

(archived) CBB Survey 2015 WO-1387

CBB Survey 2015

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1. General Information	
Name of CBB	Florence Cord Blood Bank
CBB Director	Riccardo
CBB Director	Saccardi
Address	Largo Brambilla, 3
Address	50134
Address	Florence
Phone Number	+39-0557947672
Website	www.cbbtoscana.it / www.aou-careggi.toscana.it/internet/index.php?option=com_content&view=article&id=477&Itemid=951&lang=it
Date CBB Started Collecting Cord Blood Units (month/day/year)	06/22/1994
Number of Public Cord Blood Units	2,148
Planned Number of Public Cord Blood Units Stored in 2015	120
Lists on BMDW	Yes
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	IBMDR
2. Cord Blood Units in Inventory	
Current Processing Method	Liquid+ red auto
Current Processing Method	Vapour+ red auto
Previous Processing Method	Liquid+ red manual
Previous Processing Method	Vapour+ red manual
Previous Processing Method	Liquid+ plasma only
Previous Processing Method	Vapour+ plasma only
Year Current Process Method Started	2008
Percent of Units Plasma and RBC Reduced (manual)	24
Percent of Units Plasma and RBC Reduced (automated)	74
Percent of Units No Volume Reduction	2
3. Accreditations, Licenses and Certifications	
FACT-Netcord	No
AABB	No
Competent Authority/ National Health Authority	Yes
Name of Competent Authority	CNT/CNS
Audited by National Stem Cell Registry	Yes

ISO	Yes
Other	IND Qualification, FDA listed
4. Cord Blood Collection	
Current Collection Practice <small>Is the collection In/Ex -Utero or both?</small>	Both
Current Antiseptic	Chlorhexidine
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	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
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	SEPAX
Pre Freeze Processing Methods- Unit in Inventory	Other: Volume reduction without HES
Pre Freeze Processing Methods- Current	SEPAX
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)	26.0
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	Toxoplasmosis
PCR Performed on IgM+ Result	EBV

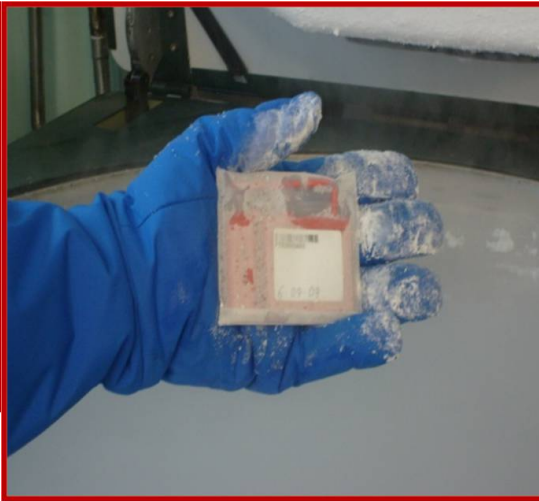
Extra Material Currently Stored	Cord blood DNA
Extra Material Currently Stored	Cord blood material for DNA extraction
Extra Material Currently Stored	Plasma/cord blood
Extra Material Currently Stored	Maternal material for DNA extraction
Extra Material Currently Stored	Maternal plasma/serum
Current Post 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 CFU	presence of growth
Current Post Processing Threshold for Accepting a CBU for Public Use Viability	90
9. Storage	
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	Temperature monitoring
10. HLA Typing	
Current Level of HLA Typing at Time of Listing HLA-A	HR
Current Level of HLA Typing at Time of Listing HLA-B	HR
Current Level of HLA Typing at Time of Listing HLA-C	HR
Current Level of HLA Typing at Time of Listing HLA-DRB1	HR
Current Level of HLA Typing at Time of Listing HLA-DQB1	LR
Current Level of HLA Typing at Time of Listing HLA-DPB1	LR
Accreditation of HLA Lab	EFI accredited lab
Average Turnaround Time for Extended HLA Typing Results in days	8
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	60
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	40
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	1-2 weeks
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	CBB
Who Selects Transport Company	The transport company (currently World Courier) is selected by IBMDR; some Transplantation Centers select the transport company for DNA.
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

14. Pictures of cord blood units in the inventory



Buffy-coat



HES conc



Whole CB



Plasma removal

15. Infectious Disease Marker (IDM) CURRENTLY performed.



WO-1387-IDM-2015.pdf

Holiday Calendar

Team Calendars

