Cord Blood Bank Technology Survey 2017

1.

1. General data
Name of the Cord Blood Bank:

Sanquin Cord Blood Bank

2.

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

1994

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. : 4750
Cord Blood Units in inventory for Related Allogeneic (directed). : 150
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 : 200
In 2018 : 40

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: Matchis

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?

2008

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.

4. Accreditations-licenses-certifications

13. FACT-Netcord accreditation
Is your Cord Blood Bank FACT-Netcord accredited?

Yes

Year of last on-site inspection (FACT):

2015

State year of your first accreditation:

2009

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:

2016

Name of the institution Competent Authority:

Dutch Ministry of Health

Link to the license website of the institution Competent Authority:

www.farmatec.nl

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

No

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

Dutch Competent Authority

5. Cord Blood Collection

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

Both

19. Current antiseptic. Check all that apply.

Other, please describe: Cleaning by using alcohol and desinfecting by using Iodium swabsticks

20. Collection bag

Double needle

21. Agitation during collection

Manual

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.

Qualified transporter

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

150 - 199

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
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.

24-48H

8. Processing-Packaging

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

AXP
RBC/plasma reduction with HES
Ficoll sedimentation
No processing

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

AXP
No processing

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

No additive

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

DMSO

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

BioArchive
Programmed freezer

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

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					
HBV NAT	X			X	
Hepatitis C Antibody	X			X	
HCV NAT	X			X	
HIV 1/2 Antibody					
HIV 1 and 2 + 0 Antibodies	X			X	
HIV p24 Antigen					
HIV NAT Antigen	X			X	
HTLV I/II Antibodies	X			X	
HTLV NAT	X			X	
CMV Antibody - IgG					
CMV Antibody - IgM					
CMV Anitbody Total	X				
Syphilis	X				
West Nile Virus					

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

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

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

41. 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	

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

	Please specify threshold	Please provide method	Not performed
Minimum TNC (10E7)	150	Cell analyzer	
Minimum CD34 (10E6) single platform	>1.25 x 10E6	Flowcytometer	
Minimum CD34 (10E6) double platform	NA		
Total-CFU (10E5)	Growth	Methocult	
Viability (10E5)	>85%	7-AAD CD34	

10. Storage

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

BioArchive tank
Conventional tank-Liquid phase
Double walled liquid Nitrogen

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

Centralized system-remote monitoring
LN2 level
System default

11. Verification/Extended HLA Typing

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

EFI accredited lab

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

9 Days

12. Confirmatory/verification typing.

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

Yes

48. 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

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

90-100%

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

Yes

13. Reservation/cancellation policies

51. 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 reservation request

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

30 days

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

No

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

No

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

Yes

56. 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

57. 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?

Yes

58. [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					
Upon request when CBU is reserved					
As standard when verification typing is performed					
Upon request when verification typing is performed					
Only once shipment is requested			X		
Not performed					
shipment is requested					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

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

Yes

60. 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:	>70%	7-AAD	CD34

61. 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: Grandfather CBU; a-HBcAg at maternal sample
Other, please describe: IDM on cord blood

62. Current packaging for shipment to transplant centre.

Metal Canister
Transport rack

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

One attached segment

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

Less than one week

65. Is there a fee for cancellation of shipment?

Yes, if release testing has begun

66. 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

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

Yes

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

Requesting transplant centre or registry

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

Mushroom

15. Adverse Events Reporting

70. Adverse Event Reporting

Competent authority
Internal report
National registry
WMDA