CB banking specifics WO-1374

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Section 1 General Info

Question	CBB answer
The information has been reviewed in year :	
Name of the cord blood bank:	Carolinas Cord Blood Bank
Number of cord blood units the cord blood bank plans to store for public use (unrelated patients):	1,176

Section 2 Cord Blood Units in Inventory

Question	CBB answer
Current processing method(s):	
Plasma and RBC reduced (automatic)	checktrue
Plasma reduction only	checkfalse
Plasma and RBC reduced (manual)	checkfalse
RBC reduction only	checkfalse
Total Nucleated Cell Count (x10E7) of your cord blood units stored for Unrelated Patients (Public Use).	
< 125 :	19559
125 - 149 :	6640
150 - 199 :	5774
200 - 250 :	1550
> 250 :	481

Section 3 Cord Blood Collection

Question	CBB answer
Current practice for collecting cord blood:	In-utero and ex-utero
Current antiseptic:	Chlorhexidine + Alcohol
Collection bag:	Single needle
Agitation during collection:	Automatic

Section 4 Conditioning and transport from Collection Centre to cord blood bank

Question	CBB answer
Secondary bag used by the cord blood bank (sealed, plastic bag or similar to avoid any leakage):	yes
Transport conditions:	
Insulating transport container	checktrue
Active refrigeration system	checkfalse
Passive refrigeration system (gel, blocks)	checkfalse
Electronic temperature probe	checktrue
Non-electronic temperature probe	checkfalse
Qualified transporter	checktrue
Unqualified transporter	checkfalse
Air transport	checktrue
Ground transport	checktrue
Other,	checkfalse
Temperature range for storage and transportation of fresh product:	Defined (above +8°C)

Section 5 Evaluation

Question	CBB answer
Pre-processing Evaluation: Current threshold for accepting a cord blood unit for public use in the cord blood bank:	
Net weight in grams (excluding bag and anticoagulant) before processing	60 - 69.99 grams
TNC (10E7) before processing	< 125
Viability CD45 positive cells (%)	NA- not evaluated pre-processing
Viability CD45 positive cells (method)	
Viability CD34 positive cells (%)	NA- not evaluated pre-processing
Viability CD34 positive cells (method)	
Criteria that are completed before accepting a cord blood unit for public use in the cord blood bank:	
Medical History	checkfalse
Collection Report	checktrue
Informed Consent	checktrue
Maternal IDM results	checkfalse
Temperature and integrity of the bag	checktrue
Other,	checkfalse
Used method for CD34 enumeration:	Other: BD SCE Kit
The cord blood banks uses external proficiency testing for QC of the cord blood banks FACS lab:	yes
The cord blood bank performs post processing/pre-freeze CD34 cell count:	yes
Acceptable time from collection to processing:	24-48H

Section 6 Processing-Packaging

Question	CBB answer	
The pre-freeze processing method(s) cord blood bank uses at any sta	age in time:	
AXP	checkfalse	
SEPAX	checktrue	
Optipress	checkfalse	
Prepacyte	checkfalse	
Manual- plasma and red cell reduction	checktrue	
RBC/plasma reduction with HES	checktrue	
Ficoll sedimentation	checkfalse	
Centrifugation and volume reduction	checkfalse	
No processing	checkfalse	
Manual- plasma reduction only	checkfalse	
Other,	checkfalse	
The current pre-freeze processing method(s):		
AXP	checkfalse	
SEPAX	checktrue	
Optipress	checkfalse	
Prepacyte	e checkfalse	
Manual- plasma and red cell reduction	checkfalse	
RBC/plasma reduction with HES	checktrue	
Ficoll sedimentation	checkfalse	
Centrifugation and volume reduction	checkfalse	
No processing	checkfalse	
Manual- plasma reduction only	checkfalse	
Other,	checkfalse	
Additives currently in use in addition to anticoagulants and DMSO du	ing processing:	
HES	checktrue	
Prepacyte	checkfalse	
Plasmalyte	checkfalse	
Albumin	checkfalse	
Isotonic salt solution NaCI (saline)	checkfalse	
No additive	checkfalse	
Other,	checkfalse	
Cryoprotectant additives currently in use:	DMSO- Dextran	
Cryopreservation method currently in use:		
BioArchive	checktrue	
MVE 1850 Vapor freezer	checkfalse	
Programmed cryopreservation with Air Liquid program (FREEZAL)	checkfalse	
Programmed freezer	checkfalse	
Two-step (equilibrium) freezing	checkfalse	

Cryobag currently in use:	Single bag (two fractions)	
Currently used packaging when a unit is stored:	Metal canister and overwrap	
Segments currently stored with the unit by the cord blood bank:		
One attached segment	checkfalse	
Two or more attached segments	checktrue	
Separate segments detached from the bag, but stored with the CBU	checkfalse	
Other samples	checkfalse	
None	checkfalse	

Section 7 Testing

Question	CBB answer	
Does your cord blood bank currently sto	re extra material?	
Cord blood DNA	checkfalse	
Cord blood material for DNA extraction	checktrue	
Plasma/cord blood	checktrue	
Maternal DNA	checkfalse	
Maternal material for DNA extraction	checktrue	
Maternal plasma/serum	checktrue	
HLA typing at time of listing:		
HLA-A	Low resolution	
HLA-B	Low resolution	
HLA-C	Low resolution	
HLA-DRB1	High Resolution	
HLA-DRB2	High Resolution	
HLA-DPB1	High Resolution	

Section 8 Storage

Question	CBB answer
The following type(s) of storage container is currently us	ed by the cord blood bank:
BioArchive tank	checktrue
Conventional storage tank-Vapor phase	checkfalse
Conventional tank-Liquid phase	checktrue
Double walled liquid Nitrogen	checkfalse
Type following type(s) of storage monitoring is currently by the cord blood bank:	
Alarm on individual tanks only	checkfalse
Centralized system-local	checktrue
Centralized system-remote monitoring	checkfalse

LN2 level	checktrue
Lid opening	checkfalse
System default	checkfalse
Temperature monitoring	checkfalse
No temperature monitoring	checkfalse

Section 9 Adverse Events Reporting

Question	CBB answer
Adverse Event Reporting used by the cord blood bank	
Competent authority	checkfalse
Internal report	checkfalse
National registry	checktrue
Transplant centre	checkfalse
WMDA	checkfalse