(archived) CBB Survey 2015 WO-1345

CBB Survey 2015

1. General Information	
Name of CBB	LifeCord/LifeSouth Community Blood Centers
CBB Director	Yesi
CBB Director	Sevilla
Address	4039 Newberry Road
Address	32607
Address	Gainesville
Phone Number	1 352 224-1600
Website	www.lifesouthcord.org
Date CBB Started Collecting Cord Blood Units (month/day/year)	06/01/1998
Number of Public Cord Blood Units	6,216
Planned Number of Public Cord Blood Units Stored in 2015	1,000
Lists on BMDW	No
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	National Marrow Donor Program (NMDP)
2. Cord Blood Units in Inventory	
Current Processing Method	Liquid+ red auto
Previous Processing Method	Vapour+ red manual
Previous Processing Method	Vapour+ plasma only
Year Current Process Method Started	2012
Percent of Units Plasma and RBC Reduced (manual)	5
Percent of Units Plasma and RBC Reduced (automated)	28
Percent of Units RBC Reduced Only	67
Percent of Units No Volume Reduction	0
3. Accreditations, Licenses and Certifications	
FACT-Netcord	Yes
AABB	No
Competent Authority/ National Health Authority	Yes
Name of Competent Authority	FDA
Audited by National Stem Cell Registry	Yes
ISO	No
Other	QC Lab - CLIA

4. Cord Blood Collection	
Current Collection Practice Is the collection In/Ex -Utero or both?	In-utero
Collection Bag	Single needle
Agitation during Collection	Manual
5. Conditioning/Transport from Collection Site to CBB	
Transport Conditions	Qualified transporter
Transport Conditions	Insulating transport container
Transport Conditions	Passive refrigeration system
Transport Conditions	Electronic temperature probe
Transport Conditions	Air transport
Transport Conditions	Ground transport
Temp. for Storage and Transport	Other (lower limit +1-35°C, higher limit +6-30°C)
6. Pre-Processing Evaluation	
Completed Prior to Accepting a CBU	Medical history, collection report, informed consent
Completed Prior to Accepting a CBU	Labeling criteria
Current Threshold for Accepting a CBU	Viability threshold CD45
Method for CD34 Remuneration	ISHAGE guidelines
External Proficiency Testing for QC of FACS Lab	Stem cell technology, CAP
Post Processing/ Pre Freeze CD34+ Cell Count	Yes
Time from Collection to Processing	up to 48H
7. Processing and Packaging	
Pre Freeze Processing Methods- Unit in Inventory	SEPAX
Pre Freeze Processing Methods- Unit in Inventory	Volume reduction with HES-Manual
Pre Freeze Processing Methods- Current	SEPAX
Additives Currently in Use	HES
Current Cryopreservation Method	BioArchive
Current Cryoprotectant Additive	Ready for use DMSO-Dextran
Current Cryobag	Single bag 80:20
Current Target Cryopreservation Volume (mL)	29.0
Current Packaging for Storage	Overwrap
Current Packaging for Storage	Canister
Current Packaging for Storage	One attached segment
Current Packaging for Storage	More than one segment
8. Testing	
Extra Material Currently Stored	Cord blood DNA
Extra Material Currently Stored	Cord blood material for DNA extraction
Extra Material Currently Stored	Plasma/cord blood
Extra Material Currently Stored	Maternal DNA
Extra Material Currently Stored	Maternal material for DNA extraction

Extra Material Currently Stored	Maternal plasma/serum
Current Post Processing Threshold for Accepting a CBU for Public Use TNC	50
Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Single Platform	1.25
Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Double Platform	NA
Current Post Processing Threshold for Accepting a CBU for Public Use CFU-GM	Growth
Current Post Processing Threshold for Accepting a CBU for Public Use CFU	Growth
Current Post Processing Threshold for Accepting a CBU for Public Use Viability	85
9. Storage	
Type of Storage Container Used	BioArchive
Type of Storage Container Used	Conventional storage tank vapor phase
Type of Storage Container Used	Conventional tank liquid phase
Monitoring of Storage	Centralized alarm system local
Monitoring of Storage	Centralized system remote monitoring
Monitoring of Storage	LN2 level
Monitoring of Storage	System default
Monitoring of Storage	Temperature monitoring
10. HLA Typing	
Current Level of HLA Typing at Time of Listing HLA-A	LR
Current Level of HLA Typing at Time of Listing HLA-B	LR
Current Level of HLA Typing at Time of Listing HLA-C	LR
Current Level of HLA Typing at Time of Listing HLA-DRB1	HR
Current Level of HLA Typing at Time of Listing HLA-DQB1	HR
Current Level of HLA Typing at Time of Listing HLA-DPB1	HR
Accreditation of HLA Lab	ASHI accredited lab
Average Turnaround Time for Extended HLA Typing Results in days	?10
Attached Segment Used for Confirmatory/ Verification Typing	Yes
Units Listed without Attached Segment and have not been Previously Typed on Attached Segment	No
Percentage of CBUs that have an Attached Segment	75-90%
Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement	Yes
11. Reservation and Cancellation Policies	
What Point is a CBU Reserved for a Patient	Shipment request
Length of Time a CBU can be Reserved in days	Other

Length of Time a CBU can be Reserved in days	30 days prior to shipment date and 30 days post shipment date
Reservation Fee	No
Reservation Cancellation Fee in Absence of Shipment Request	No
Can Reservation be Extended	Yes
Is a Unit Report Provided on a Unit that is Reserved for Another Patient	No
Is TC Informed when CBU is Released	Yes
12. Release and Shipment	
Hemoglobinopathy Screening Performed Prior to Release	Yes
Criteria to Ship a CBU Viability and Cell Count	85%
Current Packaging for Shipment to TC	Metal canister
Current Packaging for Shipment to TC	One attached segment
Current Packaging for Shipment to TC	Overwrap
Current Packaging for Shipment to TC	Protective sleeve
Current Packaging for Shipment to TC	3 or more segments
Current Packaging for Shipment to TC	2 attached segments
Time Between Shipment Request and Sending CBU	4 days-1 week
Fee for Shipment Cancellation	No
Dry Shippers Validated to Maintain Temperature of at least -150 for 48 hours Beyond Expected Arrival	Yes
Electronic Temperature Data Logger on All Dry Shippers	Yes
Who Selects Transport Company	Requesting transplant centre
Shape of Transport Container	Mushroom
13. Adverse Events Reporting	
Who are S(P)EARS Reported To Competent Authority	Yes
Who are S(P)EARS Reported To Internal Report	Yes
Who are S(P)EARS Reported To National Registry	Yes

14. Pictures of cord blood units in the inventory

15. Infectious Disease Marker (IDM) CURRENTLY performed.

Holiday Calendar

Team Calendars