

CBB Survey 2015 WO-1360

CBB Survey 2015

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1. General Information	
Name of CBB	St.Eugenio Hospital
CBB Director	Italo
CBB Director	De Meis
Address	piazzale dell'Umanesimo 10
Address	00144
Address	Rome
Phone Number	0039 06 51002259
Website	cordbloodbank@aslrmc.it
Date CBB Started Collecting Cord Blood Units (month/day/year)	03/01/1995
Number of Public Cord Blood Units	846
Planned Number of Public Cord Blood Units Stored in 2015	70
Lists on BMDW	Yes
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	ITALIAN BONE MARROW DONOR REGISTRY IBMDR
2. Cord Blood Units in Inventory	
Current Processing Method	Liquid+ plasma only
Year Current Process Method Started	2010
Percent of Units Plasma and RBC Reduced (manual)	30
Percent of Units No Volume Reduction	70
3. Accreditations, Licenses and Certifications	
FACT-Netcord	No
AABB	No
Competent Authority/ National Health Authority	Yes
Name of Competent Authority	Centro Nazionale Sangue-Centro Nazionale Trapianti
Audited by National Stem Cell Registry	No
ISO	Yes
4. Cord Blood Collection	
Current Collection Practice Is the collection In/Ex -Utero or both?	Both
Current Antiseptic	Betadine
Collection Bag	Double needle

Agitation during Collection	Manual
5. Conditioning/Transport from Collection Site to CBB	
Secondary Bag Used	Yes
Transport Conditions	Qualified transporter
Transport Conditions	Unqualified transporter
Transport Conditions	Active refrigeration system
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	Transport report
Current Threshold for Accepting a CBU	Viability threshold CD45
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	No processing
Pre Freeze Processing Methods- Unit in Inventory	Optipress
Pre Freeze Processing Methods- Unit in Inventory	Other: Volume reduction manual
Pre Freeze Processing Methods- Current	Other: Volume reduction manual
Additives Currently in Use	No additive
Current Cryopreservation Method	Conventional CRF
Current Cryoprotectant Additive	DMSO
Current Cryobag	Single bag (one fraction)
Current Cryobag	Other: Two bags 50:50
Current Target Cryopreservation Volume (mL)	130.0
Current Packaging for Storage	Overwrap
Current Packaging for Storage	Canister
Current Packaging for Storage	More than one segment
Current Packaging for Storage	Additional separate segments
8. Testing	
PCR Performed on IgM+ Result	CMV
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	120
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 CD34 (10^6) Double Platform	NA
Current Post Processing Threshold for Accepting a CBU for Public Use CFU-GM	NA
Current Post Processing Threshold for Accepting a CBU for Public Use Viability	80
9. Storage	
Type of Storage Container Used	Conventional tank liquid phase
Monitoring of Storage	Alarm on individual tanks only
Monitoring of Storage	Centralized system remote monitoring
Monitoring of Storage	LN2 level
Monitoring of Storage	Lid opening
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	
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	9
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	below 50%
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
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

12. Release and Shipment	
Hemoglobinopathy Screening Performed Prior to Release	Yes
Criteria to Ship a CBU Viability and Cell Count	>40% / >50%
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	Separate segment
Time Between Shipment Request and Sending CBU	1-2 weeks
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	WORLD COURIER
Shape of Transport Container	Other
Shape of Transport Container	cylindrical in the cubic container
13. Adverse Events Reporting	
Who are S(P)EARS Reported To Competent Authority	Yes
Who are S(P)EARS Reported To National Registry	Yes
Who are S(P)EARS Reported To Transplant Center	Yes

14. Pictures of cord blood units in the inventory

15. Infectious Disease Marker (IDM) CURRENTLY performed.



WO-1360-IDM-2015.pdf

Holiday Calendar

Team Calendars
