Cord Blood Bank Technology Survey 2017

Response ID:7 Data

1.

1. General data
Name of the Cord Blood Bank:

Finnish Cord Blood Bank

2.

2. In what year did your Cord Blood Bank start collecting cord blood units?

1999

3. Type of cord blood units in the inventory of your Cord Blood Bank (please note the number of cord blood units stored on December 31, 2016).

Cord Blood Units in inventory for Unrelated Allogeneic. : 3342
Cord Blood Units in inventory for Related Allogeneic (directed). : 0
Cord Blood Units in inventory for Autologous. : 0

4. How many cord blood units do you plan to store for public use (unrelated patients)?

In 2017 : 0
In 2018 : 0

5. Does your Cord Blood Bank list units in BMDW (www.bmdw.org)?

Yes

6. Is your Cord Blood Bank affiliated with a National Stem Cell Donor Registry? If yes, list the name of the registry.

Yes, please list the name of the registry: Finnish Stem Cell Registry

3. Cord Blood Units in Inventory

7. What is your current processing method? Check all that apply.

Plasma and RBC reduced (automatic)

8. What year did your Cord Blood Bank start using your current processes?

1999

9. If possible, please upload a picture of cord blood units in your inventory for your current practise in use. You can upload a maximum of five pictures per question.

10. If possible, please upload a picture of cord blood units in your inventory for volume reduction. You can upload a maximum of five pictures per question.

11. If possible, please upload a picture of cord blood units in your inventory for no volume reduction. You can upload a maximum of five pictures per question.

12. Total Nucleated Cell Count (x10E7) of your cord blood units stored for Unrelated Patients (Public Use).

Please specify the number of cord blood units per category.

< 125 : 499
125 - 149 : 1966
150 - 199 : 722
200 - 250 : 110
> 250 : 45

4. Accreditations-licenses-certifications

13. FACT-Netcord accreditation

Is your Cord Blood Bank FACT-Netcord accredited?

Yes

Year of last on-site inspection (FACT):

2016

State year of your first accreditation:

2003

14. AABB accreditation

Is your Cord Blood Bank AABB accredited?

No

15. Competent Authority/National Health Authority (state-based).

Is your Cord Blood Bank licensed by a (state-based) Competent Authority?

Yes

Does the Competent Authority perform on-site inspections?

Yes, please specify year of the last inspection.

Year of last on-site inspection of your Competent Authority:

2017

Name of the institution Competent Authority:

Fimea - Finnish Medicines Agency

Link to the license website of the institution Competent Authority:

http://www.fimea.fi/web/en/frontpage

16. Does your National Stem Cell Donor Registry perform on-site inspections?

Yes

17. Please describe other accreditations, licenses, or certifications of your Cord Blood Bank.

5. Cord Blood Collection

18. What is your current practice for collecting cord blood?

Both

19. Current antiseptic. Check all that apply.

Alcohol

20. Collection bag

Double needle

21. Agitation during collection

None

6. Conditioning and transport from Collection Centre to Cord Blood Bank.

22. Do you use a secondary bag (sealed, plastic bag or similar to avoid any leakage)?

Yes

23. Transport conditions.

Insulating transport container
Passive refrigeration system (gel, blocks)
Electronic temperature probe
Qualified transporter

Ground transport

24. Specify temperature range for storage and transportation of fresh product.

Defined (above +8°C)

7. Evaluation

25. Pre-processing Evaluation
Please specify your current threshold for accepting a cord blood unit for public use in your cord blood bank.

Net weight in grams (excluding bag and anticoagulant) before processing

NA- not evaluated pre-processing

TNC (10E7) before processing

125 - 149

Viability CD45 positive cells (%)

NA- not evaluated pre-processing

Viability CD45 positive cells (method)

7AAD

Viability CD34 positive cells (%)

NA- not evaluated pre-processing

Viability CD34 positive cells (method)

7AAD

26. Pre Processing Evaluation
Please mark the criteria that are completed before accepting a cord blood unit for public use in your Cord Blood Bank. Check all that apply.

Medical History
Collection Report
Informed Consent
Maternal IDM results
Temperature and integrity of the bag

27. Which method is used for CD34 enumeration?

ISHAGE guidelines

28. Do you use external proficiency testing for QC of your FACS lab?

Yes, please specify (e.g. UKNEQAS): UKNEQAS

29. Does your Cord Blood Bank perform post processing/pre-freeze CD34 cell count?

Yes

30. Acceptable time from collection to processing.

12-24H

8. Processing-Packaging

31. Please select the pre freeze processing methods you have used at any stage in time. Check all that apply.

SEPAX
RBC/plasma reduction with HES

32. What are your current pre-freeze processing methods? Check all that apply.

SEPAX

33. Please specify additives currently in use in addition to anticoagulants and DMSO during processing. Check all that apply.

HES

34. Please specify cryoprotectant additives currently in use. Check all that apply.

DMSO- Dextran

35. Please specify cryopreservation method currently in use. Check all that apply.

BioArchive

36. Please specify cryobag currently in use. Check all that apply.

Single bag (two fractions)

37. What packaging is currently used when a unit is stored? Check all that apply.

Metal canister
Overwrap

38. How many segments do you currently store with the unit? Check all that apply.

Two or more attached segments

9. Testing

39. Using the list below, indicate which Infectious Disease Marker (IDM) testing of the maternal donor and/or cord blood is CURRENTLY performed by your Cord Blood Bank.

	Standard on Maternal Sample	Standard on cord blood sample	Testing available by request on maternal sample	Testing available by request on cord blood sample	Not done
Hepatitis B Surface Antigen	X	X			
Hepatitis B core Antibody	X	X			
Hepatitis B Surface Antibody	X	X			
HBV NAT	X	X			
Hepatitis C Antibody	X	X			
HCV NAT	X	X			
HIV 1/2 Antibody	X	X			
HIV 1 and 2 + 0 Antibodies	X	X			
HIV p24 Antigen	X	X			
HIV NAT Antigen	X	X			
HTLV I/II Antibodies	X	X			
HTLV NAT			X	X	
CMV Antibody - IgG	X				

CMV Antibody - IgM	X				
CMV Anitbody Total	X				
Syphilis	X	X			
West Nile Virus NAT			X	X	
West Nile Virus Antibody			X	X	
T. Cruzi Antibody (Chagas Disease)			X	X	
EBV Antibody - IgG			X	X	
EBV Antibody - IgM			X	X	
EBV Antibody Total			X	X	
Toxoplasmosis Antibody - IgG			X	X	
Toxoplasmosis Antibody - IgM			X	X	
Toxoplasmosis Antibody Total			X		

40. In case the Antibody - IgM is positive (for CMV, Toxoplasmosis or EBV) does your Cord Blood Bank perform a PCR? Please mark checkbox, when your Cord Blood Bank performs PCR testing. Check all that apply.

CMV
Toxoplasmosis
EBV

41. Does your Cord Blood Bank currently store extra material?

Cord blood material for DNA extraction
Plasma/cord blood
Maternal DNA
Maternal material for DNA extraction
Maternal plasma/serum

42. HLA typing at time of listing.

	Low Resolution	Intermediate Resolution	High Resolution	Not performed
HLA-A		X		
HLA-B		X		
HLA-C		X		
HLA-DRB1		X		
HLA-DQB1		X		
HLA-DPB1		X		

43. Current threshold for accepting a cord blood unit for public use (post processing)

	Please specify threshold	Please provide method	Not performed
Minimum TNC (10E7)	120	Sysmex	
Minimum CD34 (10E6) single platform	NA		
Minimum CD34 (10E6) double platform	NA		
Total-CFU (10E5)	NA		
Viability (10E5)	NA		

10. Storage

44. What type of storage container is currently used in your cord blood bank?

BioArchive tank
Conventional tank-Liquid phase

45. What type of storage monitoring is currently used in your cord blood bank?

Centralized system-local
Centralized system-remote monitoring
LN2 level

11. Verification/Extended HLA Typing

46. Is extended/verification typing performed at an ASHI, EFI or CAP accredited lab?

EFI accredited lab

47. What is the average turnaround time for extended HLA typing results?

5 Days

12. Confirmatory/verification typing.

48. Does your Cord Blood Bank use an attached (contiguous) segment (if available) for confirmatory/verification HLA typing currently?

Yes

49. Does your Cord Blood Bank list cord blood units that do NOT have attached segments and have NOT previously been confirmatory typed on attached segments?

No

50. What is the percentage of cord blood units in your inventory that will be sent with attached segment?

90-100%

51. Is your current practice to perform confirmatory/verification typing on all cord blood units prior to release?

Yes

13. Reservation/cancellation policies

52. At what point is a cord blood unit reserved for a patient and not available for other patients? Check all that apply.

At time of HLA typing request
At time of reservation request
At time of shipment request

53. What is the length of time a cord blood unit can be reserved?

60 days

54. Is there a fee to reserve a cord blood unit?

No

55. Is there a fee to cancel the reservation for a cord blood unit in the absence of a subsequent request for shipment?

No

56. Do you allow for an extension on a reservation of a cord blood unit?

Yes

57. Will your Cord Blood Bank provide a cord blood unit report on a cord blood unit that is already reserved for another patient (and thus not available) without specifying that the cord blood unit is already reserved?

No

58. If your Cord Blood Bank releases a cord blood unit from a patient's search (as opposed to the transplant centre indicating that the cord blood unit may be released), do you inform the transplant centre of the release?

No

59. [OLD VERSION] Using the list below, please indicate which tests are currently performed by your Cord Blood Bank on a thawed attached segment and at which stage.

	TNC count	Total viable CD34 count	% viability of CD34	% viability of CD45	CFUs
Any time upon request					X
As standard when CBU is reserved					X
Upon request when CBU is reserved					X
As standard when verification typing is performed					X
Upon request when verification typing is performed					X
Only once shipment is requested					X
Not performed					X

Using the list below, please indicate which tests are currently performed by your Cord Blood Bank on a thawed attached segment and at which stage.

	TNC count	Total viable CD34 count	% viability of CD34	% viability of CD45	CFUs
As standard when verification typing is performed					
As standard when CBU is reserved					
Upon request when CBU is reserved					
Upon request when verification typing is performed					
Only once shipment is requested			X	X	
Not performed	X				

14. Release-Shipment

60. Does your Cord Blood Bank perform hemoglobinopathy screening before release?

Yes

61. Criteria to allow a Cord Blood Unit to be shipped to transplant centres. See Appendix V of FACT Netcord Standards 6th Edition.

	Acceptable range of values	Please provide method	Please provide additional information
Viability / cell count:	50-100	Trypan Blue	CFU > 2.5 x10^5

62. Criteria to allow a cord blood unit to be shipped to transplant centres. See Appendix V of FACT Netcord Standards 6th Edition.
What do you perform at the time a cord blood unit is released to be shipped to a transplant centre? Check all that apply.

Identity testing with HLA
IDMs not performed prior to listing, please describe:

63. Current packaging for shipment to transplant centre.

Metal Canister
Overwrap
Protective sleeve

64. How many segments do you currently send with the unit?

One attached segment

65. How much time is required from the date the shipment order is placed until the unit is shipped?

Less than one week

66. Is there a fee for cancellation of shipment?

No

67. Does your Cord Blood Bank validate its dry shippers to ensure they maintain the temperature at ≤ -150°C at least 48 hours beyond the expected arrival time at the receiving facility?

Yes

68. Do all dry shippers used by your Cord Blood Bank contain an electronic temperature data logger?

Yes

69. Who typically chooses the courier company for international transports?

Requesting transplant centre or registry

70. Please specify the shape of the transport container you currently use.

Mushroom

15. Adverse Events Reporting

71. Adverse Event Reporting

Competent authority
Transplant centre
WMDA