(archived) CBB Survey 2015 WO-1376

CBB Survey 2015

1. General Information	
Name of CBB	University of Colorado Cord Blood Bank
CBB Director	Brian
CBB Director	Freed
Address	12635 E. Montview Blvd
Address	Ste. 300
Address	80045
Address	Aurora
Phone Number	303-724-1306
Website	www.clinimmune.org
Date CBB Started Collecting Cord Blood Units (month/day/year)	11/12/1996
Number of Public Cord Blood Units	8,092
Planned Number of Public Cord Blood Units Stored in 2015	200
Lists on BMDW	Yes
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	NMDP
2. Cord Blood Units in Inventory	
Current Processing Method	Vapour+ red manual
Current Processing Method	Vapour+ red auto
Previous Processing Method	Liquid+ red manual
Previous Processing Method	Liquid- red manual
Previous Processing Method	Liquid+ red auto
Previous Processing Method	Liquid- red auto
Year Current Process Method Started	2009
Percent of Units Plasma and RBC Reduced (manual)	60
Percent of Units Plasma and RBC Reduced (automated)	40
3. Accreditations, Licenses and Certifications	
FACT-Netcord	No
AABB	Yes
Competent Authority/ National Health Authority	No
Audited by National Stem Cell Registry	Yes
ISO	No

Other	FDA Licensed #1855 FDA registered
4. Cord Blood Collection	
Current Collection Practice Is the collection In/Ex -Utero or both?	In-utero
Current Antiseptic	Chlorhexidine
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
Method for CD34 Remuneration	ISHAGE guidelines
External Proficiency Testing for QC of FACS Lab	CAP
Post Processing/ Pre Freeze CD34+ Cell Count	Yes
Time from Collection to Processing	Other
Time from Collection to Processing	Missing
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
Pre Freeze Processing Methods- Current	Volume reduction with HES manual
Additives Currently in Use	HES
Current Cryopreservation Method	Conventional CRF
Current Cryoprotectant Additive	Ready for use DMSO-Dextran
Current Cryoprotectant Additive	Other: DMSO Dextran compounded on site for each use
Current Cryobag	Single bag (one fraction)
Current Cryobag	Other: Some units are too lsrge for one bag and must be frozen in two bags of equal volume
Current Target Cryopreservation Volume (mL)	41.9
Current Packaging for Storage	Overwrap
Current Packaging for Storage	Canister
Current Packaging for Storage	More than one segment
Current Packaging for Storage	Other: Three viable TNC at 0.5ml - two for post thaw QC - one for FDA reserve sample after release
8. Testing	

Extra Material Currently Stored	Cord blood material for DNA extraction
Extra Material Currently Stored	Plasma/cord blood
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	NA
Current Post Processing Threshold for Accepting a CBU for Public Use Viability	85
9. Storage	
Type of Storage Container Used	Conventional storage tank vapor phase
Monitoring of Storage	Centralized system remote monitoring
Monitoring of Storage	LN2 level
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	IR
Current Level of HLA Typing at Time of Listing HLA-DRB1	HR
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	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	Yes
Percentage of CBUs that have an Attached Segment	75-90%
Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement	No
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	Other

Length of Time a CBU can be Reserved in days	until further notice
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
12. Release and Shipment	
Hemoglobinopathy Screening Performed Prior to Release	Yes
Criteria to Ship a CBU Viability and Cell Count	>= 70% post thaw viable cell aliquot
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
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	CBB
Who Selects Transport Company	Network Global Logistics for Domestic; World or Quick for INT
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