CBB Survey 2015 WO-1397

CBB Survey 2015

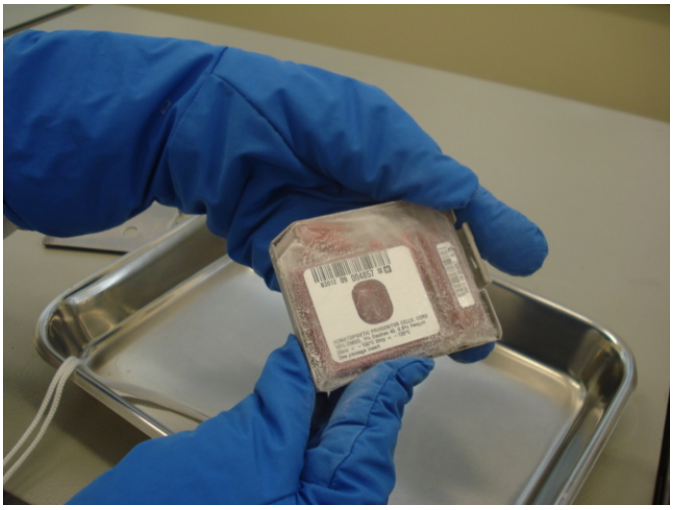
1. General Information	
Name of CBB	BSCUP HEMOSC
CBB Director	Andréa
CBB Director	Hoepers
Address	Av. Othon Gama D'eça
Address	n° 756
Address	Centro
Address	88015-240
Address	Florianópolis/SC
Phone Number	055483251-9791
Website	www.hemosc.org.br
Date CBB Started Collecting Cord Blood Units (month/day/year)	01/09/2009
Number of Public Cord Blood Units	686
Planned Number of Public Cord Blood Units Stored in 2015	247
Lists on BMDW	No
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	REDE BRASILCORD
2. Cord Blood Units in Inventory	
Current Processing Method	Liquid+ red manual
Current Processing Method	Liquid+ red auto
Year Current Process Method Started	2009
Percent of Units Plasma and RBC Reduced (manual)	1
Percent of Units Plasma and RBC Reduced (automated)	99
3. Accreditations, Licenses and Certifications	
FACT-Netcord	No
AABB	No
Competent Authority/ National Health Authority	Yes
Name of Competent Authority	ANVISA - Agencia Nacional de Vigilancia Sanitária
Audited by National Stem Cell Registry	Yes
ISO	Yes
Other	AABB Fact/Jacie
4. Cord Blood Collection	

Current Collection Practice Is the collection In/Ex -Utero or both?	Both
Current Antiseptic	Chlorhexidine
Collection Bag	Double needle
Agitation during Collection	Automatic
5. Conditioning/Transport from Collection Site to CBB	
Secondary Bag Used	Yes
Transport Conditions	Qualified transporter
Transport Conditions	Insulating transport container
Transport Conditions	Passive refrigeration system
Transport Conditions	Electronic temperature probe
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	interwiew
Method for CD34 Remuneration	ISHAGE guidelines
External Proficiency Testing for QC of FACS Lab	Yes, other
External Proficiency Testing for QC of FACS Lab	Controlab
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)	25.0
Current Packaging for Storage	Overwrap
Current Packaging for Storage	Canister
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	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	90
9. Storage	
Type of Storage Container Used	BioArchive
Monitoring of Storage	Centralized alarm system local
Monitoring of Storage	Centralized system remote monitoring
Monitoring of Storage	LN2 level
10. HLA Typing	
Current Level of HLA Typing at Time of Listing HLA-A	IR
Current Level of HLA Typing at Time of Listing HLA-B	IR
Current Level of HLA Typing at Time of Listing HLA-C	HR
Current Level of HLA Typing at Time of Listing HLA-DRB1	IR
Current Level of HLA Typing at Time of Listing HLA-DQB1	
Current Level of HLA Typing at Time of Listing HLA-DPB1	
Accreditation of HLA Lab	No 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	Yes
Percentage of CBUs that have an Attached Segment	90-100%
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	CBU report request
Length of Time a CBU can be Reserved in days	30
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
Criteria to Ship a CBU HLA Identity Testing	Yes
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	Separate segment
Time Between Shipment Request and Sending CBU	0-3 days
Fee for Shipment Cancellation	No
Dry Shippers Validated to Maintain Temperature of at least -150 for 48 hours Beyond Expected Arrival	Yes
Who Selects Transport Company	Requesting transplant centre
Shape of Transport Container	Mushroom
13. Adverse Events Reporting	
Who are S(P)EARS Reported To Internal Report	Yes

14. Pictures of cord blood units in the inventory



15. Infectious Disease Marker (IDM) CURRENTLY performed.

Holiday Calendar

Team Calendars