(archived) CBB Survey 2015 WO-1348

CBB Survey 2015

1. General Information	
Name of CBB	Finnish Cord Blood Bank
CBB Director	Matti
CBB Director	Korhonen
Address	Kivihaantie 7
Address	00310
Address	Helsinki
Phone Number	+358 29 300 1010
Website	www.bloodservice.fi
Date CBB Started Collecting Cord Blood Units (month/day/year)	01/01/1998
Number of Public Cord Blood Units	3,358
Planned Number of Public Cord Blood Units Stored in 2015	0
Lists on BMDW	Yes
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	Finnish Stem Cell Registry
2. Cord Blood Units in Inventory	
Current Processing Method	Liquid+ red auto
Previous Processing Method	Liquid+ red manual
Year Current Process Method Started	2004
Percent of Units Plasma and RBC Reduced (manual)	15
Percent of Units Plasma and RBC Reduced (automated)	85
3. Accreditations, Licenses and Certifications	
FACT-Netcord	In process of accreditation
AABB	No
Competent Authority/ National Health Authority	Yes
Name of Competent Authority	Finnish Medicines Agency
Audited by National Stem Cell Registry	Yes
ISO	No
4. Cord Blood Collection	
Current Collection Practice Is the collection In/Ex -Utero or both?	Ex-utero
Current Antiseptic	Alcohol
Collection Bag	Double needle

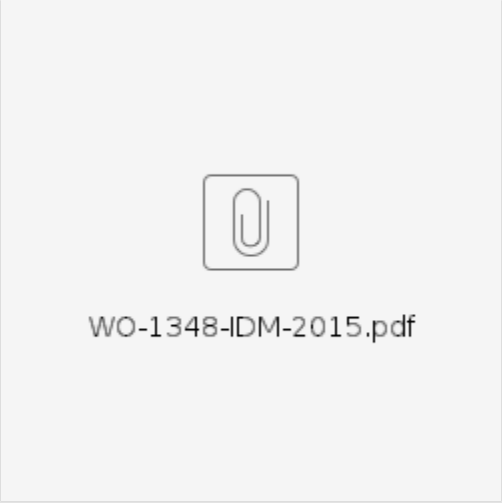
Agitation during Collection	None
5. Conditioning/Transport from Collection Site to CBB	
Secondary Bag Used	Yes
Transport Conditions	Qualified transporter
Transport Conditions	Insulating transport container
Transport Conditions	Passive refrigeration system
Transport Conditions	Electronic temperature probe
Transport Conditions	Ground transport
Temp. for Storage and Transport	Room temperature
6. Pre-Processing Evaluation	
Completed Prior to Accepting a CBU	Medical history, collection report, informed consent
Completed Prior to Accepting a CBU	Infectious Disease Markers (must be negative/non-reactive)
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
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	150
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	NA
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 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	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	EFI accredited lab
Average Turnaround Time for Extended HLA Typing Results in days	6
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	HLA typing request
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	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	90

Criteria to Ship a CBU HLA Identity Testing	Yes
Current Packaging for Shipment to TC	Metal canister
Current Packaging for Shipment to TC	Overwrap
Current Packaging for Shipment to TC	Protective sleeve
Current Packaging for Shipment to TC	2 attached segments
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	We suggest transport company and the requesting transplant centre must approve. We use World Courier.
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