(archived) CBB Survey 2015 WO-1380

CBB Survey 2015

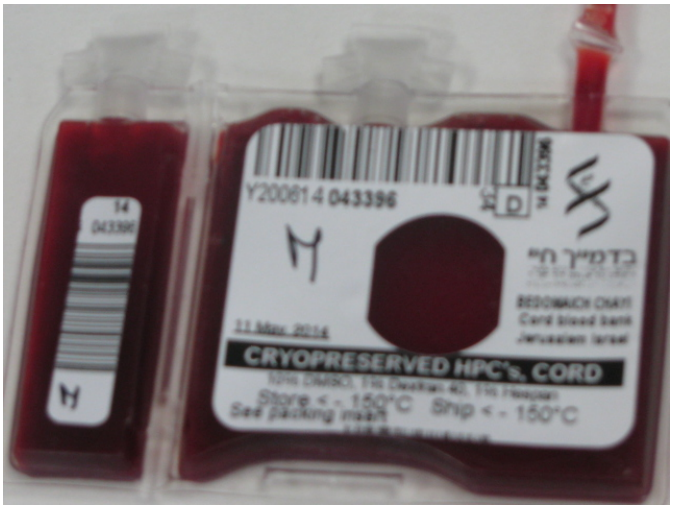
1. General Information	
Name of CBB	Bedomaich Chayi CBB
CBB Director	Gideon
CBB Director	Bach
Address	5 HaMarpe St.
Address	P.O.B. 50220
Address	91056
Address	Jerusalem
Phone Number	+972-2-6499899
Website	www.cordblood.org.il
Date CBB Started Collecting Cord Blood Units (month/day/year)	01/01/2006
Number of Public Cord Blood Units	4,784
Planned Number of Public Cord Blood Units Stored in 2015	600
Lists on BMDW	Yes
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	Hadassah Bone Marrow and CB registry, Jerusalem, Israel
2. Cord Blood Units in Inventory	
Current Processing Method	Vapour+ red manual
Current Processing Method	Vapour+ red auto
Year Current Process Method Started	2006
Percent of Units Plasma and RBC Reduced (manual)	85
Percent of Units Plasma and RBC Reduced (automated)	15
3. Accreditations, Licenses and Certifications	
FACT-Netcord	No
AABB	No
Competent Authority/ National Health Authority	Yes
Name of Competent Authority	Israeli ministry of health
Audited by National Stem Cell Registry	Yes
ISO	No
Other	GMP Certificate by the Institute for the Standardization and Control of Pharmaceuticals, Ministry of Health, Jerusalem, Israel
4. Cord Blood Collection	

Current Collection Practice Is the collection In/Ex -Utero or both?	In-utero
Current Antiseptic	Chlorhexidine
Current Antiseptic	Alcohol
Collection Bag	Single needle
Agitation during Collection	Manual
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
Method for CD34 Remuneration	ISHAGE guidelines
External Proficiency Testing for QC of FACS Lab	UKNEQAS
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
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 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	
PCR Performed on IgM+ Result	CMV
PCR Performed on IgM+ Result	EBV
Extra Material Currently Stored	Cord blood material for DNA extraction
Extra Material Currently Stored	Plasma/cord blood
Extra Material Currently Stored	Maternal plasma/serum

Current Post Processing Threshold for Accepting a CBU for Public Use TNC	100
Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Single Platform	1.50
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 Viability	80
9. Storage	
Type of Storage Container Used	Conventional storage tank vapor phase
Monitoring of Storage	Centralized alarm system local
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	IR
Current Level of HLA Typing at Time of Listing HLA-B	IR
Current Level of HLA Typing at Time of Listing HLA-C	
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	EFI accredited lab
Average Turnaround Time for Extended HLA Typing Results in days	3
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	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	Reservation request
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	reservation can be extended by request. a fee is charged for extending the reservation and it is discounted from the CBU release fee
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	Minimum 60% TNC recovery and 60% Viability
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	Transport rack
Time Between Shipment Request and Sending CBU	Other
Time to Prepare a Cord Blood Unit for Shipment	CBUs can be shipped within 3-4 days. it is recommended to request a CBU at least 14 days in advance for completing a CFU assay on a frozen sample from the attached segment
Fee for Shipment Cancellation	Yes
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
Who are S(P)EARS Reported To Transplant Center	Yes
Who are S(P)EARS Reported To WMDA	Yes

14. Pictures of cord blood units in the inventory



15. Infectious Disease Marker (IDM) CURRENTLY performed.

Holiday Calendar

Team Calendars