluated for cell recovery by measuring the collection and product volumes, the hematocrit and the counts of total nucleated cells (TNC), mononuclear cells (MNC), CD34+ cells and CFU, before and after AXP processing. We also determined these indices after freezing, storage in the BioArchive System and thawing.

RESULTS: Results are presented as the mean ± S.D. for all values. The starting volume of cord used in this study was 100 ± 18 ml (range 72 to 121 ml). The AXP process achieved MNC fraction volumes of 20.0 ± 0.7 ml (range 19-20 ml) with a final average hematocrit of 29 ± 4% (range 26-35%). The post-processing recovery of CD34+ cells was 98.2 ± 8.0% (range 84-114 %) and those of CFU 94.6 ± 7.0% (range 74-105 %), of MNC 97.9 ± 4.9% (range 89-112%) and of TNC 84.8 ± 9.2% (range 69-101%). Less than 1% of TNC were lost into the excess plasma bags. Post-thaw the recoveries of CFU and viable CD34+ cells were 96 ± 4.8% (range 85-103%) and 94 ± 2.1% (90-97%), respectively.

CONCLUSIONS: The AXP efficiently and reproducibly separates cord blood mononuclear and CD34+ cells into a consistent, uniform volume. These cells retained their viability post BioArchive freezing, storage and retrieval (>94%). Thus, AXP coupled with the BioArchive System supports a very high quality standard for automated cord blood processing.

For additional information, contact John Chapman at jchapman@thermogenesis.com.

imagination at work

PROCESSING CORD BLOOD USING THE AXP AUTOXPRESS PLATFORM

Collect placental blood into CPD

Spike or sterile dock collection bag to AXP processing set and transfer blood to processing/ plasma bag.

Load AXP processing set into AXP device

Centrifuge at 1,400 x g for 20 minutes to segregate WBC at RBC/plasma interface and 80 x g for 20 minutes to express the RBC to the RBC bag and WBC to freezing bag

Remove bag set from AXP device

After separating freezing bag and cryoprotectant line from bag set, introduce 5 mL DMSO/Dextran 40 into freezing bag

Tube seal and separate freezing bag from cryoprotectant line

Table 1:
Control of Volume Reduction by AXP Processing

Pre-process cord blood volume (mL)	100 ± 18
Post-process reduced cord blood volume (mL)	20.0 ± 0.7
Post-process reduced cord blood hematocrit (%)	29 ± 4

Table 2:
Nucleated and CFU Cell Content in Freezing Bag

CELL POPULATION	PRE-PROCESS (CORD BLOOD)	POST-PROCESS (HARVESTED BC FRACTION)
Total Nucleated Cells x 10^6	1252 ± 346	997 ± 235
Total Mononuclear Cells x 10^6	516 ± 189	494 ± 166
Total CD34+ Cells x 10^3 (% Viable)	3635 ± 1767 (99.7 ± 0.3)	3619 ± 1919 (99.7 ± 0.2)
CFU x 10^6	2.6 ± 1.1	2.4 ± 1.0

Figure 3:
Recovery of Cord Blood Cells in Buffy Coat Fraction by AXP AutoXpress Platform.

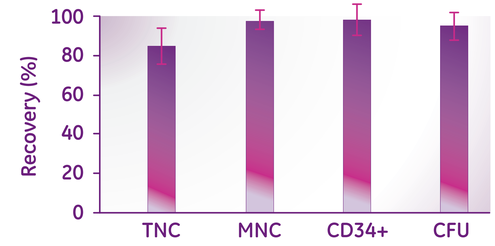

Table 3:
Nucleated Cell Loss (% of Total) in Packed RBC and Plasma Bags

COMPONENTS	TOTAL NUCLEATED CELL LOSS (% OF TOTAL)	CD34+ CELL LOSS (% OF TOTAL)
RBC	18 ± 10	0.3 ± 0.3
Plasma	0.7 ± 0.3	—

Figure 4:
Post Thaw Viability of CD34+ Cells and CFU Recovery