CB banking specifics WO-1911

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Section 1 General Info

Question	CBB answer
The information has been reviewed in year :	
Name of the cord blood bank:	Galicia Cord Blood Bank
Number of cord blood units the cord blood bank plans to store for public use (unrelated patients):	6377

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 :	4862
125 - 149 :	743
150 - 199 :	590
200 - 250 :	137
> 250 :	45

Section 3 Cord Blood Collection

Question	CBB answer
Current practice for collecting cord blood:	In-utero and ex-utero
Current antiseptic:	Chlorhexidine BETADINE, ALCOHOL
Collection bag:	Double needle
Agitation during collection:	Manual

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	checktrue
Passive refrigeration system (gel, blocks)	checktrue
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:	Temperature between +2 to +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	> 100 grams
TNC (10E7) before processing	150 - 199
Viability CD45 positive cells (%)	80 - 89%
Viability CD45 positive cells (method)	7AAD
Viability CD34 positive cells (%)	80 - 89%
Viability CD34 positive cells (method)	7AAD
Criteria that are completed before accepting a cord blood unit for public use in the cord blood bank	ά.
Medical History	
Collection Report	checktrue
Informed Consent	checktrue
Maternal IDM results	checktrue
Temperature and integrity of the bag	checktrue
Other, Zika test, SARS-CoV-2 test	checktrue
Used method for CD34 enumeration:	Flow cytometry
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

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	checkfalse
RBC/plasma reduction with HES	checktrue
FicoII sedimentation	checkfalse
Centrifugation and volume reduction	checktrue
No processing	checkfalse
Manual- plasma reduction only	checkfalse
Other,	checkfalse
The current pre-freeze processing method(s):	
AXP	checkfalse
SEPAX	checktrue
Optipress	checkfalse
Prepacyte	checkfalse
Manual- plasma and red cell reduction	checkfalse
RBC/plasma reduction with HES	checkfalse
FicoII 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	ring processing:
HES	checktrue
Prepacyte	checkfalse
Plasmalyte	checkfalse
Albumin	checkfalse
Isotonic salt solution NaCl (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	checktrue	
Cord blood material for DNA extraction	checktrue	
Plasma/cord blood	checktrue	
Maternal DNA	checktrue	
Maternal material for DNA extraction	checktrue	
Maternal plasma/serum	checktrue	
HLA typing at time of listing:		
HLA-A	High Resolution	
HLA-B	High Resolution	
HLA-C	High 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	checkfalse
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	checktrue

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

Section 9 Adverse Events Reporting

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

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Section 1 General Info

Question	CBB answer
The information has been reviewed in year :	
Name of the cord blood bank:	GALICIAN CORD BLOOD BANK
Number of cord blood units the cord blood bank plans to store for public use (unrelated patients):	6376

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 :	4862	
125 - 149 :	743	
150 - 199 :	589	

200 - 250 :	137
> 250 :	45

Section 3 Cord Blood Collection

Question	CBB answer
Current practice for collecting cord blood:	In-utero and ex-utero
Current antiseptic:	Alcohol CLORHEXIDINE, BETADINE
Collection bag:	Double needle
Agitation during collection:	Manual

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	checktrue
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:	Temperature between +2 to +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	> 100 grams
TNC (10E7) before processing	150 - 199
Viability CD45 positive cells (%)	80 - 89%
Viability CD45 positive cells (method)	7AAD

Viability CD34 positive cells (%)	80 - 89%
Viability CD34 positive cells (method)	7AAD
Criteria that are completed before accepting a cord blood unit for public use in the cord blood bank	κ:
Medical History	checktrue
Collection Report	checktrue
Informed Consent	checktrue
Maternal IDM results	checktrue
Temperature and integrity of the bag	checktrue
Other,	checkfalse
Used method for CD34 enumeration:	CITOMETER
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:	12-24H

Section 6 Processing-Packaging

Question	CBB answer
The pre-freeze processing method(s) cord blood bank uses at any stage in time:	
AXP	checkfalse
SEPAX	checktrue
Optipress	checkfalse
Prepacyte	checkfalse
Manual- plasma and red cell reduction	checkfalse
RBC/plasma reduction with HES	checkfalse
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	checkfalse
Manual- plasma and red cell reduction	checkfalse
RBC/plasma reduction with HES	checkfalse
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 during processing:		
HES	checktrue	
Prepacyte	checkfalse	
Plasmalyte	checkfalse	
Albumin	checkfalse	
Isotonic salt solution NaCl (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 fra		
Currently used packaging when a unit is stored:	Metal canister	
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	checktrue
Cord blood material for DNA extraction	checktrue
Plasma/cord blood	checktrue
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Maternal material for DNA extraction	checktrue
Maternal plasma/serum	checktrue
HLA typing at time of listing:	
HLA-A	High Resolution
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HLA-DRB1	High Resolution

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Section 8 Storage

Question	CBB answer
The following type(s) of storage container is currently used by the cord blood bar	
BioArchive tank	checktrue
Conventional storage tank-Vapor phase	checkfalse
Conventional tank-Liquid phase	checkfalse
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	checktrue
LN2 level	checktrue
Lid opening	checkfalse
System default	checktrue
Temperature monitoring	checktrue
No temperature monitoring	checktrue

Section 9 Adverse Events Reporting

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